



# COMMONWEALTH OF VIRGINIA

## Meeting of the Board of Pharmacy

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

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

### Tentative Agenda of Public Hearing and Full Board Meeting

*September 9, 2020 Meeting*

9AM

**\*\*\*\*Refer to the Third Page of Agenda for Meeting Access Information\*\*\*\***

<u>TOPIC</u>	<u>PAGES</u>
<b>Call to Order of Public Hearing:</b> Kris Ratliff, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
<b>Public Hearing:</b>	
• Placement of chemicals into Schedule I	122-124
<b>Adjournment of Public Hearing</b>	
<b>Call to Order of Full Board Meeting:</b> Kris Ratliff, Chairman	
• Approval of Agenda	
<b>Approval of Previous Board Meeting Minutes:</b>	1-45
○ June 16, 2020, Virtual Full Board Meeting	
○ June 16, 2020, Virtual Public Hearings	
○ June 23, 2020, Special Conference Committee	
○ July 21, 2020, Virtual Workgroup Meeting - Drug Disposal	
○ August 4, 2020, Virtual Workgroup Meeting - Protocols for Initiating Treatment	
○ August 5, 2020, Formal Hearing	
○ August 17, 2020, Virtual Workgroup Meeting - Protocols for Initiating Treatment	
○ August 18, 2020, Special Conference Committee	
<b>Call for Public Comment:</b> 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.	
<b>DHP Director’s Report:</b> David Brown, DC	
<b>Legislative/Regulatory/Guidance:</b> Elaine Yeatts/Caroline Juran	
• Report of Regulatory Actions	46-47
• Adoption of emergency regulations regarding:	48-55
○ Limited-use license and permit for non-profit facilities	
○ Pharmaceutical processors – cannabis dispensing facilities, temporary residency, controlled substance registrations for laboratories	56-99
○ Statewide protocols for pharmacists to initiate treatment	100-106
○ Pharmacy technician educational standards	107-121
• Adoption of final regulations placing chemicals into Schedule I	122-128
• Adoption of final regulations for labeling of dispensed prescriptions	129-154

- Adoption of exempt regulation regarding collaborative practice agreements **155-160**
- Adoption of fast-track regulation for use of industrial hemp by pharmaceutical processors **161-166**
- Petition for rulemaking regarding pharmaceutical processors **167-183**
- Adoption of FAQs regarding use of pesticides by pharmaceutical processors, testing requirements for pesticide chemical residue, and assignment of expiration date for cannabis oil **184-185**
- Adoption of statewide protocols for pharmacists to initiate treatment **186-206**
- Adoption of Recommendations offered by Drug Disposal Workgroup **207-208**
- Adoption of amendment to bylaws – delegation of authority regarding exceptions to requirement for PIC to have 2 years of experience **209-213**

**Old Business:**

- Information for licensure renewal notification regarding dispensing of naloxone per request from Joint Commission on Health Care **214-216**

**New Business:**

- Request to delegate authority to chairman, in consultation with executive director, for appointing persons to evaluation committee for pharmaceutical processor request for application process
- Adoption of Pharmacist (**Attachment 1**) and Pharmacy Technician (**Attachment 2**) Workforce Survey Reports

**Reports:**

- Chairman’s Report – Kris Ratliff **217**
- Report on Board of Health Professions – Ryan Logan **218-228**
- Report on Licensure Program – Beth O’Halloran **229**
- Report on Inspection Program – Sammy Johnson **230**
- Report on Pharmaceutical Processors – Annette Kelley **231**
- Report on Disciplinary Program – Ellen B. Shinaberry
- Executive Director’s Report – Caroline D. Juran

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

**Adjourn**

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

**\*\*\*A panel of the Board will convene at 1:30pm or immediately following adjournment of the board meeting, whichever is later.\*\*\***

## Virginia Board of Pharmacy

### **Instructions for Accessing September 9, 2020 Limited In-Person/Virtual Public Hearing/Full Board Meeting and Providing Public Comment**

- **Access:** The public hearing and full board meeting on 9/9/2020 will be held in-person. Use of WebEx will only be used for the public to offer comment, if unable to attend in-person, and observe the meeting. Perimeter Center building access remains restricted to the public due to the COVID-19 pandemic. Participation capacity is limited and is on a first-come, first-serve basis due to the capacity limits related to social distancing requirements and CISCO WebEx technology. ***Please note that there is limited onsite seating for public participation.*** No additional seating will be provided once capacity has been reached. There are 5 seats for the public in Board Room 4. Entry to the conference center is only through the side door on the West side of the building. Masks must be worn at all times.
- **Public comment:** Public comment may be received in-person or via WebEx.
  - Persons offering public comment via WebEx must email [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov) **no later than 8am on September 9, 2020** indicating that they wish to offer comment. Be sure to specify if the comment is associated with the public hearing or the full board meeting. Comment may be offered by these individuals when their names are announced by the chairman.
  - Persons intending to offer public comment in-person must sign-up on the list located just outside entry into Board Room 4. If the 5 seats designated for the public in Board Room 4 are occupied, please remain in the hallway socially distanced from others and staff will escort you into the room when it is your time to offer comment.
- Public participation connections via WebEx will be muted following the public comment periods.
- Should the Board enter into a closed session, public participants will be blocked on WebEx from seeing and hearing the discussion and persons on-site must exit the board room while the board deliberates. When the Board re-enters into open session, public participation connections to see and hear the discussions will be restored and persons on-site may re-enter the room.
- Please connect via WebEx from a location without background noise.
- Dial (804) 367-4578 to report an interruption during the broadcast.
- FOIA Council *Electronic Meetings Public Comment* form for submitting feedback on this electronic meeting may be accessed at <http://foiacouncil.dls.virginia.gov/sample%20letters/welcome.htm>

#### **JOIN THE INTERACTIVE MEETING:**

<https://virginia-dhp.my.webex.com/virginia-dhp.my/j.php?MTID=m04c60ce55f2303fac9dd35dc609f98dc>

**Meeting number (access code):** 132 792 7107

**Meeting password:** PharmMeet!

**JOIN BY AUDIO ONLY:** +1-408-418-9388

**Meeting number (access code):** 132 792 7107 **Meeting password:** 74276633

(DRAFT/UNAPPROVED)

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

June 16, 2020  
Virtual Meeting

Department of Health Professions  
Perimeter Center  
9960 Mayland Drive  
3<sup>rd</sup> Floor  
Henrico, Virginia 23233

**CALL TO ORDER:**

A virtual WebEx meeting of the Board of Pharmacy was called to order at 9:21 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING:**

Cynthia Warriner, Chairman (On-Site)

**MEMBERS PRESENT:**

James L. Jenkins, Jr. (On-Site)

**MEMBERS  
PARTICIPATING  
VIRTUALLY:**

Kristopher S. Ratliff, Vice-Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
Ryan Logan  
Cheryl H. Nelson  
Patricia Richards-Spruill  
Rebecca Thornbury  
William Lee

**STAFF PRESENT:**

Caroline D. Juran, Executive Director (On-Site)  
James Rutkowski, Assistant Attorney General (On-Site)  
Kiara Christian, Executive Assistant (On-Site)

**STAFF PARTICIPATING  
VIRTUALLY**

Annette Kelley, Deputy Executive Director  
Beth O' Halloran, Deputy Executive Director  
Ellen B. Shinaberry, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP  
Barbara Allison-Bryant, M.D., Chief Deputy, DHP

**PHARMACISTS  
AWARDED 1 HOUR OF**



LIVE OR REAL-TIME  
INTERACTIVE  
CONTINUING  
EDUCATION FOR  
VIRTUALLY  
ATTENDING MEETING:

John Lubkowski  
Theodore Yantsides

QUORUM:

With ten members participating, a quorum was established.

APPROVAL OF  
AGENDA:

Ms. Warriner reported that staff recommended additions to the tentative agenda previously provided.

MOTION:

**The agenda was unanimously approved as amended as described below:**

- **Two more examination accommodation requests were added that will be considered when addressing the one already listed on the agenda;**
- **A new draft Guidance Document regarding the *Use of Telemedicine by Registered Practitioners for Cannabis Oil* was added to the bottom of the first page of the agenda following the discussion on Guidance Document 110-48;**
- **The election for Chairman and Vice Chairman and the Reports section were moved up on agenda to be heard right after Old Business. (motion by Jenkins, second by Richards-Spruill )**

APPROVAL OF  
PREVIOUS BOARD  
MEETING MINUTES

Ms. Warriner asked that the minutes for the May Full Board Meeting be edited under the Chairman's report, to include the Boards' congratulations extended to Ms. Juran for her recent election as President-Elect of NABP.

Mr. Ratliff offered the following edit to the May full board meeting minutes: Under the *Update on Regulatory Actions*, insert that Mr. Ratliff expressed concern for the *Prohibition against incentives to transfer prescriptions* regulatory packet that has been in the Governor's Office for over 700 days and that staff had indicated they routinely check on the status of this regulatory packet and others.

MOTION:

**The Board voted unanimously to adopt the minutes for the May 18, 2020, Virtual Full Board Meeting and Public Hearings on Scheduling Actions as amended below:**

- **under the Chairman's report, to include the Boards' congratulations extended to Ms. Juran for her recent election as**

**President-Elect of NABP;**

- **Under the *Update on Regulatory Actions*, insert that Mr. Ratliff expressed concern for the *Prohibition against incentives to transfer prescriptions* regulatory packet that has been in the Governor’s Office for over 700 days and that staff had indicated they routinely check on the status of this regulatory packet and others. (motion by Nelson , second by Ratliff )**

**PUBLIC COMMENTS:**

Ms. Warriner stated as indicated in the meeting notice on Regulatory Townhall and in the agenda package that comments would be received during this public comment period from only those persons who submitted an email to Caroline Juran no later than 8am on June 16, 2020 indicating that they wish to offer comment. Ms. Juran received an email from the individuals listed below and Ms. Warriner invited them to offer comment.

Phil Abraham, Director & General Counsel for Vectre Corp, offered comment on behalf of Covetrus Maine, an online nonresident pharmacy servicing animals. He shared that he provided comment at the May board meeting regarding support of Covetrus Maine’s pharmacy license renewal, and thanked the board for approving their renewal. He offered support of draft Guidance Document 110-49 *Credentials for Non-Resident Pharmacies Dispensing only for Animals*.

Christina Barrille, Executive Director of the Virginia Pharmacists Association, thanked Ms. Warriner for her leadership and service to the board. She also thanked Ms. Thornbury for her service on the board. Ms. Barrille shared that if the board decides not to move forward with mandating one hour of CE for naloxone, VPhA is suggesting that the board focus on the new statewide protocols authorized during the 2020 General Assembly Session or on medical cannabis education. Additionally, VPhA encourages the board to allow volunteer hours in free clinics and health departments to suffice as live or real-time interactive CE. VPhA supports the board looking at pharmacy workflow, and suggests that any changes to pharmacy technician duties be directed to a pharmacy technician workgroup addressing legislation from the 2020 General Assembly session. Ms. Barrille offered VPhA’s support if needed.

Mark Hickman, representing VSHP, offered comment regarding remote order processing by pharmacy technicians outside of a pharmacy. Mr. Hickman echoed Ms. Barrille’s comments in that changes to pharmacy technician duties should be forwarded to a pharmacy technician workgroup. VSHP supports a regulatory amendment that would allow for pharmacist volunteering at a free clinic or health department to receive live or real-time interactive CE credit. VSHP supports extending the allowable time period

for changing a pharmacist-in-charge (PIC) from 14 days to 30 days. Natalie Nguyen, pharmacist representing VSHP, added that this would be helpful as companies are constantly acquiring each other which makes it difficult to designate a PIC immediately. Responding to a question from the Board, Ms. Nguyen commented that concerns regarding inventory control and diversion should be taken into consideration.

Jeenu Phillip, Director, Pharmacy Affairs, Walgreens commented regarding possible exceptions for the minimum two-year experience for becoming PIC. He recommended the Board adopt guidance for approving exceptions and offered suggested language.

Tom Lynch, CEO, MedMen Enterprises, Inc. thanked the Board for allowing him to provide comment. He requested approval of the corrective action response submitted in response to the December 2019 inspection performed of the pharmaceutical processor PharmaCann and an allowance to extend the reinspection date to 6/2021.

DHP DIRECTOR'S  
REPORT:

Dr. Brown began his report by acknowledging recent events surrounding COVID-19 and protests, and shared some steps being taking by the Governor to protect minorities. Dr. Brown also provided some updates issued in Executive Order 58, the extension of the Declaration of Emergency, and movement into Phase II. Lastly, Dr. Brown shared some changes in response to COVID-19 taking place within the agency and the waiving of certain regulations.

LEGISLATIVE/  
REGULATORY/  
GUIDANCE

Update on  
Regulatory/Policy Actions  
Resulting from 2020  
General Assembly

Ms. Yeatts referenced page 23 of the agenda packet which provided a summary of regulatory and non-regulatory actions that the Board or board staff must take based on legislation passed during the 2020 General Assembly Session.

Update on Regulatory  
Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet on page 25. She indicated the brown bagging and white bagging regulations and the delivery of Schedule VI prescription devices regulations were now in the Secretary's office. The placement of chemicals into Schedule I and the scheduling for conformity to DEA scheduling regulations would become effective on August 5, 2020.

**ACTION ITEM:**

**The Board requested staff to reach out to Governor’s office regarding the status of the regulations prohibiting against incentives to transfer prescriptions.**

Adopt Exempt Regulations  
for Pharmaceutical  
Processors

Ms. Yeatts provided an overview of the proposed exempt regulations in the agenda package. The proposed amendments reflect changes in the law which are eligible for exempt action since they are anticipated to be non-controversial.

**MOTION:**

**The board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented. (motion by Ratliff, seconded by Jenkins)**

Consider Petition for  
Rulemaking to Amend  
18VAC110-20-276 to  
Allow Remote Order  
Processing by Pharmacy  
Technicians Outside a  
Pharmacy

Ms. Christian shared electronically through the WebEx platform the comments received from the National Association of Chain Drug Stores that were not included in the agenda packet and allow board members a few minutes to review the information. The board then discussed the petition and the comments received. It expressed some concern for oversight of pharmacy technicians working remotely from a location other than the pharmacy. It was stated that this is currently allowed under the emergency waived provisions associated with COVID-19. Comments regarding ensuring proper safeguards are in place, as well as preserving the pharmacist to pharmacy technician ratio were expressed.

**MOTION:**

**The Board voted unanimously to decline the petition for rulemaking, but refer the issue to the Regulation Committee in November for further consideration. (motion by Richards-Spruill, seconded by Bolyard)**

Consider Adoption of Fast-  
track Regulation to Allow  
Volunteer CE to Satisfy  
Live CE  
Requirement

Ms. Yeatts shared that currently a pharmacist may obtain one hour of continuing education (CE) credit for volunteering for three hours to provide pharmacy services as a pharmacist, without compensation, to low-income individuals at a local health department or free clinic, but that counsel has indicated the CE does not satisfy the live or real-time interactive CE requirement. However, the Board could adopt a fast-track regulatory amendment of 18VAC110-21-120 to allow the volunteer CE to satisfy the live or real-time CE requirement.

**MOTION:**

**The board voted unanimously to amend 18VAC110-21-120 through a fast-track action by inserting a new number 3 within subsection C indicating that a maximum of 2 hours for voluntary services in accordance with subsection D may be included in the 3 hours of live or real-time interactive CE. (motion by Logan, seconded by Richards-Spruill)**

Adoption of Emergency  
Regulations for Limited-  
Use License and Permit for  
Non-Profit Facilities

Mr. Jenkins asked how “non-profit” was defined since there appear to be general disparities in the financial status of large non-profit entities verses smaller non-profit entities. Staff and counsel indicated that the term is not defined in the relevant legislation, HB 1654 and SB 1074. Staff confirmed for the Board that it could gather this information for the September board meeting and still have time to satisfy the legislative requirement to promulgate regulations to be effective within 280 days of enactment of the legislation.

**ACTION ITEM:**

**The Board requested counsel to research the definition of “non-profit” and provide this information to the board for its consideration at the September board meeting when it will reconsider adoption of the emergency regulations for a limited-use license and permit for non-profit facilities.**

**MOTION:**

**The board voted 8-2 to not approve the emergency regulations for a limited-use license and permit for non-profit facilities at this time but to have counsel research the definition of “non-profit” and report back at the September full Board meeting. (motion by Nelson, seconded by Jenkins; opposed Boone, Lee)**

Adopt Guidance Document  
110-49 *Credentials for  
Nonresident Pharmacies  
Dispensing Only  
for Animals*

Ms. Juran provided an overview of the draft guidance document and reminded the Board that this was an action item from the May 18, 2020 virtual board meeting resulting from the discussion on Covetrus Maine.

**MOTION:**

**The board voted unanimously to adopt as presented a new Guidance Document 110-49, *Credentials for Nonresident Pharmacies Dispensing Only for Animals*. (motion by Nelson, seconded by Boone)**

Adopt Guidance Document  
110-48 *Verification  
Sources for a  
Pharmaceutical Processor*

Ms. Juran provided an overview of the draft guidance document stating that it accomplishes the following: informs pharmaceutical processors how it may verify through the Virginia Cannabis Patient Registration current registration status of patients, parents/guardians, and registered agents; how registered practitioner and processor permit information may be verified; and how to verify a patient’s last dispensing of cannabis oil through the Prescription Monitoring Program. It was commented that the terms “cannabidiol oil and THC-A oil” found in the draft document should be changed to “cannabis oil” based on the law change effective July 1, 2020.

**MOTION:**

**The board voted 9-0 to amend Guidance Document 110-48 *Verification Sources for a Pharmaceutical Processor* by replacing the terms “cannabidiol oil and THC-A oil” with “cannabis oil” and adopt the guidance document as amended. (motion by Ratliff, seconded by Lee;**

**Thornbury's connection was temporarily dropped)**

Adoption of Guidance Document *Use of Telemedicine by Registered Practitioners of Cannabis Oil*

Ms. Christian shared electronically through the WebEx platform the draft guidance document that was added to the amended agenda. It was noted that the current language regarding HB 1460 referenced in the draft should be replaced with the relevant Code section as of July 1, 2020.

**MOTION:**

**The Board voted unanimously to amend the new draft Guidance Document *Use of Telemedicine by Registered Practitioners of Cannabis Oil* by replacing the referenced language of HB 1460 with the relevant Code section as of July 1, 2020 and to adopt the guidance document as amended. (motion by Nelson, seconded by Richards-Spruill)**

Amend Guidance Documents 110-4, 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, 110-35

Ms. Juran stated that staff had recently developed a process for awarding CE to preceptors and recommended that the Board consider additional questions and answers that could be included in Guidance Document 110-4. Ms. Christian shared electronically through the WebEx platform a revised Guidance Document 110-4 that included such questions, along with the other suggested questions that were on the original draft in the agenda package such as those addressing the new live or real-time interactive CE requirement.

**MOTION:**

**The Board voted unanimously to adopt Guidance Document 110-4 as presented electronically by staff. (motion Nelson, seconded by Thornbury)**

Ms. Juran provided an overview of the suggested amendments to Guidance Documents 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, 110-35 which primarily resulted from recent legislative changes or regulatory changes effective December 11, 2019 based on the most recent periodic regulatory review. Specifically, she stated:

- 110-8: Board of Nursing no longer issues a separate prescriptive authority number to nurse practitioners; physician assistants now have a collaborating physician or podiatrist, not a supervising medical practitioner; and TPA-certified optometrists may now prescribe gabapentin in Schedule V;
- 110-9: several deficiencies and citations need amending based on the periodic regulatory amendments;
- 110-16: language regarding physically counting inventory and reconciliation of perpetual inventories can be removed since the language is now in 18VAC110-20-240 and the referenced CFR section needs to be updated with current language;
- 110-20: regulation citations need amending since a new chapter 21 was created in December 2019 for addressing requirements for individual licensees;

- 110-22: referenced language for 18VAC110-20-270 needs to be replaced with current language;
- 110-27: new requirements for at least one hard-wired communication method in security system and notification of PIC or pharmacist working at pharmacy of security breach needs to be added, along with new requirement for at least two-years of experience for serving as PIC; clarification needed to use License Lookup to determine if pharmacy technician held registration within past 5 years which would require submission of a reinstatement application, not a new application;
- 110-35: similar amendments needed for nurse practitioners and physician assistants as indicated in 110-8.

**MOTION:**

**The board voted unanimously to adopt Guidance Documents 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, and 110-35 as presented in the agenda package. (motion by Jenkins, seconded by Boone)**

Repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40

Ms. Juran recommended the board repeal these guidance documents based on the most recent periodic regulatory review resulting in regulatory amendments effective December 11, 2019 and indicated the following:

- 110-14: sample size was addressed in SB 1045 and SB 976 during the 2020 General Assembly Session and is now found in 54.1-3442.6 of the Code;
- 110-19: transferring of orders between medical equipment suppliers is now addressed in 18VAC110-20-680;
- 110-32: use of drop box for the collection of prescriptions is now addressed in 18VAC110-20-270;
- 110-40: storage of Schedule II drugs is now addressed in 18VAC110-20-200.

**MOTION:**

**The Board voted unanimously to repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40 as presented. (motion by Richards-Spruill, seconded by Logan)**

Request to Amend Guidance Document 110-39 *Guidance for Continuous Hours Worked by Pharmacists and Breaks*

Ms. Juran commented that a pharmacist wanting to stay anonymous expressed concern about the current guidance which does not require a pharmacy to close during a pharmacist's break. The pharmacist told Ms. Juran that the guidance allows employers to require the pharmacy to remain open which does not provide an uninterrupted break for the pharmacist on-duty. After some discussion, the Board concluded that this topic should be discussed at the Regulation Committee meeting where more time could be devoted to consider the matter.

**MOTION:**

**The Board voted unanimously to refer the request to amend Guidance Document 110-39 *Guidance for Continuous Hours Worked by***

**Pharmacists and Breaks to the Regulation Committee which is scheduled to meet in November 2020. (motion by Lee, seconded by Ratliff)**

Request for Guidance for Granting Exception to Minimum Two Years' Experience for PIC Eligibility

The Board had some discussion on possible exceptions to the two year pharmacist eligibility requirement for serving as PIC such as in a rural area. Mr. Ratliff recommended looking at past experience, consider if denial would harm the underserved, and consider if person completed PIC training. Mr. Bolyard stated it should be evaluated on a case-by-case basis and to consider if an emerging leader program has been completed. It was discussed that the Board's Bylaws currently have several delegated authorities for allowing consideration of certain matters in a timely manner. The current timeframe for changing a PIC is 14 days and often requests come in at the last minute.

**MOTION:**

**The board voted unanimously to amend the Bylaws, Guidance Document 110-12, to delegate to the Executive Director, in consultation with the Board Chairman, the ability to approve or deny a request for an exception to the two-year pharmacist eligibility requirement to serve as the PIC, with the ability for the applicant to request an Informal Conference if denied. (motion by Lee, seconded by Nelson)**

Request to Amend Regulation to Extend Change of PIC Timeframe from 14 to 30 Days

Mr. Bolyard indicated that he is requesting the Board extend the change of PIC timeframe from 14 days to 30 days. He stated it is too short and creates difficulties; don't always know if need a new PIC; inventories can take 6 hours and Sunday evenings are often the best time to perform the inventory; a temporarily assigned PIC may not always be the best candidate; on-duty pharmacists are also responsible for drug security; can be hard to find good candidates in rural areas; 8 states currently allow 30 days and Maryland has no PIC requirement. Mr. Lee recommended possibly extending to 21 days. Mr. Logan recommended possibly requiring inventory to be performed after 15 days during a 30-day window. Ms. Thornbury supported a longer timeframe based on challenges in rural areas. Ms. Yeatts questioned what information NABP may have on this subject.

**MOTION:**

**The Board voted unanimously to refer the request to amend 18VAC110-20-110 to extend the change of PIC timeframe from 14 to 30 days to the Regulation Committee which is scheduled to meet in November 2020. (motion by Logan, seconded by Bolyard)**

**OLD BUSINESS:**

Consideration for Requiring CE on a Specific Topic in 2021

Ms. Warriner reminded the Board that this was an action item from the December 2019 board meeting. After some discussion regarding various possible CE topics and past mandated topics, it was stated that the new requirement for pharmacists to obtain 3 hours of live or real-time interactive



CE may be sufficient for 2020 and that it may be perceived overly burdensome to mandate CE in a specific topic for 2021. Ms. Juran confirmed that the Board generally considers this topic annually during the September board meeting and therefore can be considered next year for mandating a specific CE topic in 2022. No action was taken by the Board.

Verbal Update on Action  
Item from December 2019  
Board Meeting regarding  
Virginia  
Immunization Information  
System

Ms. Juran reported the following from her discussion with VDH:

- Staff included an article March 2020 board's e-newsletter encouraging pharmacists to enroll in the Virginia Immunization Information System (VIIS);
- Currently there is no mandate for a pharmacist to report to VIIS, but it is believed many already do;
- those that will receive and administer a COVID-19 vaccine from the government will be required to report to VIIS, therefore, it is important to initiate onboarding and enrollment with VIIS now;
- VIIS can support increased usage via mandatory reporting from all health care providers but VDH has not performed a fiscal impact analysis on the burden associated with such a mandate.

**ACTION ITEM:**

Elections for Chairman and  
Vice Chairman

**MOTION:**

**The board voted unanimously to elect Kristopher Ratliff to serve as Chairman for the term July 1, 2020 through June 30, 2021. (motion by Lee, seconded by Nelson)**

Mr. Bolyard nominated and Mr. Jenkins seconded Cheryl Nelson to serve as Vice Chairman. Mr. Ratliff nominated William Lee to serve as Vice Chairman; the nomination lacked a second.

**MOTION:**

**The Board voted unanimously to elect Cheryl Nelson to serve as Vice Chairman for the term July 1, 2020 through June 30, 2021. (motion by Bolyard, seconded by Jenkins)**

**REPORTS:**

Chairman's Report

Ms. Warriner thanked staff and the board for having the opportunity to serve and represent the Commonwealth during her eight years on the board. She expressed appreciation for the honor to serve as chairman twice and she encouraged the board to participate in future NABP meetings as she found them to be very rewarding as an NABP member, appointed committee leader, and elected committee member.

Report on Board of Health  
Professions

Mr. Logan shared that the meeting scheduled for May 27, 2020 was cancelled. No new information to report at this time.

Report on Inspection and

### Licensure Program

Ms. O' Halloran reviewed the Licensure Report was included in the agenda packet on page 170. Ms. O' Halloran reviewed the Inspection Report on page 170 of the agenda packet. She offered that licensing and inspection numbers are down due to the COVID-19 inspections. Ms. O' Halloran noted that some facilities may not be eligible for a documented occurrence. Ms. O' Halloran clarified that pharmacies were not receiving inspections at this time, but that other facility types were.

### Report on Pharmaceutical Processors

Ms. Kelley reviewed the licensing report included in the agenda packet. She noted that Columbia Care and Greenleaf Medical were awarded their pharmaceutical processor permit. Dharma has an upcoming inspection. Ms. Juran added that originally it was estimated that there were 27,000 epilepsy patients that could take benefit from use of the Pharmaceutical Processor program.

### Report on Disciplinary Program

Report can be found beginning on page 183 of the agenda packet. Ms. Shinaberry reminded the board that all proceedings were cancelled in March, April, and May. Proceedings scheduled to resume on June 23, 2020, and that the caseload in beginning to increase. No questions were asked of staff.

### Executive Director's Report

Ms. Juran report can be found on page 210 of the agenda package. Ms. Juran recognized Ms. Warriner and Ms. Thornbury each for their eight years of service on the Board and to the citizens of the Commonwealth. Their second term expires on June 30, 2020 and they are ineligible for reappointment. Both served in leadership roles as board chairman and will be greatly missed. Ms. Thornbury offered comments of appreciation to her fellow board members and staff. Ms. Juran also reported on her participation with VDH and NABP on weekly calls to discuss COVID-19 related issues. She stated that staff is doing an amazing job teleworking and completing their responsibilities. She commented that she will provide a presentation for the oversight of wholesale distributors and manufacturers to the HWI Committee on July 7, 2020.

**Mr. Bolyard disconnected at this point and was no longer participating in the virtual meeting.**

### NEW BUSINESS:

Review of the inspection report for PharmaCann's pharmaceutical processor location, PharmaCann's submitted corrective action plan, and PharmaCann's application for a pharmaceutical processor permit

### Closed Session:

**Upon a motion by Mr. Ratliff and seconded by Ms. Nelson, the Board voted 9-0, to convene a closed meeting pursuant to §§ 2.2-3711(A)(27) and 54.1-108 of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding review of the inspection**

report for PharmaCann’s pharmaceutical processor location, PharmaCann’s submitted corrective action plan, and PharmaCann’s application for a pharmaceutical processor permit. Additionally, he moved that Caroline Juran, Annette Kelley, Jim Rutkowski, and Kiara Christian attend the closed meeting.

**Reconvene:** Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (Motion by Ratliff, seconded by Nelson)

**Decision:** The Board voted 9:0 to deny PharmaCann’s request for an extension for reinspection in June 2021, rescind the conditional approval issued to PharmaCann, and deny PharmaCann’s application for a pharmaceutical processor permit. (motion by Jenkins, seconded by Richards-Spruill)

**MOTION:** The Board voted 9:0 to grant authority to the Executive Director to initiate a Request for Application (RFA) for Health Service Area I for awarding conditional approval to a new pharmaceutical processor. (motion by Logan, seconded by Nelson)

ADA examination  
accommodation requests  
for Hope Danielle Watson,  
Mary Patricia Baxter, and  
Christina Nguyen

**Closed Session:** Upon a motion by Mr. Ratliff and seconded by Ms. Nelson, the Board voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(16) of the Code of Virginia (“Code”), for the purpose of deliberation to reach a decision regarding review of the examination accommodation requests submitted by pharmacist applicants Hope Danielle Watson, Mary Patricia Baxter, and Christina Nguyen. Additionally, he moved that Caroline Juran, Beth O’Halloran, Jim Rutkowski, and Kiara Christian attend the closed meeting.

**Reconvene:** Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (motion by Ratliff, seconded by Nelson)

**Decisions:**  
**Hope Danielle Watson** The Board voted 9:0 to approve the examination accommodation requests for pharmacist applicant Hope Danielle Watson as follows:

- **Extended time equal to time and a half**
- **Separate room**
- **Snacks and beverage**
- **Insulin**
- **Insulin testing supplies**
- **Indwelling insulin pump**
- **Personal diabetes manager and/or continuous glucose monitor**
- **All approved items must be inspected by the proctor. (motion by Thornbury, seconded by Logan)**

**Christina Nguyen**

**The Board voted 9:0 to approve the examination accommodation requests for pharmacist applicant Christina Nguyen as follows:**

- **Extended time equal to time and 1/2 in an area with limited distractions. (motion by Richards-Spruill, seconded by Nelson)**

**Mary Patricia Baxter**

**The Board voted 9:0 to approve the examination accommodation requests for pharmacist applicant Mary Patricia Baxter as follows:**

- **Increased font size on computer screen. (motion by Boone, seconded by Logan)**

**ADJOURNMENT:**

With all business concluded, the meeting adjourned at 6:15PM.

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Cynthia Warriner, Chairman

\_\_\_\_\_  
Caroline D. Juran, Executive Director

\_\_\_\_\_  
DATE:

\_\_\_\_\_  
DATE:

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY  
PUBLIC HEARING FOR DELIVERY OF DISPENSED PRESCRIPTIONS;  
LABELING**

June 16, 2020  
Commonwealth Conference Center  
Third Floor  
Conference Room 5

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

**CALL TO ORDER:**

A Webex virtual public hearing was called to order at 9:04 a.m. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING:**

Cynthia Warriner, Chairman (on-site)

**MEMBERS PRESENT:**

James L. Jenkins, Jr. (On-Site)

**MEMBERS PARTICIPATING  
VIRTUALLY:**

Kristopher S. Ratliff, Vice Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
Ryan Logan  
Cheryl H. Nelson  
Patricia Richards-Spruill  
Rebecca Thornbury  
William Lee

**STAFF PRESENT:**

Caroline D. Juran, Executive Director (On-Site)  
James Rutkowski, Assistant Attorney General (On-Site)  
Kiara Christian, Executive Assistant (On-Site)

**STAFF PARTICIPATING  
VIRTUALLY:**

Annette Kelley, Deputy Executive Director  
Beth O' Halloran, Deputy Executive Director  
Ellen B. Shinaberry, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP  
Barbara Allison-Bryant, MD, Chief Deputy, DHP

**CALL FOR PUBLIC COMMENT:**

The Board intends to amend section 275 of Chapter 20 pertaining to the procedure for identifying all pharmacies involved in the filling and dispensing of a prescription. The amendment would specify that a unique identifier on the prescription label 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.

PUBLIC COMMENT:

Lauren Paul, Sr. Director, Pharmacy Regulatory Affairs, CVS Caremark thanked the board for opportunity to comment. Petition was submitted in Sep 2017 to make changes to labeling when picking up a prescription from a pharmacy that was filled by a different pharmacy. She commented that this hearing is the sixth discussion through meetings, third formal comment period. She offered support of the amendment, and has spoken to the board multiple times. She pointed out in the Economic Impact Analysis provided by the Department of Planning and Budget in response to this petition that older adults and adults with visual impairments prefer larger size print on labels.

Christina Barrille, Executive Director, VPhA, thanked the board for the opportunity to provide comment. She referred to comment provided by Virginia pharmacists on the Regulatory Town Hall Website. She shared concerns regarding patient safety, if the chance for counseling from a pharmacist may be taken away and that senior citizens will be greatly impacted. Healthcare providers need to have access to information, having the complete information on the label will help if a provider needs to contact the pharmacy. She commented that the proposed amendment takes away a patient's choice of where to fill their pharmacy. She shared concerns from the Richmond Academy of Medicine indicating that pharmacists are not the only providers impacted by this change.

Mark Hickman representing the Virginia Society of Health-System Pharmacists asked the board to take context of the various situation of delivery sites and potential impact to pharmacist-patient relationship into consideration during their decision-making. He shared that VSHP will provide additional comment later if the Board approves the petition for rulemaking.

ADJOURN:

The public hearing adjourned at 9:21 am.

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Cynthia Warriner, Chairman

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Caroline D. Juran, Executive Director

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Date

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Date

**(DRAFT/UNAPPROVED)**

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

Tuesday, June 23, 2020  
Commonwealth Conference Center  
Second Floor  
Board Room 3

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

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CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:15 am.

PRESIDING: Kristopher Ratliff, Committee Chair

MEMBERS PRESENT: Patricia Richards-Spruill, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager  
Ileita Redd, Discipline Program Specialist  
Jess Kelley, DHP Adjudication Specialist

ANTHONY SONIUS  
Registration No. 0230-033045  
Anthony Sonius, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the May 14, 2020, Notice.

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

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

Decision:

Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order for the suspension of not less than one year of the right of Mr. Sonius to renew his registration.

TABITHA VANKLEI  
Registration No. 0230-028097

Tabitha Vanklei, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the May 14, 2020 Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order for the revocation the right of Ms. Vanklei to renew her registration.

SOFIE CO.  
Permit No. 0201-003602

Hillary Lee, Associate Director of Quality Assurance and Nasrin Pourkani, Pharmacist-in-Charge of Sofie Co., appeared to discuss allegations that Sofie Co. may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 14, 2020 Notice.



Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee voted unanimously enter an Order to issue a monetary penalty to Sofie Co.

MICHAEL K. ELLIS  
Registration No. 0230-012060

Michael K. Ellis, pharmacy technician, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacy technician as stated in the May 14, 2020, Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order for the suspension of the right of Mr. Ellis to renew his registration.

ADJOURNED:

4:05 pm

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Kristopher Ratliff, Chair

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Ellen B. Shinaberry  
Deputy Executive Director

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Date

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Date

**(DRAFT/UNAPPROVED)**

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF DRUG DISPOSAL WORKGROUP**

Tuesday, July 21, 2020  
Virtual Meeting  
3<sup>rd</sup> Floor

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

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**CALL TO ORDER:**

A virtual Webex meeting of a drug disposal workgroup convened by the Board of Pharmacy was called to order at 9:00 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING:**

Cheryl Nelson, *Workgroup Chairman (On-Site)*

**WORKGROUP MEMBERS  
PARTICIPATING VIRTUALLY:**

William Lee, *Board Member*  
Glenn Bolyard, *Board Member*  
Christina Barrille, *Executive Director, Virginia Pharmacists Association*  
Nicole Lawter, *representing Virginia Association of Free and Charitable Clinics*  
Natalie Nguyen, *representing Virginia Society of Health-System Pharmacists*  
Jodi Roth, *representing Virginia Association of Chain Drug Stores*  
Justin Wood, *Diversions Program Manager, Washington Field Division, Drug Enforcement Administration*  
Jennifer Wicker, *representing Virginia Hospital and Healthcare Association*

**STAFF PARTICIPATING:**

Caroline Juran, *Executive Director (On-Site)*  
Elaine Yeatts, *Senior Policy Analyst*  
Beth O' Halloran, *Deputy Executive Director*  
James Johnson, *Deputy Executive Director*  
Ellen Shinaberry, *Deputy Executive Director*  
Kiara Christian, *Executive Assistant (On-Site)*

**APPROVAL OF MINUTES:**

Ms. Nelson noted that Mr. Ratliff planned to chair the workgroup meeting, but was unable due to a last-minute conflict.

**PUBLIC COMMENT:**

As noticed in the agenda, Ms. Nelson invited those persons who had requested to offer comment prior to 8am on July 21, 2020 to offer public comment to the workgroup. Cal Whitehead had contacted Ms. Juran indicating that representatives of Covanta would like to offer comment. Leslie Griffith, Dan Moran, and Rachel Graziotto with Covanta provided a brief overview with slides of the role of Covanta in drug destruction services. No other persons requested to offer or provided public comment.

**DISCUSSIONS:**

Ms. Juran provided a high level overview of items provided in the agenda packet, including history of past board actions related to drug disposal.

Justin Wood, DEA, provided an update on national drug takeback events and allowances for collection boxes under federal regulation. Mr. Lee and Ms. Nguyen recommended to Mr. Wood that physicians should be authorized to take back unwanted drugs for destruction in addition to pharmacies. Mr. Wood indicated he would share this information with the DEA policy office. He did confirm that such a provision would require amendment to the federal law and/or regulation.

Ms. Barrille inquired on the availability of a website that provides information specific to drug disposal information Virginia and suggested that providing drug destruction guidance in multiple languages may prove to be helpful.

Staff reported that VaAware was a website created in approximately 2015 that included drug disposal information and other substance abuse related information. It was maintained by various state agencies. It was replaced with the Curbthecrisis website that is maintained by DBHDS and focuses more on addiction services.

Mr. Lee suggested that it may be reasonable for the Board to encourage pharmacists to address drug disposal at the time of counseling patient.

Ms. Nguyen emphasized that adding information to the guidance document to assist pharmacists target patients on certain medications may be helpful.

Ms. Lawter commented that public awareness for how to properly dispose of unwanted medications would be important, and asked that the board consider partnering with other agencies to share information.

**MOTION:**

**The workgroup voted unanimously to forward the following recommendations to the full board for its consideration at the next full board meeting scheduled for September 9, 2020:**

- **Providing link to DEA and NABP lists of authorized collectors on board website;**
  - **Relocating information on website to more prominent location;**
  - **Emphasizing to pharmacists and other providers importance of informing patients, at point of receiving new prescriptions, of proper drug disposal;**
  - **Recommending to DEA that it consider expanding allowances for prescribers to participate as an authorized drug collector to receive unused medications from patients for destruction;**
  - **Recommending standardization of information published by state agencies to improve communication;**
  - **Recommending information on proper drug disposal be available in different languages.**
- (motion by Bolyard, Second by Lawter)**

**ADJOURNED:**

With all business concluded, the workgroup adjourned the meeting at 3:05 pm.

Cheryl Nelson, Chair

Caroline Juran, Executive Director

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Date

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Date

VIRGINIA BOARD OF PHARMACY  
MINUTES OF STATEWIDE PROTOCOLS WORKGROUP TO INITIATE TREATMENT

Tuesday, August 4, 2020  
Virtual Meeting

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

**CALL TO ORDER:**

A virtual Webex meeting of a Statewide Protocol workgroup convened by the Board of Pharmacy was called to order at 9:13 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING VIRTUALLY:**

Ryan Logan, *RPh, Workgroup Chairman*

**WORKGROUP MEMBERS  
PARTICIPATING VIRTUALLY:**

Kristopher Ratliff, *DPh, Chairman, Board of Pharmacy*  
Jake Miller, *D.O., Member, Board of Medicine*  
Brenda Stokes, *M.D., Member, Board of Medicine*  
Emily Yeatts, *VDH, Reproductive Health Supervisor*  
Stephanie Wheawill, *PharmD, VDH, Director of Division of Pharmacy Services*

**STAFF PARTICIPATING  
VIRTUALLY:**

Caroline Juran, *RPh, Executive Director, Board of Pharmacy*  
William Harp, *M.D., Executive Director, Board of Medicine*  
Elaine Yeatts, *DHP, Senior Policy Analyst*  
Jim Rutkowski, *Assistant Attorney General*  
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*  
Beth O'Halloran, *Pharmacist, Deputy Executive Director, Board of Pharmacy*  
Ellen Shinaberry, *PharmD, Deputy Executive Director, Board of Pharmacy*  
Kiara Christian, *Executive Assistant, Board of Pharmacy*

Due to inclement weather and state offices in the metro-Richmond area being closed this day, all workgroup members and staff listed above participated virtually. No other workgroup members or staff participated virtually or from the Perimeter Center building.

**APPROVAL OF AGENDA:  
MOTION:**

**The workgroup voted unanimously to approve the agenda as presented. (motion by Ratliff, seconded by Wheawill)**

**PUBLIC COMMENT:**

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to offer comment prior to 8am on August 4, 2020 to offer public comment to the workgroup.

Clark Barrineau, representing Medical Society of Virginia, thanked everyone for a good legislative session and emphasized that it is critical to keep the requirement for referral to primary care providers in mind during the development of the statewide protocols.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA), shared that it introduced HB1506. She thanked Delegate Sickles, Senator Dunnivant and the Medical Society of Virginia for their assistance with the legislation. She said that VPhA members are excited to offer patients another convenient access to point of care and bridging the gap and referring patients back to physicians in order to provide a better relationship between patients and their medical provider. She offered support to the workgroup.

Jill McCormack, Regional Director of Government Affairs for the National Association of Chain Drug Stores, echoed Ms. Barrille's comments about the work that went into the legislative session. She recommended that the workgroup consider protocols that address generally accepted standards of care vs. specific requirements dictating how pharmacist must provide care to patients. She offered that pharmacists should not be required to complete redundant training that could create barriers. She asked that the counseling requirement for naloxone be made broader allowing pharmacist the flexibility to use the best available and most up to date information for education, instead of a specific brochure. She asked that the workgroup allow access to all possible contraceptive options that may be appropriate given unique circumstances and preferences, and that the workgroup not replicate the 15-day waiting period required of Maryland as this appears arbitrary and creates delays. She requested the protocol for prenatal vitamins replace "evidence based



guidelines” and with a reference to ACOG, WHO, or FDA guidelines.

Jodi Roth, representing the Virginia Association of Chain Drug Stores, echoed comments of Christina Barrille and Jill McCormack.

**CHARGE OF WORKGROUP, 2<sup>nd</sup>  
Enactment Clause of HB 1506:**

Mr. Logan reviewed the charge of the workgroup, and Ms. Juran provided background of HB 1506. It was noted that this workgroup will meet twice to develop recommended statewide protocols for board consideration for pharmacists to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Naloxone, or other opioid antagonist, including paraphernalia for administering it;
- Epinephrine;
- Injectable or self-administered hormonal contraception provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
- Prenatal vitamins for which a prescription is required;
- Dietary fluoride supplement, in accordance with the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below recommendation of the US Department of Health and Human Services;
- Medication covered by the patient’s health carrier when the patients out-of-pocket cost is lower than out-of-pocket purchase of the over-the-counter equivalent of the same drug.

It was stated the workgroup must also develop recommended emergency regulations for board consideration to implement the provisions.

**OVERVIEW OF PHARMACIST  
EDUCATIONAL/TRAINING  
STANDARDS:**

Dave L. Dixon, PharmD, FACC, FCCP, FNLA, BCPS, BCACP, CDCES, CLS, Associate Professor in Ambulatory Care and Vice Chair of Clinical Services in the Department of Pharmacotherapy and Outcome Science at the Virginia Commonwealth University School of Pharmacy, shared a PowerPoint presentation (Attachment

1) and provided a brief overview of Pharmacy Education and Training Standards. He concluded: detailed dosing guidelines in the statewide protocols are likely unnecessary as dosing for epinephrine, naloxone, prenatal vitamins, fluoride, and OTC medications is standardized and does not change; hormonal contraception dosing is based on symptoms and patient preference, and that additional guidance or training on assessing symptoms and patient preferences may be appropriate; and, that pharmacists regularly dispense and make dosing recommendations for the medications being discussed today, therefore, additional guidance or training is not needed.

### **REVIEW OF WORKFORCE STATISTICS:**

Ms. Juran shared the following statistics from the Draft 2019 Pharmacist Workforce Survey:

- 15,875 pharmacist licensees, 97% of renewing pharmacists responded to the survey;
- 8,734 in Virginia's workforce with 7,137 FTEs;
- Large community pharmacies (>10 locations) most common working establishment, followed by hospital pharmacies and smaller pharmacies;
- Educational attainment continues to increase; 66% in 2019 held pharmacy doctorate with 34% holding baccalaureate;
- 19% completed 1-year residency program; 7% completed 2-year residency program; 10% hold board certification;
- 66% female, median age of 44;
- 528 participate in collaborative practice management agreements involving anticoagulation, diabetes, hypertension, hypercholesterolemia, asthma, tobacco cessation, or travel medications;
- 32% provide immunization services, 29% provide medication management services, and 25% provide compounding services.

### **RECOMMENDED COMPONENTS OF STATEWIDE PROTOCOL:**

The workgroup reviewed the excerpt included in the agenda packet from *PHARMACIST STATEWIDE PROTOCOLS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY*, March 2017.

**DEVELOPMENT OF  
RECOMMENDED STATEWIDE  
PROTOCOLS:**

The workgroup discussed the material included in the agenda packet for each drug category.

**Naloxone, other opioid antagonist,  
including paraphernalia**

Dr. Stokes questioned if there could be some inclusion criteria put into the guidance similar to Board of Medicine (BOM) co-prescribing requirements. It was noted that certain populations should be excluded from receiving naloxone such as hospice or end of life patients. Staff noted they would refer to the BOM regulations for possible language.

Ms. Juran confirmed that the dispensing of naloxone would be reported to the PMP. Dr. Wheawill commented about the counseling requirement. Ms. Yeatts suggested that the Department of Behavioral Health and Developmental Services be consulted regarding use of the REVIVE! Brochure. Ms. Juran confirmed for Dr. Miller that the pharmacist cannot require the patient to obtain the naloxone.

**Epinephrine**

Dr. Miller recommended the protocol should allow for prescribing/dispensing epinephrine to children. However, the current statute restricts protocols to 18 years of age and older. Under Patient Inclusion Criteria, it was recommended to insert “or demonstrating signs and symptoms of anaphylaxis” after “at risk for experiencing anaphylaxis”. It was suggested to include language on how to identify persons “at risk” such as someone with a dispensing history of obtaining epinephrine or who informs the pharmacist of a history of allergies that could result in anaphylaxis.

**Prenatal Vitamins**

The workgroup identified that sometimes patients use their OB/GYN as their primary care provider, and offered that the notification should be to the patient’s primary care provider and/or OB/GYN. Under Pharmacist Education and Training, Ms. Juran noted that NACDS provided comment suggesting that “evidence based guidelines” be replaced with “guidelines from ACOG, FDA, or WHO”. Dr. Stokes recommended leaving as written since the broader language would include these specific guidelines. Staff reported that the referenced statute under Notification of Primary Care Provider in all of the draft protocols should read 54.1-3303.1.

### **Fluoride Supplements**

Ms. Juran shared that the American Dental Association (ADA) does not recommend the use of fluoride supplements to persons over the age of 16. Ms. Yeatts recommended that the protocol should simply read that the ADA does not recommend the use of fluoride supplements in persons 18 years of age and older.

### **Over-the-Counter Medications**

The workgroup had some discussion about the term “equivalent” and if the protocol was intended to capture both OTC drugs and prescription drugs. Suggested examples provided for the protocol included the prescribing of an OTC if the health carrier would cover the expense which may be cheaper than paying out-of-pocket for the OTC drug, and the prescribing of a prescription drug in the same therapeutic class as an OTC drug, e.g., nasal corticosteroid sprays or antacids, that may be covered by the health carrier and cheaper than paying out-of-pocket for the similar or “equivalent” OTC drug. Mr. Ratliff recommended the protocol also include needles, syringes, and diabetic test strips, because often the prescriber fails to issue a prescription for these accompanying items. There was some discussion regarding whether “medication” included paraphernalia and medical devices.

### **Hormonal Contraceptives**

Ms. Emily Yeatts and Dr. Stokes indicated they liked Colorado’s protocol, algorithm, and color-coded questionnaire the best of the options provided in the agenda packet. Both recommended that the protocol should include emergency contraception. Ms. Emily Yeatts recommended inserting “vaping” in the questionnaire and including a question about use of emergency contraception in the last five days. For depot medroxyprogesterone acetate, it was recommended to look at Oregon or California’s algorithm. There was discussion that pharmacists should be required to obtain ACPE-accredited training through continuing education as was recommended by Dr. Dixon from VCU. It was noted that several states appear to recognize a 4-hour online ACPE-accredited program. Staff indicated they would work on preparing a draft protocol for the next meeting.

### **Regulations**

There was discussion that the regulations should include a recordkeeping requirement. Ms. Elaine Yeatts recommended looking at the Board of Medicine’s requirements of six years. There was consensus that six years would not be overly burdensome.

**ADJOURNED:**

With all business concluded, the workgroup adjourned the meeting at 12:33 pm.

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Ryan Logan, Chair

\_\_\_\_\_  
\_\_\_\_\_  
Caroline Juran, Executive Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

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

Wednesday, August 5, 2020  
Commonwealth Conference Center  
Second Floor  
Board Room 2

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

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

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CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 0919.

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT: Melvin Boone  
Bill Lee  
Ryan Logan  
Cheryl Nelson  
Patricia Richards-Spruill

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

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

JAMES JOSEPH KELLEY, JR.  
License No. 0202-010072

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

Jess Kelly, DHP Adjudication Specialist, presented the case.

Mr. Kelley was present and was represented by counsel Michael Goodman.

Sarah E. Rogers, DHP Senior Investigator testified in person on behalf of the Commonwealth.

Mr. Kelley testified on his own behalf.

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CLOSED MEETING:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of James Joseph Kelley, Jr. Additionally, he moved that Caroline Juran, Ellen Shinaberry, Kiara Christian and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Mr. Lee, and duly seconded by Ms. Richards-Spruill, the panel voted 6-0 to accept the Findings and Facts and Conclusion of Law proposed by Ms. Kelly. Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Nelson, the panel voted 6-0 to reinstate the pharmacist license of Mr. Kelley with certain terms and conditions.

ADJOURN:

With all business concluded, the meeting adjourned at 12:53 pm.

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Kris Ratliff, Chair

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Caroline D. Juran  
Executive Director

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Date

**VIRGINIA BOARD OF PHARMACY  
MINUTES OF STATEWIDE PROTOCOLS WORKGROUP TO INITIATE TREATMENT**

Tuesday, August 17, 2020  
Virtual Meeting

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

**CALL TO ORDER:**

A virtual Webex meeting of a Statewide Protocol workgroup convened by the Board of Pharmacy was called to order at 9:03 AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the workgroup convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING VIRTUALLY:**

Ryan Logan, RPh, *Workgroup Chairman*

**WORKGROUP MEMBERS  
PARTICIPATING VIRTUALLY:**

Kristopher Ratliff, DPh, *Chairman, Board of Pharmacy*  
Jake Miller, D.O., *Member, Board of Medicine*  
Brenda Stokes, M.D., *Member, Board of Medicine*  
Emily Yeatts, VDH, *Reproductive Health Supervisor*  
Stephanie Wheawill, PharmD, VDH, *Director of Division of Pharmacy Services* (departed meeting during discussion of contraceptive protocols due to availability conflict and rejoined prior to conclusion of this topic discussion)  
Christy Gray, MPH, CHES, CHTS-CP, VDH, *Director, Division of Immunization* (departed meeting at 10:38am)

**STAFF PARTICIPATING  
VIRTUALLY:**

Caroline Juran, RPh, *Executive Director, Board of Pharmacy*  
William Harp, M.D., *Executive Director, Board of Medicine*  
Elaine Yeatts, DHP, *Senior Policy Analyst*  
Jim Rutkowski, *Assistant Attorney General*  
Sammy Johnson, *Pharmacist, Deputy Executive Director, Board of Pharmacy*  
Beth O'Halloran, *Pharmacist, Deputy Executive Director, Board of Pharmacy*  
Ellen Shinaberry, PharmD, *Deputy Executive Director, Board of Pharmacy*  
Kiara Christian, *Executive Assistant, Board of Pharmacy*



All workgroup members and staff listed above participated virtually.

**APPROVAL OF AGENDA:  
MOTION:**

**The workgroup voted unanimously to approve the agenda as presented. (motion by Stokes, seconded by Ratliff)**

**Ms. Emily Yeatts was unable to participate in the vote due to connectivity issues, but rejoined the meeting following the vote.**

**PUBLIC COMMENT:**

As noticed in the agenda, Mr. Logan invited those persons who had requested via email to Ms. Juran to offer comment prior to 8am on August 17, 2020 to offer public comment to the workgroup.

Christina Barrille, Executive Director, Virginia Pharmacists Association (VPhA), and Kelly Goode, PharmD reviewed VPhA's written public comment which was screen-shared for viewing at this time. Key comments included: clarification for the Board that devices are intended to be included in the statewide protocol for lowering costs to the patient; recommendation to consider Kentucky's protocol regarding naltrexone; suggestion to provide clarity regarding patient inclusion in the epinephrine protocol, but to not be too prescriptive; recommendation to not require an appointment in the contraception protocol; refer to the most recent 2020 version of the US Medical Eligibility Criteria for Contraception; clarify language regarding breastfeeding; recommendation to include question regarding vaping; consider requirement for pharmacist to follow-up with patient who has never used hormonal contraception before; clarify use of ulipristal on emergency contraception protocol; recommendation to contact OB/GYN on prenatal vitamin protocol; suggestion for board to communicate legislative need to amend age in fluoride protocol; and recommendation to offer best practice in notifying practitioner, but not to be too prescriptive.

Ms. Juran shared that she had received an email from Sharon Gatewood, PharmD that echoed the comments provided by VPhA.

Natalie Nguyen, PharmD, representing Virginia Society of Health-System Pharmacists, offered support of the

comments provided by VPhA. She recommended that the board standardize the minimum information that must be communicated with healthcare providers. She also asked the workgroup to consider adding to patient exclusion criteria that an individual with a documented allergic reaction to Naloxone be excluded from the Naloxone Protocol. She recommended additions to inclusion information for epinephrine to include a definition of reporting a diagnosis of allergies that may result in anaphylaxis, and to add medication with high reaction probability. She asked that a definition for the therapeutic category be provided in the protocol related to out of pocket cost. She questioned if the required CE would be an annual requirement. It was also recommended that the date of last physical exam or pap be required in the protocol for hormonal contraception.

Jill McCormack, Regional Director of Government Affairs, National Association of Chain Drug Stores (NACDS), suggested that language be included to support new products coming into the market into the epinephrine protocol. She said that they agree with VPhA that the law includes medical supplies and devices into the protocol related to out-of-pocket cost. She recommended that the protocol mirror the requirements in the health commissioner's standing order. She shared that NACDS appreciates the inclusion of emergency contraceptive into the Emergency and Hormonal contraceptive protocol. She recommended that all methods of training be allowed. Ms. McCormack stated pharmacists have found it challenging in other states to use the state paper forms on this subject and requested an allowance for a pharmacy to convert the state form into an electronic form to facilitate electronic use in the future. She recommended pharmacists have the ability to schedule patient appointments for prescribing contraception.

**APPROVAL OF MINUTES:**

**The workgroup voted unanimously to approve the August 4, 2020 Workgroup meeting minutes as presented. (motion by Miller, second by Stokes)**

**Adopt recommended statewide protocols for board consideration for pharmacists to initiate treatment with, dispense, or administer the following drugs and**

devices to persons 18 years or age or older:

**NALOXONE OR OTHER OPIOID ANTAGONIST, INCLUDING SUCH CONTROLLED PARAPHENALIA, AS DEFINED IN §54.1-3466, AS MAY BE NECESSARY TO ADMINISTER SUCH NALOXONE OR OTHER OPIOID ANTAGONIST**

The workgroup briefly discussed adding naltrexone to the protocol and concluded that it would review Kentucky's protocol at a later time for possible inclusion in the protocol in the future. The workgroup also had some discussion about which providers should receive notification and if the exclusion criteria should be modified to outline certain medical conditions that should be excluded from receiving naloxone under this protocol. Ms. Juran shared that the Department of Behavioral Health and Developmental Services recommends pharmacists provide patients with the REVIVE! naloxone brochure when dispensing naloxone, consistent with the Board's current naloxone protocol under the Health Commissioner's standing order.

**MOTION:**

**The workgroup voted unanimously to amend the naloxone protocol as follows:**

- **Under Patient Exclusion Criteria – regarding pain patients, insert sentence at the end of the bullet to refer patient to primary care provider to determine if naloxone is appropriate**

**and to recommend to the full board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)**

**EPINEPHRINE**

The workgroup discussed whether the patient inclusion criteria should include patients who are taking drugs with a black box warning that use of the drug may result in anaphylaxis. The workgroup concluded that the current language was written broadly and should remain in place.

**MOTION:**

**The workgroup voted unanimously to recommend to the full board that it adopt the epinephrine protocol as presented. (motion by Miller, seconded by Stokes)**

**PRENATAL VITAMINS FOR WHICH A PRESCRIPTION IS REQUIRED**

There was some discussion by the workgroup regarding how a pharmacist should notify the primary care provider when initiating therapy under the statewide protocols. There appeared to be a general consensus that it should be left to the pharmacist's discretion and that a fax may be sufficient.

The workgroup considered a recommendation to notify the patient's primary care provider and OB/GYN.

**MOTION:**

**The workgroup voted unanimously to amend the prenatal vitamin statewide protocol as follows:**

- **Under Notification of Primary Care Provider, insert in the first sentence “and obstetrician/gynecologist (OB/GYN)” after “provider”;**

**And to recommend to the full board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)**

**DIETARY FLUORIDE SUPPLEMENTS, IN ACCORDANCE WITH RECOMMENDATIONS OF THE AMERICAN DENTAL ASSOCIATION FOR PRESCRIBING OF SUCH SUPPLEMENTS FOR PERSONS WHOSE DRINKING WATER HAS FLUORIDE CONTENT BELOW THE CONCENTRATION RECOMMENDED BY THE U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES**

The workgroup acknowledged that the law restricts statewide protocols to patients 18 years of age and older and that the American Dental Association does not recommend use of fluoride supplements to persons of this age category.

**MOTION:**

**The workgroup voted unanimously to recommend to the full board that it adopt the fluoride supplement protocol as presented. (motion by Miller, seconded by Stokes)**

**MEDICATIONS COVERED BY THE PATIENTS HEALTH CARRIER WHEN THE PATIENTS OUT-OF-POCKET COST IS LOWER THAN THE OUT-OF-POCKET COST TO PURCHASE AN OVER-THE-COUNTER EQUIVALENT OF THE SAME DRUG**

Dr. Miller objected to the draft language allowing for the prescribing of a medication in the same “therapeutic category” and recommended that the drug be identical to the originally prescribed drug. The workgroup discussed the statutory definition of “therapeutically equivalent drug products”. There was discussion regarding whether the law supports this protocol including an allowance for pharmacists to prescribe and dispense ancillary devices required for drug administration. The workgroup proceeded in a manner that the law may not support inclusion of devices. Several members, including Dr. Ratliff and Dr. Miller, supported inclusion of devices and recommended a legislative proposal in 2021 for such an allowance, if necessary.

**MOTION:**

**The workgroup voted unanimously to amend the protocol to lower out-of-pocket expense as follows:**

- Under Pharmacist Education and Training – strike “over-the-counter”;
- Under Patient Inclusion Criteria – second bullet, replace “in the same therapeutic category” with “a therapeutically equivalent drug product, as defined in §54.1-3401,” and include a footnote referencing the statutory definition at the bottom of the page

**and to recommend to the full Board that it adopt the protocol as amended. (motion by Miller, seconded by Stokes)**

**INJECTABLE OR SELF-ADMINISTERED HORMONAL CONTRACEPTIVES, PROVIDED THE PATIENT COMPLETES AN ASSESMENT CONSISTENT WITH THE UNITED STATES MEDICAL ELIGIBILITY CRITERIA FOR CONTRACEPTIVE USE**

The workgroup discussed if there was a need for ongoing pharmacist training on this topic to be outlined in the protocol. They concluded that a one-time continuing education (CE) requirement was sufficient. It was suggested that the Board could post a list of applicable CE on its website. Staff raised some concerns with using a color-coded self-screening questionnaire that correlates with a color-coded US Summary of Eligibility Criteria as it may disadvantage persons who are color-blind and may increase opportunity for errors if the CDC updates its chart before board staff is aware or able to update the color-coded version. The workgroup concluded it should not use a color-coded system and to facilitate ease of use the self-screening questionnaire could simply reference the categories as indicated on the US Summary of Eligibility Criteria for Contraceptive Use.

There was discussion about patient eligibility criteria for this protocol and the process to handle ineligible patients with referrals to healthcare providers. The workgroup also discussed possible tracking of patients who may transfer to different pharmacies. The workgroup acknowledged that if the patient did not want to obtain the drug from the pharmacy that initiated the therapy, the prescribing pharmacist should issue a prescription to the patient to take to another pharmacy for dispensing.

There was some discussion about the record keeping requirements for this protocol and consideration for the recommendation to allow for a pharmacist to instruct the patient to take a pregnancy test, when necessary to rule out pregnancy. The workgroup recommended referring such patient to a primary care provider and not including such an allowance in the protocol.

The workgroup discussed the draft algorithms. It was recommended that box number three be removed from the two draft algorithms since the medication screening could be accomplished in the first box when screening for contraindications. It was recommended to conform the references to blood pressure on the two documents to 140/90. The workgroup agreed that it would be acceptable for an electronic version of the self-screening questionnaire to be created by a pharmacy if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

**MOTION:**

**The workgroup voted unanimously to amend the Pharmacist Hormonal Contraceptive Statewide Protocol as follows:**

- **Under Patient Inclusion Criteria – insert “most current version of the” before “Centers” and insert “i.e., the prescribed drug is assessed at a “1” or “2” for all conditions applicable to the patient” after “use”;**
- **Under Process for Handling Ineligible Patients – add at the end of section “If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.”**
- **Under Further Conditions – strike 1b regarding referral of abuse; strike 2 regarding dispensing as soon as practicable; strike 3a regarding prohibition for requiring an appointment; and insert in 3b, a sentence confirming that the “evidence of a clinical visit” may be obtained by the response on the self-screening questionnaire regarding the date of the patient’s last women’s health clinical visit.;**
- **Under Notification of Primary Care Provider – insert requirement to also notify the patient’s OB/GYN;**

**Amend the *Virginia Hormonal Contraceptive Self-Screening Questionnaire* as follows:**

- **In the title, insert “Routine” after “Virginia”;**
- **Insert the pregnancy screening questions from the draft algorithms to this document;**
- **Insert question regarding number of cigarettes per day;**

**Amend the *Standard Procedures Algorithm for Virginia Pharmacists Prescribing of Contraceptives* as follows:**

- Delete box three and insert “/Medications” after “Contraindicating Conditions” in box 1;
- In box 6, insert “Regular” prior to “Quick”;
- In box 7, amend to conform to notification requirement in law.

**Amend the *Standard Procedures Algorithm for Pharmacists Prescribing and Administering Depot Medroxyprogesterone Acetate* as follows:**

- Delete box three and insert “/Medications” after “Contraindicating Conditions” in box 1;
- In box 4, change “160/100” to “140/90”;
- In box 6, Ongoing Administration, change “15” to “13” and strike “Do not administer if <11 weeks ago.”
- In box 7, amend to conform to notification requirement in law.

**Amend *Pharmacist Emergency Contraception Statewide Protocol* as follows:**

- Under Patient Inclusion Criteria – insert “most current version of the” before “Centers”;
- Under Process for Handling Ineligible Patients – add at the end of section “If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.”
- Under Additional Prescribing and Dispensing Considerations – insert “Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse.” and “Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.”;
- Under Notification of Primary Care Provider – insert requirement to also notify the patient’s OB/GYN.

**and to recommend to the full Board that it adopt the Pharmacist Hormonal Contraceptive Statewide Protocol, the Algorithm for Virginia Pharmacists Prescribing of Contraceptives, the Algorithm for Pharmacists Prescribing and Administering Depot Medroxyprogesterone Acetate, the Virginia Routine Hormonal Contraceptive Self-Screening**

**Questionnaire, and the Pharmacist Emergency Contraception Statewide Protocol as amended and the Virginia Emergency Contraception Self-Screening Questionnaire as presented. (motion by Miller, seconded by Stokes; Wheawill abstained)**

It was suggested that the Board could contact schools of pharmacy to request that it develop written educational materials for pharmacists to provide to patients regarding “key facts” surrounding the use of EC, which could include the statements from the Additional Prescribing and Dispensing Considerations section of the protocol. Links to educational materials could be posted on the Board’s website.

**ADOPT RECOMMENDED  
EMERGENCY REGULATIONS FOR  
BOARD CONSIDERATION TO  
IMPLEMENT PROVISIONS**

The workgroup reviewed the draft emergency regulations for implementing these provisions.

**MOTION:**

**The workgroup voted unanimously to amend 18VAC110-21-46 by inserting in (B)(2) “If the drug being initiated is an injectable or self-administered hormonal contraceptive or a prenatal vitamin, the pharmacist shall also notify the patient’s obstetrician or gynecologist” after “notification”, and to recommend to the full Board that it adopt 18VAC110-20-150 as presented and 18VAC110-21-46 as amended. (motion by Miller, seconded by Stokes; Wheawill abstained)**

**ADJOURNED:**

With all business concluded, the workgroup adjourned the meeting at 4:53 pm.

\_\_\_\_\_  
Ryan Logan, Chairman

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Caroline Juran, Executive Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date



**(DRAFT/UNAPPROVED)**

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

Tuesday, August 18, 2020  
Commonwealth Conference Center  
Second Floor  
Board Room 2

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

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**CALL TO ORDER:** A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:33 am.

**PRESIDING:** Patricia Richards-Spruill, Committee Chair

**MEMBERS PRESENT:** Melvin Boone, Committee Member  
Cheryl H. Nelson, Observing

**STAFF PRESENT:** Mykl Egan, Discipline Case Manager  
Ileita Redd, Discipline Program Specialist  
Jess Kelley, DHP Adjudication Specialist

**FEDAH S. ABOABDO**  
License No. 0230-217102

Fedah S. Aboabdo, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the July 2, 2020, Notice. She was represented by Monica Monday, Esq.

**Closed Meeting:** Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Fedah S. Aboabdo. Additionally, he moved that Mykl Egan, Ileita Redd, and Cheryl Nelson 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. Richards-Spruill, the Committee unanimously voted to place Ms. Aboabdo on probation for not less than one year under certain terms and conditions.

JOSEPH EMMANUELLE  
License No. 0202-204360

Joseph Emmanuelle, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the July 7, 2020, Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Joseph Emmanuelle. Additionally, he moved that Mykl Egan, Ileita Redd and Cheryl Nelson 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. Richards-Spruill, the Committee unanimously voted to order Mr. Emmanuelle to take additional hours of continuing education.

ASHLEY N. RICHARDSON  
Registration No. 0230-021053

Ashley N. Richardson, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the July 2, 2020, Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of

Ashley Richardson. Additionally, he moved that Mykl Egan, Ileita Redd, and Cheryl Nelson 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. Richards-Spruill, the Committee unanimously voted to Reprimand Ms. Richardson and order her to take additional hours of continuing education.

ALANTRA M. HOLMAN  
Registration No. 0230-028679

Alantra Holman, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the July 2, 2020, Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Alantra Holman. Additionally, he moved that Mykl Egan, Ileita Redd and Cheryl Nelson 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. Richards-Spruill, the Committee unanimously voted to Reprimand Ms. Richardson and order her

to take two additional hours of continuing education.

ADJOURNED:

4:00 pm

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Patricia Richards-Spruill, Chair

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Ellen B. Shinaberry  
Deputy Executive Director



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Date

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Date

**Agenda Item: Regulatory Actions - Chart of Regulatory Actions  
As of August 26, 2020**

Board		Board of Pharmacy
Chapter	Action / Stage Information	
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Use of medication carousels and RFID technology</u> [Action 5480]</p> <p>NOIRA - Register Date: 9/14/20 Comment until 10/14/20</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Delivery of dispensed prescriptions; labeling</u> [Action 5093]</p> <p>Proposed - Register Date: 2/3/20 Board to consider final regulations</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Handling fee</u> [Action 5519]</p> <p>Fast-Track - At Secretary's Office for 55 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Prohibition against incentives to transfer prescriptions</u> [Action 4186]</p> <p>Final - At Governor's Office for 826 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Increase in fees</u> [Action 4938]</p> <p>Final - Register Date: 9/14/20 Regulation effective: 10/14/20</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Brown bagging and white bagging</u> [Action 4968]</p> <p>Final - At Secretary's Office for 77 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p> <u>Placement of chemicals in Schedule I</u> [Action 5517]</p> <p>Final - Register Date: 7/6/20 Effective: 8/5/20</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p> <u>Scheduling for conformity to DEA scheduling</u> [Action 5518]</p> <p>Final - Register Date: 7/6/20 Effective: 8/5/20</p>
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	<p><u>CE credit for volunteer hours</u> [Action 5546]</p> <p>Fast-Track - At Secretary's Office for 30 days</p>

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehouse	<u>Delivery of Schedule VI prescription devices</u> [Action 5084] Final - <i>At Secretary's Office for 30 days</i>
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	<u>Prohibition of products for vaping or inhalation with vitamin E acetate</u> [Action 5452] Emergency/NOIRA - <i>Emergency effective 8/6/20</i> <i>Comment on NOIRA: 8/31/20 to 9/30/20</i>
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	<u>Registered agents and wholesale distribution</u> [Action 5398] Proposed - <i>At Secretary's Office for 44 days</i>
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	 <u>Conforming to 2020 legislation</u> [Action 5545] Final - <i>Register Date: 8/31/20</i> <i>Effective: 9/30/20</i>

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

**Included in your agenda package are:**

Copy of the summary of legislation passed in the 2020 General Assembly

Amendment to Code in HB1654/SB1074

A copy of the draft emergency regulations

**Staff note:**

Board counsel will provide information about the definition of “non-profit”

**Board action:**

Adoption of emergency regulations as required by the 2<sup>nd</sup> enactment clause in the legislation

# HB 1654 Schedule VI controlled substances and hypodermic syringes and needles; limited-use license.

Introduced by: Dan I. Helmer | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED: (all summaries)

**Schedule VI controlled substances; hypodermic syringes and needles; limited-use license.** Allows the Board of Pharmacy to issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. The bill requires such nonprofit facilities to obtain a limited-use permit from the Board and comply with regulations for such a permit. This bill directs the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill. This bill is identical to SB 1074.

### CHAPTER 609

*An Act to amend and reenact §§ 54.1-3304.1 and 54.1-3467 of the Code of Virginia, relating to Schedule VI controlled substances; hypodermic syringes and needles; limited-use license.*

[H 1654]

Approved April 2, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3304.1 and 54.1-3467 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3304.1. Authority to license and regulate practitioners; permits.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

C. *The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.*

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.



**BOARD OF PHARMACY**

**Limited use permit**

Part I

Definitions and Fees

**18VAC110-30-10. Definitions.**

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

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

of Medicine or a nurse practitioner with a current active license issued by the Joint Boards of Nursing and Medicine.

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

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

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

## Part II

### Licensure and Permit Requirements

#### **18VAC110-30-20. Application for licensure.**

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

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

~~B. C. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine, or podiatry issued~~

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

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

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

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

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

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

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

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

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

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

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

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

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

a. A pharmacy technician registered with the board; or

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

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

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

b. The preparation of prescription labels or patient information;

- c. The removal of the drug to be dispensed from inventory;
  - d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;
  - e. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
  - f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and
  - g. Applicable laws and regulations related to dispensing.
4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.
5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.
- B. Prior to the dispensing, the licensee shall:

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

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

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

## Part VII

### Grounds for Disciplinary Action

#### **18VAC110-30-270. Grounds for disciplinary action.**

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, osteopathic medicine or podiatry, or as a physician assistant or nurse practitioner suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice in the Commonwealth of Virginia.

**Agenda Item: Adoption of Emergency Regulations for Pharmaceutical Processors of Cannabis oil – Dispensing facilities, temporary residency, etc.**

**Included in your agenda package are:**

Copy of SB976 as passed by the 2020 General Assembly (emergency authority in 2<sup>nd</sup> enactment)

Copy of the proposed regulations as recommended by Staff

**Board action:**

Adoption of emergency regulations

# 2020 SESSION

another bill | print version

## SB 976 Pharmaceutical processors; operation of cannabis dispensing facilities.

Introduced by: David W. Marsden | all patrons ... notes | add to my profiles

### SUMMARY AS ENACTED WITH GOVERNOR'S RECOMMENDATION: (all summaries)

**Board of Pharmacy; pharmaceutical processors; cannabis dispensing facilities.** Defines "cannabis dispensing facilities" and allows the Board of Pharmacy to issue up to five permits for cannabis dispensing facilities per health service area. The bill requires the Board to establish a ratio of one pharmacist for every six pharmacy interns, technicians, and technician trainees for pharmaceutical processors and cannabis dispensing facilities. The bill directs the Board of Pharmacy to require that, after processing and before dispensing cannabis oil, a pharmaceutical processor make a sample available from each homogenized batch of product for testing at an independent laboratory located in Virginia that meets Board requirements. The bill requires that the Board promulgate regulations that include an allowance for the sale of devices for administration of dispensed products and an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification. The bill also requires the Board to adopt regulations for pharmaceutical processors that include requirements for (i) processes for safely and securely cultivating cannabis plants intended for producing cannabis oil; (ii) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (iii) the secure disposal of plant remains; (iv) dosage limitations, which shall provide that each dispensed dose of cannabis oil not exceed 10 milligrams of tetrahydrocannabinol; and (v) a process for registering cannabis oil products. The bill requires the Board of Pharmacy to promulgate required regulations within 280 days of the bill's enactment.

#### CHAPTER 1278

*An Act to amend and reenact §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; cannabis dispensing facilities.*

[S 976]

Approved April 22, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows:

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

A. As used in this section:



~~"Cannabidiol oil" means any formulation of 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 five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol.~~

~~"Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.~~ "Cannabis oil" means any formulation of processed Cannabis plant extract or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

~~"THC-A oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinolic acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinolic acid per dose 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 cannabis oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. *The practitioner shall use his professional judgement to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances.*

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 cannabis oil for the treatment or to alleviate the symptoms of a patient's 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. A 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, may designate an individual to act as his registered agent for the purposes of receiving ~~cannabidiol oil or THC-A cannabis~~ oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.

H. 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, his registered agent, 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.

I. 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 ~~Committee~~ for Courts of Justice ~~and the Senate Committee on the Judiciary~~, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed ~~physicians~~ practitioners 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 ~~or cannabis dispensing facility~~ involved in the treatment of a registered patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

#### § 54.1-3442.5. Definitions.

As used in this article:

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

"*Cannabis dispensing facility*" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis oil produced by a pharmaceutical processor to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

"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 cannabis~~ oil, produces ~~cannabidiol oil or THC-A cannabis~~ oil, and dispenses ~~cannabidiol oil or THC-A cannabis~~ oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

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

"Registered agent" 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.~~

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

A. No person shall operate a pharmaceutical processor *or a cannabis dispensing facility* 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 *or cannabis dispensing facility*. 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 *pharmaceutical processor and up to five cannabis dispensing facilities* 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 *and cannabis dispensing facility*.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors *and cannabis dispensing facilities*. 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 cannabis oil to a registered patient, his registered agent, 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;~~ (x) ~~the secure disposal of plant remains;~~ (xi) ~~a process for registering a cannabidiol oil and THC-A oil product;~~ (xii) dosage limitations, which shall provide that each dispensed dose of ~~cannabidiol oil or THC-A cannabis oil~~ not exceed 10 milligrams of tetrahydrocannabinol; ~~and (xiii)~~ (x) a process for the wholesale distribution of and the transfer of ~~cannabidiol oil and THC-A cannabis oil products between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility;~~ (xi) *an allowance for the sale of devices for administration of dispensed products; and (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis oil; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) the secure disposal of plant remains; and (d) a process for registering cannabis oil products.*

D. *The Board shall require that after processing and before dispensing cannabis oil, a pharmaceutical processor shall make a sample available from each homogenized batch of product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis.*

E. *A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board in regulation.*

*D-F. Every pharmaceutical processor or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times.*

*E-G. The Board shall require an applicant for a pharmaceutical processor and cannabis dispensing facility 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-H. In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the Board or who has at least two years of experience cultivating plants and (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.*

*I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.*

*G-J. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, 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 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.*

*H-K. Every pharmaceutical processor and cannabis dispensing facility shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.*

*L. A pharmacist at the pharmaceutical processor and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time.*

*M. Any person who proposes to use an automated process or procedure during the production of cannabis oil that is not otherwise authorized in law or regulation or at a time when a pharmacist will not be on-site may apply to the Board for approval to use such process or procedure pursuant to subsections B through E of § 54.1-3307.2.*

§ 54.1-3442.7. Dispensing cannabis oil; report.

*A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabidiol oil or THC-A cannabis oil only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia as made evident*

to the Board, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3, (ii) such patient's registered agent, or (iii) 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 or temporarily resides in Virginia as made evident to the Board 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 or cannabis dispensing facility shall 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, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, 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, registered agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of ~~cannabidiol oil or THC-A~~ cannabis oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only ~~cannabidiol oil and THC-A~~ cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House ~~and Senate Committees~~ Committee for Courts of Justice and the Senate Committee on the Judiciary on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board, including the number of practitioners, patients, registered agents, 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. The concentration of tetrahydrocannabinol in any THC-A cannabis oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any ~~THC-A onsite cannabis oil on site~~ is within such range and. A pharmaceutical processor producing cannabis oil shall establish a stability testing schedule of THC-A cannabis oil.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor or cannabis dispensing facility under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of ~~cannabidiol oil or THC-A~~ cannabis oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing ~~cannabidiol oil or THC-A~~ cannabis oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such ~~cannabidiol oil or THC-A~~ cannabis oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor or cannabis dispensing facility pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing ~~cannabidiol oil or THC-A~~ cannabis oil in accordance with the provisions of this article and Board regulations or (b) such ~~cannabidiol oil or THC-A~~ cannabis oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

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.

## **Emergency Regulations Governing Pharmaceutical Processors**

### **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:

"90-day supply" means the amount of cannabis oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Batch" means a quantity of cannabis oil from a production lot that is identified by a batch number or other unique identifier.

"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 cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Dispensing error" means one or more of the following was discovered after the final verification by the pharmacist, regardless of whether the patient received the oil:

1. Variation from the intended oil to be dispensed, including:
  - a. Incorrect oil;
  - b. Incorrect oil strength;
  - c. Incorrect dosage form;
  - d. Incorrect patient; or
  - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
  - a. Known therapeutic duplication;
  - b. Known drug-disease contraindications;
  - c. Known drug-drug interactions;
  - d. Incorrect drug dosage or duration of drug treatment;

- e. Known drug-allergy interactions;
  - f. A clinically significant, avoidable delay in therapy; or
  - g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of an oil to the incorrect patient.
  4. An act or omission relating to the dispensing of cannabis 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 cannabis oil ~~are~~ is 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.

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

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

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

"PIC" means the pharmacist-in-charge.

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

"Qualifying patient" means a Virginia resident, or a person who temporarily resides in Virginia, who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabis oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease.



"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis oil to such patient.

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

"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.

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

Room or Phase	Temperature	Humidity
Mother room	65 - 75 <del>85</del> °	50% - 60 <del>75</del> %
Nursery phase	65 <del>71</del> - 85° F	50 <del>65</del> % - 75%
Vegetation phase	65 <del>71</del> - 85° F	50 <del>55</del> % - 65 <del>75</del> %
Flower/harvest phase	65 <del>71</del> - 85° F	40 <del>55</del> % - 60 <del>75</del> %
Drying/extraction rooms	< 75° F	40 <del>55</del> % - 60 <del>75</del> %

"Temporarily resides" means a person that does not maintain a principle place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

#### 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 whose original registration certificate has been lost, stolen, or destroyed. \$50

##### C. Registration by a qualifying patient, parent, legal guardian or registered agent.

1. Initial registration of a patient. \$50
2. Annual renewal of registration of a patient. \$50
3. Initial registration of a parent or legal guardian.

4. Annual renewal of registration of a parent or guardian.	\$25
5. Initial registration or annual renewal of a registered agent.	\$25
6. Replacement of registration for a qualifying patient, parent, legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed.	\$25

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. Change of ownership not requiring a criminal background check.	\$100
7. Change of ownership requiring a criminal background check.	\$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	\$1,000
9. Reinspection fee.	\$1,000
10. Registration of each cannabis oil product.	\$25

E. Cannabis dispensing facility permit.

<u>1. Initial permit.</u>	<u>\$5,000</u>
<u>2. Annual renewal of permit.</u>	<u>\$1,500</u>
<u>3. Change of name of dispensing facility.</u>	<u>\$100</u>
<u>4. Change of PIC or any other information provided on the permit application.</u>	<u>\$100</u>
<u>5. Change of ownership not requiring a criminal background check.</u>	<u>\$100</u>
<u>6. Change of ownership requiring a criminal background check.</u>	<u>\$250</u>
<u>7. Any acquisition, expansion, remodel, or change of location requiring an inspection.</u>	<u>\$1,000</u>
<u>8. Reinspection fee.</u>	<u>\$1,000</u>

## Part II

### Requirements for Practitioners and Patients

#### **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, excluding information on products or educational materials on the benefits and risks of cannabis oil;
2. Offer a discount or any other thing of value to a qualifying patient, parent, guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis oil product;
3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis 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, cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis 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 cannabis 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 cannabis oil other than those approved by the U.S. Food and Drug Administration.

#### **18VAC110-60-50. Registration of a patient, parent, legal guardian, or registered agent.**

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying 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. Alternatively, proof of temporary residency of the qualifying patient and of a parent or legal guardian, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the Board which contains information sufficient to document temporary residency in Virginia;

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 patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis oil on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;

2. Proof of identity in the form of a copy of a government-issued identification card;

3. Payment of the applicable fee; and

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

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

D. Patients, parents, legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis oil.

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

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, legal guardian, or registered agent 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 temporary 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, legal guardian, or registered agent 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 cannabis 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, parent, legal guardian, or registered agent 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 of Virginia.

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

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, or legal guardian, or registered agent) 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 registrant provided false, misleading, or incorrect information to the board;
3. The registrant is no longer a resident of Virginia or is no longer temporarily residing in Virginia;
4. The registrant obtained more than a 90-day supply of cannabis oil in a 90-day period;
5. The registrant provided or sold cannabis oil to any person, including another registrant;
6. The registrant permitted another person to use the registration of the registrant, except as required for a registered agent to act on behalf of a patient;
7. The registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the registrant;

8. The registration of the registrant was lost, stolen, or destroyed, and the registrant 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 registrant failed to notify the board of a change in registration information or notified the board of such change more than 15 days after the change; or
10. The registrant violated any federal or state law or regulation.

### **Part III**

## **Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities**

### **18VAC110-60-100. Publication of notice for submission of applications for a pharmaceutical processor permit.**

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.

### **18VAC110-60-135. Application process for and granting of cannabis dispensing facility permits.**

A. Pursuant to 54.1-3442.6, the board may issue up to five cannabis dispensing facility permits for each health service area, which are owned, at least in part, by the pharmaceutical processor located in that health service area, for the dispensing of cannabis oil that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;
2. The name and address of the facility's owners with 5% or greater ownership;
3. Name and signature of pharmacist-in-charge practicing at the facility;

4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis oil products;

5. Information necessary for the board to conduct a criminal background check on the applicant;

C. Prior to issuing the permit, an inspection shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

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 of the Code of Virginia shall have any form of ownership, be employed by, or act as an agent of a cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if they are in receipt of cannabis oil from a pharmaceutical processor .

I. Once the facility is in possession of cannabis oil, a pharmacist shall be on site at all times during the declared hours of operation.

**18VAC110-60-136. Denial of a cannabis dispensing facility permit application.**

A. The board may deny an application for a cannabis dispensing facility if the applicant:

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

2. Fails to pay all applicable fees; or

3. Fails to comply with all requirements for a cannabis dispensing facility.

B. If the board denies an application of cannabis dispensing facility, 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 of Virginia.

**18VAC110-60-140. Notification of changes by pharmaceutical processor or cannabis dispensing facility.**

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 or cannabis dispensing facility shall provide any notification or information that is required from a pharmaceutical processor or cannabis dispensing facility.

B. Prior to making any change to the pharmaceutical processor or cannabis dispensing facility name, the pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility, change the location of an existing pharmaceutical processor or cannabis dispensing facility, make structural changes to an existing pharmaceutical processor or cannabis dispensing facility, 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, oil acquired from industrial hemp extract, or cannabis oil shall not be moved to a new location until approval is granted by the inspector or board staff.

**18VAC110-60-150. Pharmaceutical processor or cannabis dispensing facility closings; going out of business; change of ownership.**

A. At least 30 days prior to the date a pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility.

B. The proposed disposition of all Cannabis, oil from industrial hemp extract, cannabis oil, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the Cannabis, oils, and records are to be transferred to another processor located in Virginia, or to another cannabis dispensing facility in the same health service are, the owner shall inform the board and the patients and include on the public notice the name and address of the processor or cannabis dispensing facility to whom the Cannabis, oils, 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 or cannabis dispensing facility is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as the owner 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 or cannabis dispensing facility, the owner shall notify the board of the pending change.

1. Upon any change in ownership of an existing pharmaceutical processor or cannabis dispensing facility, 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.

3. If a new owner's share constitutes 5.0% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required by of § 54.1-3442.6-E of the Code of Virginia.

**18VAC110-60-160. Grounds for action against a pharmaceutical processor or cannabis dispensing facility 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; 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 cannabis 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, cannabis 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, or registered agent, except as required for a registered agent to act on behalf of a patient;
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 or cannabis dispensing facility. 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~~ or cannabis dispensing facility.

#### **Part IV**

### **Requirements for Pharmaceutical Processor and Cannabis Dispensing Facility Personnel**

#### **18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility application shall be in full and actual charge of a pharmaceutical processor or cannabis dispensing facility and serve as the pharmacist-in-charge.

B. Except for cultivation occurring at a time when employees authorized by the PIC pursuant to § 54.1-3442.6 of the Code of Virginia access the secured area designated for cultivation when no pharmacist is on the premises, the pharmacist on duty at the pharmaceutical processor and or cannabis dispensing facility shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing, and the pharmaceutical processor and or cannabis dispensing facility shall not operate or be accessed when no pharmacist is on duty. 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. The PIC shall ensure security measures are adequate to protect the cannabis from diversion at all times.

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

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

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; 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. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabis oil as authorized by the PIC.

G. A pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

~~H. 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, oil and ensure quality of the dispensed oils. Pursuant to § 54.1-3442.6, the PIC may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The PIC shall ensure security measures are adequate to protect the cannabis from diversion at all times.~~

~~I. Except for certain employee access to secured areas designated for cultivation and other areas approved by the board and authorized by the PIC pursuant § 54.1-3442.6, at no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.~~

J.H. No person shall be employed by or serve as an agent of a pharmaceutical processor or cannabis dispensing facility without being at least 18 years of age.

K.I. 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 or cannabis dispensing facility unless such license or registration has been reinstated and is current and unrestricted.

**18VAC110-60-180. Employee training.**

A. All employees of a pharmaceutical processor or cannabis dispensing facility shall complete training prior to the employee commencing work at the pharmaceutical processor or cannabis dispensing facility. At a minimum, the training shall be in the following areas:

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 and cannabis 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 cannabis 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 that is provided at least annually, is designed to supplement initial training, and includes 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 that 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 or cannabis dispensing facility 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 or cannabis dispensing facility 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 or cannabis dispensing facility designated for production or dispensing shall not exceed six 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 cannabis 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 cannabis 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, legal guardian, or registered agent regarding (i) cannabis oil or other drugs either before or after cannabis oil has been dispensed or (ii) 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 cannabis 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 cannabis oil should be substituted for the cannabis 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. The PIC of a pharmaceutical processor shall not serve as PIC of any other facility ~~No person shall be PIC for more than one pharmaceutical processor for one processor and a pharmacy~~ at any one 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. No person shall be the PIC for more than two cannabis dispensing facilities at any one time.

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

~~C.D.~~ The PIC of a pharmaceutical processor or cannabis dispensing facility ~~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 and the cannabis oil are met;
4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis oil can be properly dispensed;
5. The following items are conspicuously posted in the pharmaceutical processor or cannabis dispensing facility in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, legal guardians, or registered agents:
  - a. Pharmaceutical processor or cannabis dispensing facility permit;
  - b. Licenses for all pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility; and
  - c. The price of all cannabis oil products offered by the pharmaceutical processor or cannabis dispensing facility; and
6. Any other required filings or notifications are made on behalf of the processor or cannabis dispensing facility as set forth in regulation.

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

~~E.F.~~ An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts or cannabis 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.G.~~ 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 that 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.H.~~ An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor or cannabis dispensing facility to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

## **Part V**

### **Operation of a Pharmaceutical Processor or Cannabis Dispensing Facility**

#### **18VAC110-60-210. General provisions.**

A. A pharmaceutical processor or cannabis dispensing facility shall only sell cannabis oil in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian or registered agent, 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 cannabis oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a patient's registered agent. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabis oil.

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

1. A person whose responsibilities necessitate access to the pharmaceutical processor or cannabis dispensing facility and then for only as long as necessary to perform the person's job duties; or
2. A person who is a registered patient, parent, or legal guardian or a registered agent, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts or cannabis oil are stored.

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

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

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

G. A pharmaceutical processor or cannabis dispensing facility that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians and registered agents of when the pharmaceutical processor or cannabis dispensing facility will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the pharmaceutical processor or cannabis dispensing facility 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, and registered agents if applicable, regarding the use of cannabis oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabis oil and for disposal of the oils in a manner that renders them nonrecoverable.

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

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

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis 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 cannabis oil, to any other facility, except for the wholesale distribution of cannabis oil products between pharmaceutical processors and to a cannabis dispensing facility;
3. Produce or manufacture cannabis oil for use outside of Virginia; or
4. Provide cannabis oil samples.



B. No cannabis dispensing facility shall:

1. Dispense cannabis oil in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;

2. Sell, deliver, transport, or distribute cannabis oil to any other facility, except that it may distribute cannabis oil back to the pharmaceutical processor from which it obtained the oil;

3. Provide cannabis oil samples.

~~B.~~ C. Except for certain employee access to secured areas designated for cultivation and authorized by the PIC pursuant § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the pharmaceutical processor or cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor or cannabis dispensing facility. At all other times, the pharmaceutical processor or cannabis dispensing facility shall be closed and properly secured.

C. No pharmaceutical processor shall sell anything other than cannabis oil products from the pharmaceutical processor, except for devices for administration of dispensed products.

D. A pharmaceutical processor or cannabis dispensing facility shall not advertise cannabis oil products, except it may post the following information on websites:

1. Name and location of the processor or facility;

2. Contact information for the processor or facility;

3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis oil products;

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor or facility.

E. No cannabis oil shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient.

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

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

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

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

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

H. No cannabis oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor or cannabis dispensing facility, except that a registered parent or legal guardian or a registered agent or an agent of the processor or cannabis dispensing facility may deliver cannabis oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors.

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

#### **18VAC110-60-230. Inventory requirements.**

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extract and cannabis 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 or cannabis oil 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 and cannabis oil, that 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 and cannabis oil in stock, that 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 cannabis oil sold, dispensed, or otherwise disposed of shall show the date of sale; the name of the pharmaceutical processor; the registered patient, parent, or legal guardian or the registered agent to whom the cannabis oil was sold; the address of such person; and the kind and quantity of cannabis oil sold.~~

C. Upon commencing business, each cannabis dispensing facility shall maintain a perpetual inventory of all cannabis oil products received and dispensed that accurately indicates the physical count of each cannabis oil product on-hand at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each cannabis oil product at least monthly with a written explanation for any difference between the physical count and the theoretical count.

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

~~D.E.~~ A complete and accurate record of all Cannabis plants, including the seeds, parts of plants and cannabis 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.

~~E.F.~~ 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.

~~F.G.~~ Inventory records shall be maintained for three years from the date the inventory was taken.

~~G.H.~~ 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 cannabis oil for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days;
2. Not maintain cannabis oil in excess of the quantity required for normal, efficient operation;

B. At no time shall a cannabis dispensing facility maintain cannabis oil in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts and cannabis oil. A cannabis dispensing facility shall properly secure cannabis oil. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

~~3.1.~~ Maintain all Cannabis plants, seeds, parts of plants, extracts and cannabis oil these items in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

~~4.2.~~ Store all cut parts of Cannabis plants, extracts, and cannabis oil ~~extracts or cannabis oil~~ in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis oil products when the pharmaceutical processor or cannabis dispensing facility is closed;

~~5.3.~~ Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabis oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts or cannabis oil;

~~6.4.~~ Keep all locks and security equipment in good working order;

~~7.5.~~ Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor, except for persons authorized by the PIC and 54.1-3442.6 of the Code of Virginia to access secured areas designated for cultivation when no pharmacist is on the premises; and

~~8.6.~~ Not allow keys to be left in the locks or accessible to non-pharmacists who are not authorized by the PIC and 54.1-3442.6 of the Code of Virginia to access secured areas designated for cultivation when no pharmacist is on the premises.

~~B.C.~~ The pharmaceutical processor or cannabis dispensing facility shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts or cannabis 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 or

cannabis dispensing facility. The installation and the device shall be based on accepted alarm industry standards and subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or other generally accepted and suitable device;
2. The device shall be monitored in accordance with accepted industry standards, be 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 pharmaceutical processor or cannabis dispensing 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 an automatic voice dialer; and

5. Access to the alarm system for the pharmaceutical processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the pharmaceutical processor or cannabis dispensing facility is closed for business. Pursuant to § 54.1-3442.6, the PIC of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation. No pharmacist shall be required to be on the premises during such authorized access. The PIC of a pharmaceutical processor and a cannabis dispensing facility shall ensure security measures are adequate to protect the cannabis from diversion at all times.

C.D. A pharmaceutical processor or cannabis dispensing facility shall keep the outside perimeter of the premises well-lit. A processor or cannabis dispensing facility shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts or cannabis 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 or facility shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabis oil sales areas, and any other area where Cannabis plants, seeds, extracts or cannabis oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor or facility 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 or facility 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 recordings 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 or cannabis dispensing facility shall erase all recordings prior to disposal or sale of the facility; and

4. The processor or facility 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 or facility is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor or facility 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 or cannabis dispensing facility PIC that it is not necessary to retain the recording.

~~D.E.~~ The processor or cannabis dispensing facility 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 at least every six months.

~~E.F.~~ A pharmaceutical processor or cannabis dispensing facility 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 or facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor or facility. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

~~F.G.~~ If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts or cannabis oil has occurred from a pharmaceutical processor or cannabis dispensing facility, the board may require additional safeguards to ensure the security of the products.

**18VAC110-60-250. Requirements for the storage and handling of Cannabis or cannabis oil.**

A. A pharmaceutical processor or cannabis dispensing facility 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 cannabis oil;
2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabis 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 or cannabis oil are 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 cannabis 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 cannabis oil; and
4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, and cannabis oil products.

C. A cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper dispensing of cannabis oil, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis oil.

~~C-D.~~ The PIC of a pharmaceutical processor and cannabis dispensing facility 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 and cannabis oil, as applicable. 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 or cannabis dispensing facilities shall include in their written policies and procedures, as applicable, a process for the following:

1. Handling mandatory and voluntary recalls of cannabis oil. The 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 or cannabis dispensing facility to (i) remove defective or potentially defective cannabis oil from the market or (ii) promote public health and safety by replacing existing cannabis 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 and cannabis oil, is segregated from all other Cannabis, seeds, parts of plants, extracts and cannabis oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts and cannabis oil disposition; and

4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts and cannabis oil product is used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

~~D.~~E. The processor shall store all Cannabis, including seeds, parts of plants, extracts and cannabis 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 and cannabis 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 and cannabis oil, inside an area or building that affords adequate security.

F. The cannabis dispensing facility shall store all cannabis oil, in such a manner as to prevent diversion, theft, or loss; shall make cannabis oil accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the oil to its secure location at the completion of the dispensing or at end of the scheduled business day.

#### **18VAC110-60-251. Wholesale distribution of cannabis oil products.**

A. Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility.

B. A pharmaceutical processor wholesale distributing the oil products shall create a record of the transaction that shows the date of distribution, the names and addresses of the processor distributing the product and the processor or cannabis dispensing facility receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be



maintained by the distributing pharmaceutical processor with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or cannabis dispensing facility receiving the product in its records of receipt. Such records shall be maintained by each ~~pharmaceutical processor facility~~ for three years in compliance with 18VAC110-60-260.

C. A pharmaceutical processor wholesale distributing the oil products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to registered patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

ED. A pharmaceutical processor wholesale distributing cannabis oil products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

DE. If a pharmaceutical processor wholesale distributing cannabis oil products uses an electronic system for the storage and retrieval of records related to distributing cannabis oil, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

#### **18VAC110-60-260. Recordkeeping requirements.**

A. If a pharmaceutical processor or cannabis dispensing facility uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabis oil, as applicable, the pharmaceutical processor or cannabis dispensing facility shall use a system that:

1. Guarantees the confidentiality of the information contained in the system;
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 (i) diversion, theft, loss, or discrepancies identified during inventory; (ii) unauthorized destruction of any cannabis oil; or (iii) any loss or unauthorized alteration of records related to cannabis oil or qualifying patients, a pharmacist, ~~or~~ pharmaceutical processor or cannabis dispensing facility shall immediately notify appropriate law-enforcement authorities and the board.

B. A pharmacist, ~~or~~ processor, or cannabis dispensing facility 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 cannabis oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist, ~~or~~ processor or cannabis dispensing facility shall make such notice no later than 24 hours after discovery of the event.

C. A pharmacist, ~~or~~ pharmaceutical processor, or cannabis dispensing facility 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.

D. A pharmacist, ~~or~~ pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony or any offense referenced in § 54.1-3442.6 of the Code of Virginia.

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

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis oil unless such laboratory:

1. Is independent from all other persons involved in the cannabis 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, cannabis dispensing facility or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis 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 (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.
3. Has obtained a controlled substances registration certificate pursuant to 54.1-3423 authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the International Electrotechnical Commission (“ISO/IEC”) 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory’s ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use non-accredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use non-accredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize non-accredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within twenty-four hours. The laboratory shall immediately stop handling, testing or analyzing cannabis for pharmaceutical processors.

5. Has and complies with a transportation protocol for transporting cannabis or cannabis oil products to or from itself, or pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis.

C. From the time that a batch of cannabis oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis 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 oil products and materials upon the completion of any testing, use, or research.

F. If a sample of cannabis oil product 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 cannabis 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 sample of cannabis oil product 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 G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product 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.

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

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);
- c. Cannabidiols (CBD); and
- d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

G. If a sample of cannabis oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

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, residual solvents, 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 or cannabis dispensing facility shall have such laboratory results available upon request to registered patients, parents, or legal guardians or registered agents, ~~and~~ registered practitioners who have certified qualifying patients, the board or agent of the board.

#### **18VAC110-60-310. Dispensing of cannabis oil.**

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

1. Prior to the initial dispensing of cannabis oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or

cannabis dispensing facility shall view a current photo identification of the patient, parent, legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three 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, legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabis oil. The pharmacist may dispense the remaining portion of the 90-day supply cannabis oil at any time except that no registered patient, parent, or legal guardian or registered agent shall receive more than a 90-day supply of cannabis oil for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility.

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 that contains:

1. A serial number assigned to the dispensing of the oil;
2. The brand name of cannabis oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;
3. The serial number assigned to the oil during production;
4. The date of dispensing the cannabis oil;
5. The quantity of cannabis oil dispensed;
6. A terpenes profile and a list of all active ingredients, including:
  - a. Tetrahydrocannabinol (THC);
  - b. Tetrahydrocannabinol acid (THC-A);
  - c. Cannabidiol (CBD); and

- d. Cannabidiolic acid (CBDA);
7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;
  8. The name and registration number of the registered patient;
  9. The name and registration number of the certifying practitioner;
  10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;
  11. The name or initials of the dispensing pharmacist;
  12. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;
  13. Any necessary cautionary statement; and
  14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's or cannabis dispensing facility's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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

E. The cannabis 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).

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

G. 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.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabis oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis oil to a registered patient, parent, or legal guardian or registered agent if the pharmacist suspects that dispensing cannabis oil to the registered patient, parent, or legal guardian or registered agent 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 or cannabis dispensing facility 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 or cannabis dispensing facility shall distribute the written policies and procedures to all pharmaceutical processor or cannabis dispensing facility employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility. The 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, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The 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 or cannabis dispensing facility shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility PIC shall:

1. Inform pharmaceutical processor or cannabis dispensing facility 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 or cannabis dispensing facility 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 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 or registered agent, 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 or cannabis dispensing facility policy, procedure, systems, or processes if any.

C. A pharmaceutical processor or cannabis dispensing facility shall maintain for three years a copy of the pharmaceutical processor's or cannabis dispensing facility's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

**18VAC110-60-321. Devices and inert product samples.**

- A. A pharmaceutical processor or cannabis dispensing facility may have for sale, on site, devices intended for the administration of dispensed cannabis oil products.
- B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, without the need for a written certification. Such inert product samples may not be sold or further distributed.

**18VAC110-60-330. Disposal of cannabis oil.**

A. To mitigate the risk of diversion, a pharmaceutical processor and cannabis dispensing facility shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated green waste, extracts and cannabis oil, as applicable. Green waste includes ~~C~~cannabis plants, including seeds, and parts of plants. , extracts or cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabis oil nonrecoverable. —Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render it unrecognizable.

B. The destruction and disposal of green waste, extracts, and cannabis oil, as applicable, shall be witnessed by ~~a pharmacist and at least one other~~ employee of the pharmaceutical processor or cannabis dispensing facility, respectively, and shall be conducted under video surveillance. the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor. The persons disposing of the green waste, extracts, or cannabis 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 ~~cannabis oil~~ product disposed of; and
  4. The signatures of the persons destroying or disposing of the green waste, extracts, or cannabis oil.
- 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 – Pharmacists initiating treatment**

**Included in your agenda package are:**

Copy of the summary of legislation passed in the 2020 General Assembly

Amendment to Code in HB1506

Copy of the draft emergency regulations

**Board action:**

Adoption of emergency regulations as required by the 2<sup>nd</sup> enactment clause in the legislation

# HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Introduced by: Mark D. Sickles | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED: (all summaries)

**Pharmacists; prescribing, dispensing, and administration of controlled substances.** Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, to promulgate emergency regulations to implement the provisions of the bill, and to convene a work group to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

## CHAPTER 731

[H 1506]

Approved April 6, 2020

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

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

- 1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;*
- 2. Epinephrine;*
- 3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;*
- 4. Prenatal vitamins for which a prescription is required;*
- 5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and*
- 6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.*

*B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.*

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, **and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment.** Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, *Helicobacter pylori* bacteria, urinary tract infection, and group A *Streptococcus* bacteria; (v) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

**BOARD OF PHARMACY**

**Initiation of treatment by a pharmacist**

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

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

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

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

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

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

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

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

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

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs and devices pursuant to § 54.1-3303.1 and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

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

A. Pursuant to § 54.1-3303.1, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

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

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

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

B. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A shall:

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

2. Notify the patient's primary health care provider that treatment has been initiated with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the drug being initiated is an injectable or self-administered hormonal contraceptive or a prenatal vitamin, the pharmacist shall also notify the patient's obstetrician or gynecologist. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.



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

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

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

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

DRAFT

**Agenda Item:     Emergency Action – Regulations for Registration of  
Pharmacy Technicians**

**Enclosed:**

Copy of HB1304 as passed by the 2020 General Assembly – 2<sup>nd</sup> enactment clause requires adoption of regulations to be effective within 280 days

Copy of DRAFT emergency regulations

**Board action:**

Adoption of emergency regulations as drafted or as amended by the Board; and  
Adoption of a Notice of Intended Regulatory Action to replace emergency regulations.

# HB 1304 Pharmacy technicians and pharmacy technician trainees; registration.

Introduced by: M. Keith Hodges | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED HOUSE: (all summaries)

**Pharmacy technicians and pharmacy technician trainees; registration.** Amends eligibility criteria for registration as a pharmacy technician to include a requirement that the individual has (i) successfully completed or was enrolled in a Board of Pharmacy-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board of Pharmacy but did not complete a Board-approved pharmacy technician training program. The bill also directs the Board to establish requirements for the issuance of a registration as a pharmacy technician to a person who (a) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (b) has passed a national certification examination required by the Board. The bill defines "pharmacy technician trainee" and sets out requirements for registration as a pharmacy technician trainee. The bill also directs the Board to convene a workgroup composed of stakeholders deemed appropriate by the Board to develop recommendations related to the addition of duties that a pharmacy technician registered by the Board may perform. This bill is identical to SB 830.

### CHAPTER 102

*An Act to amend and reenact §§ 54.1-3300 and 54.1-3321 of the Code of Virginia, relating to pharmacy technicians and pharmacy technician trainees; registration.*

[H 1304]

Approved March 3, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy,

laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

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

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

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

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

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

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

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

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

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3321. Registration of pharmacy technicians.

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

1. The entry of prescription information and drug history into a data system or other record keeping system;
2. The preparation of prescription labels or patient information;
3. The removal of the drug to be dispensed from inventory;
4. The counting, measuring, or compounding of the drug to be dispensed;
5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;
7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and
8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

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

1. ~~An application and fee specified in regulations of the Board;~~
2. ~~Evidence that he is of good moral character and has satisfactorily~~ successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and
3. ~~Evidence that he has successfully passed a national certification examination that meet the criteria approved by the Board in regulation or that he holds current certification from administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.~~

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

~~D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.~~

~~E. The Board shall promulgate regulations establishing requirements for evidence:~~

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

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

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

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

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

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

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

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. However, the provisions of subsection B 2 of § 54.1-3321 of the Code of Virginia, as amended by this act, requiring accreditation of a pharmacy technician training program shall become effective July 1, 2022.

3. The Board of Pharmacy shall convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform. The workgroup shall report its recommendations to the Secretary of Health and Human Resources and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2021.

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

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

"ACPE" means the Accreditation Council for Pharmacy Education.

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

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy and has passed approved examinations establishing proficiency in English.

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

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

"NHA" means National Healthcareer Association.

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

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

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

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
<u>3. Pharmacy technician trainee registration</u>	<u>\$20</u>
3-4. Pharmacy technician registration	\$25
4 5. Approval of a pharmacy technician training program –	\$150
5-6. Approval of a continuing education program	\$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	\$90
2. Pharmacist inactive license – due no later than December 31	\$45
3. Pharmacy technician registration – due no later than December 31	\$25
4. Pharmacy technician training program	\$75 every two years

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

1. Pharmacist license	\$30
2. Pharmacist inactive license	\$15
3. Pharmacy technician registration	\$10
4. Pharmacy technician training program	\$15



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

- |  |       |
|--|-------|
| 1. Pharmacist license  | \$210 |
| 2. Pharmacist license after revocation or suspension   | \$500 |
| 3. Pharmacy technician registration  | \$35  |
| 4. Pharmacy technician <u>or pharmacy technician trainee</u> registration after revocation or suspension   | \$125 |
| 5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of \$75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration. |       |

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

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

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;
2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;
3. Failing to maintain the confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;
5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;
6. Failing to maintain adequate safeguards against the diversion of controlled substances;
7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;
8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;
9. Failing by the pharmacist in charge to ensure that pharmacy interns, pharmacy technician trainees and pharmacy technicians working in the pharmacy are registered and that such registration is current;
10. Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;
11. Obtaining money or property of a patient or client by fraud or misrepresentation;
12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;
13. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;
14. Performing any act likely to deceive, defraud, or harm the public; or
15. Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

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

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

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

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

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

D. The pharmacy technician trainee registration shall be valid only while the student is enrolled in the pharmacy technician training program and actively progressing toward completion of such program. The registration card issued by the board shall be invalid and returned to the board upon dismissal from the program or voluntary withdrawal.

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

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

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

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

1. Satisfactory completion of a board-approved training program; and
2. A passing score on a board-approved examination.

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

~~D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy~~

~~technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.~~

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

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

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

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

a. Jointly accredited by the ASHP and ACPE;

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

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

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

2. Evidence that the applicant successfully passed a national certification examination administered by PTCB or NHA.

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

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

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

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

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

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

1. The entry of prescription information and drug history into a data system or other recordkeeping system;
2. The preparation of prescription labels or patient information;
3. The removal of the drug to be dispensed from inventory;
4. The counting, measuring, or compounding of the drug to be dispensed;
5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process; and
7. The acceptance of refill authorization from a prescriber or the prescriber's authorized agent provided there is no change to the original prescription.

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

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

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

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

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

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

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

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

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

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

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

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

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

renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

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

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

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

1. Take and pass a national certification examination administered by PTCB or NHA;
2. Document completion of 20 hours of continuing education; and
3. Pay the current renewal fee and a reinstatement fee.

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

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

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

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

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

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

DRAFT



**Agenda Item: Regulatory Action – Adoption of Final Regulations**  
**Scheduling Chemicals in Schedule I - Exempt action**

**Included in agenda package:**

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

Amendments to regulation: 18VAC110-20-322

**Staff Note:**

A public hearing was conducted before the meeting this morning.

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

**Board action:**

Adoption of final regulation in sections 322

## Notice of Public Hearing 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 September 9, 2020**. The hearing will either be held at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233 or held virtually, as noted on the posted agenda of the Board meeting to be conducted immediately after the hearing. Public comment may also be submitted electronically or in writing prior to Caroline Juran, Executive Director of the Board of Pharmacy to [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov).

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified thirteen (13) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description, chemical name, and common name for each compound.

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

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

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

3. **(2-ethylaminopropyl)benzofuran (other name: EAPB)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
4. **2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
5. **4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
6. **4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

7. **N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
8. **1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
9. **1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

10. **methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
11. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
12. **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
13. **methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

[\[edit\]](#)[back](#) | [vac](#) | [integ](#) | [hilite](#)**18VAC110-20-322. Placement of chemicals in Schedule I.**

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

## 1. Synthetic opioids.

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

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

## 2. Research chemicals.

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

b. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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

## 3. Cannabimimetic agents.

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

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

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

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

1. Synthetic opioids.

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

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

2. Research chemicals.

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

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

c. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone,  $\alpha$ -isobutylaminohexanphenone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

3. Cannabimimetic agents.

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

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

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

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

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

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

1. Synthetic opioids.

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

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

2. Research chemicals.

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

b. 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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

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

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

### 3. Cannabimimetic agents.

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

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

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

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

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

Statutory Authority

§§ 54.1-2400 and 54.1-3443 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 10, eff. February 11, 2015; amended, Virginia Register Volume 31, Issue 23, eff. August 12, 2015; Volume 32, Issue 5, eff. December 2, 2015; Volume 32, Issue 19, eff. June 15, 2016; Volume 32, Issue 25, eff. September 7, 2016; Volume 33, Issue 4, eff. November 16, 2016; Volume 33, Issue 11, eff. February 22, 2017; Volume 33, Issue 19, eff. June 14, 2017; Volume 34, Issue 1, eff. October 4, 2017; Volume 34, Issue 6, eff. December 13, 2017; Volume 34, Issue 11, eff. February 21, 2018; Volume 34, Issue 19, eff. June 13, 2018; Volume 34, Issue 25, eff. September 5, 2018; Volume 35, Issue 5, eff. November 28, 2018; Errata, 35:7, VA.R. 1060 November 26, 2018; Errata, 35:11, VA.R. 1394-1395 January 21, 2019; amended, Virginia Register Volume 35, Issue 14, eff. April 3, 2019; Volume 35, Issue 20, eff. June 26, 2019; Volume 36, Issue 6, eff. December 11, 2019; Volume 36, Issue 23, eff. August 5, 2020.

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**Agenda Item:      Proposed Action – Labeling of dispensed prescriptions**

**Staff Note:**

The Comment period on the proposed regulations was extended to 6/16/20

**Enclosed:**

Copy of public comment received on Townhall

Copy of minutes of a public hearing on 6/16/20

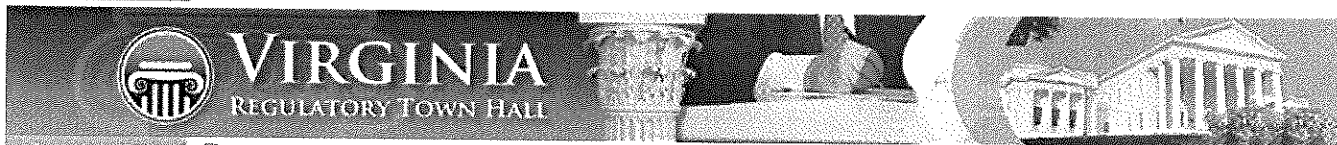
Proposed amendment to section 275

Copy of 54.1-3410 of the Code of Virginia showing requirements for a label on a dispensed prescription

**Board action:**

- 1) Adopt final amendments; or
- 2) Revise amendment; or
- 3) Withdrawn the regulatory action





**Agency** Department of Health Professions  
**Board** Board of Pharmacy  
**Chapter** Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

**Action:** Delivery of dispensed prescriptions; labeling

**Proposed Stage**

Action 5093 / Stage 8779

[Edit Stage](#) [Withdraw Stage](#) [Go to RIS Project](#)

Documents

<a href="#">Proposed Text</a>	1/29/2020 8:05 am	<a href="#">Sync Text with RIS</a>
<a href="#">Agency Background Document</a>	10/2/2019 (modified 11/20/2019)	<a href="#">Upload / Replace</a>
<a href="#">Attorney General Certification</a>	10/9/2019	
<a href="#">DPB Economic Impact Analysis</a>	11/22/2019	
<a href="#">Agency Response to EIA</a>	1/8/2020	<a href="#">Upload / Replace</a>
<a href="#">Governor's Review Memo</a>	1/7/2020	
<a href="#">Registrar Transmittal</a>	1/8/2020	

Status

<b>Incorporation by Reference</b>	No
<b>Exempt from APA</b>	No, this stage/action is subject to article 2 of the <i>Administrative Process Act</i> and the standard executive branch review process.
<b>Attorney General Review</b>	Submitted to OAG: 10/2/2019 Review Completed: 10/9/2019 Result: Certified
<b>DPB Review</b>	Submitted on 10/9/2019 Economist: <a href="#">Jini Rao</a> Policy Analyst: <a href="#">Cari Corr</a> Review Completed: 11/22/2019 <i>DPB's policy memo is "Governor's Confidential Working Papers"</i>
<b>Secretary Review</b>	Secretary of Health and Human Resources Review Completed: 12/23/2019
<b>Governor's Review</b>	Review Completed: 1/7/2020 Result: Approved
<b>Virginia Registrar</b>	Submitted on 1/8/2020 <a href="#">The Virginia Register of Regulations</a> Publication Date: 2/3/2020 <a href="#">Volume: 36 Issue: 12</a>
<b>Public Hearings</b>	<a href="#">03/24/2020 9:00 AM</a> canceled <a href="#">06/16/2020 9:00 AM</a>

<b>Comment Period</b>	<b><u>Ended 6/16/2020</u></b> <b><u>16 comments</u></b>
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**Contact Information**

<b>Name / Title:</b>	Caroline Juran, RPh / <i>Executive Director</i>
<b>Address:</b>	9960 Mayland Drive Suite 300 Richmond, VA 23233-1463
<b>Email Address:</b>	<a href="mailto:caroline.juran@dhp.virginia.gov"><u>caroline.juran@dhp.virginia.gov</u></a>
<b>Telephone:</b>	(804)367-4456 FAX: (804)527-4472 TDD: (-)

*This person is the primary contact for this chapter.*

*This stage was created by Elaine J. Yeatts on 10/02/2019*

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## Summary of Public Comment on Proposed Regulations Board of Pharmacy

Proposed regulations were published on February 3, 2020 with 60-day comment period. However, due to the cancellation of the public hearing scheduled for March 24, 2020, the comment period was extended to June 16, 2020 to provide an opportunity for a hearing on that date. The following comments were received at the hearing.

<b>Commenter</b>	<b>Comment</b>
Lauren Paul Representing CVS Health	Reiterated support for the proposed regulations, noting that this hearing is the sixth discussion through meetings and the third formal comment period. She offered support of the amendment, citing among other things, the advantages of a larger print label for the elderly and others
Christina Barille Representing the Va. Pharmacists Association	Expressed concerns about patient safety & referred to the comment in opposition on Townhall
Mark Hickman Representing the Va. Society of Health System Pharmacists	Asked the board to take context of the various situation of delivery sites and potential impact to pharmacist/patient relationship into consideration during their decision-making

The following comments were received on Townhall:

<b>Commenter</b>	<b>Comment in Support of proposed regulation</b>
Lauren Paul Representing CVS Health	Consumer would have access to information as the unique identifier would only be used for pharmacy holding prescription for delivery. Would not interfere with checks and balances
Sarah Beth Dinwiddie	Would minimize the opportunities for medication errors and data breaches

<b>Commenter</b>	<b>Comment in Opposition to proposed regulation</b>
Steven Hylton	Action is favorable to corporate entities and detrimental to independent pharmacies
Jennifer Helmke	Patient will not have information about who filled the prescription
John Frye	Patient will be missing directions for administration and phone number of pharmacy that dispensed
Kelly Hale	
John Hasty	Consumers need information about the person at the pharmacy involved in their care
Otto Wachsmann	
Va. Breast Cancer Foundation	Already have problems with incorrect information on labels from mail order pharmacies
Richmond Academy of Medicine	Question from patient would come to the pharmacy where the prescription was picked up
	Negative effect on independent infusion providers and hospital systems

Hemophilia Association	Need transparency in labeling
Al Roberts	Detrimental to patients without adequate information on prescription label
Medical Society of Virginia	
Randall Cole	
Harry Gewanter	
American College of Rheumatology & Va. Society	

Information relating to public comment:

The Board's regulatory proposal would not change the requirements of § 54.1-3410 in the Code of Virginia relating to information that must be on a prescription label:

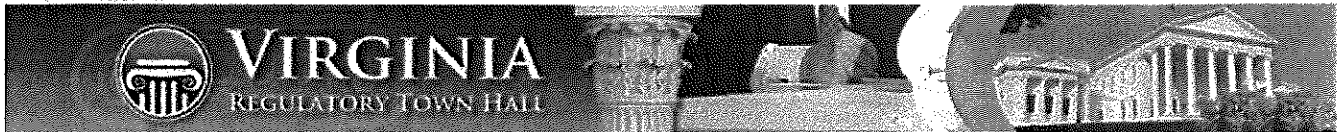
§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person...

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:...

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.


**Agency** Department of Health Professions

**Board** Board of Pharmacy

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

<b>Action</b>	<u>Delivery of dispensed prescriptions; labeling</u>
<b>Stage</b>	<u>Proposed</u>
<b>Comment Period</b>	Ends 6/16/2020

16 comments

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**Commenter:** Lauren Paul, CVS Health

3/24/20 2:39 pm

**CVS Health's comments on proposed amendments 18VAC110-20-275. Delivery of dispensed prescriptions**

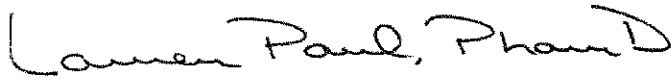
Dear Ms. Yeatts:

I am writing to you in my capacity as Sr Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy 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 our Petition for Rule-making and proposed language 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 utilized 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 pickup and delivery without being involved in the filling and dispensing. As we have mentioned previously, the Institute for Safe Medication Practices published industry guidelines for medication labels for community and mail order pharmacies in which they suggest maximizing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors.<sup>1</sup> The proposed language would assist in achieving maximum white space, while still providing an audit trail for the tracking of the prescription, as required, and providing the patient with one contact pharmacy (the dispensing pharmacy) to answer any questions or provide additional counseling.

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

Sincerely,



Lauren Paul, PharmD, MS  
Sr Director, Pharmacy Regulatory Affairs  
CVS Health

References:

1. Principles of Designing a Medication Label for Community Pharmacy and Mail Order Pharmacy Prescription Packages. Available from: <https://www.ismp.org/recommendations/designing-medication-label-community-pharmacy> (Accessed March 23, 2020).

CommentID: 80086

**Commenter:** Steven Hylton, Clark's Pharmacy

6/1/20 12:12 pm

**Labeling requires**

First of all why we do need any changes in our labeling practices? It seems very logical to have the name and address of the pharmacy providing the medications to be clearly labeled on the medication label for questions from the patients or ease of finding information by law enforcement or caregivers.

The only reason I could see for not including this information would be to deceive the patient from the knowledge of who filled their prescription.

Why would large corporations start filling prescriptions in other states to ship to their local stores?

They could be ashamed that they don't want their local pharmacist to fill the prescription. More likely they are trying to usurp the Virginia Board of Pharmacy to in order to not fill these prescriptions according to the standards set by our BOP. Another reason could be tax implications. Hiring workers and building closed doors pharmacies in other states, would not only prevent the Commonwealth from collecting taxes on these facilities and employees, but be a windfall in profit of these corporations over smaller independent pharmacies who don't have the option of filling prescriptions in a different state.

When independent pharmacies close (and they are closing) it hits the poorest areas of our state the worst. Making policies that only help certain large corporations make more money, without any benefit for our patients seems like a waste of paper and ink for this Board.

Would this regulation make our patients any safer? (these medications would be filled under the guidance of other states, do they know Virginians better than our BOP?)

Would this regulation bring in more revenue for the state to help more patients? (Tax dollars would go to other localities and wouldn't be here to help Virginians)

Would this regulation give some corporations advantages over other corporations? Only large companies (probably owned by PBMs) would benefit, making it harder for small business to keep up

Would this regulations make medications more accessible for our patients? There is no proof that this would make medications more accessible

Therefore please do not move forward with this regulation and spend more of your efforts on the current drug shortages and ways to make replacement medication easier to get paid for from these PBMs that won't less us substitute medications like generic albuterols when there is a shortage in the market

Steven C Hylton, PharmD

CommentID: 80176

**Commenter:** Sarah Beth Dinwiddie, George Washington University

6/1/20 12:25 pm

### **Unique Identifiers for Prescription Medications**

Good afternoon,

I am writing as a graduate student of public health and resident of the Commonwealth of Virginia in response to the call for public comment for the Virginia Board of Pharmacy's proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. Thank you for the opportunity to provide input regarding unique pharmacy identifiers that are required on prescription medication labels. There is a delicate balance regarding information that consumers need when it comes to their prescription medications. It is important to provide enough information so that consumers can safely understand how, when, and why to take their medications as well as who to contact and how to reach that contact when questions arise. Providing too much irrelevant information can overwhelm some consumers, leaving room for medication errors to occur. It is vital to find this delicate balance.

I write in support of the proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. Annually the FDA receives more than 100,000 reports concerning potential medication errors. The proposed amendment provides an opportunity to reduce potential medication errors. According to the US Food and Drug Administration's (FDA) article, Working to Reduce Medication Errors, prescription drug labels play an important role in preventing medication errors. The FDA recommends that drug labels be designed so that consumers do not overlook important information<sup>1</sup>. Prescription drug labels will have more room for this important information by reducing the number of unique pharmacy identifiers that are required on prescription medication labels. The important information will be clearer and more easily identified by the consumer potentially leading to a reduction in medication errors.

It goes without saying that it is vital to be able to track the pharmacies that are involved in filling and dispensing prescription medications. By including the unique identifiers for all pharmacies that are involved in filling and dispensing a prescription medication, a paper trail would be maintained that would include the final pharmacy from which a consumer obtained the prescription in case that information is ever needed. This proposed amendment does not interfere in that system of checks and balances because it continues to require that the filling and dispensing pharmacies' unique identifiers remain on the prescription label. The consumer continues to have access to the contact information for the pharmacy in case any questions or needs arise.

Lastly, by omitting the unique identifier for pharmacies that are only holding prescription medications for consumer pick up or delivery, efforts are made to minimize the points of possible data breaches. Any time unique identifiers are required for maintaining records there is potential for those identifiers to be utilized in a data breach. By minimizing unique identifiers that are provided to the general public, the chances of those data breaches occurring from this avenue are reduced. The omission of these unique identifiers is one step closer to protecting personal health information.

As a graduate student in public health, I appreciate the opportunity to be involved in the process of amending prescription drug policies. It is encouraging that the Virginia Board of Pharmacy continuously works towards the safest possible medication administration while protecting the

health care information. Thank you for the time and efforts regarding the proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. The risk of medication administration errors for those individuals filling prescriptions in the Commonwealth of Virginia will be reduced by eliminating the unique identifiers for pharmacies that are only holding prescription medications for a consumer to pick up or to be delivered to the consumer. This amendment moves toward the delicate balance of providing the correct amount of information.

1. Working to Reduce Medication Errors. Available from <https://www.fda.gov/drugs/drug-information-consumers/working-reduce-medication-errors>. Accessed May 25, 2020.

CommentID: 80177

**Commenter:** Jennifer Helmke, Bremo Pharmacy

6/1/20 5:06 pm

### **Focus on the SIG not the phone number**

Hello,

I am writing in against this change. By removing the identifying phone number of the pharmacy, it will hurt patient safety and reduce the ability to properly conduct a medication reconciliation. The amount of space a 10 digit pharmacy phone number takes up is extremely minor and would not lead to extra space for the most important part of the label, the directions.

At our pharmacy, our phone number is built into our logo and our label designs are completely customizable. Font sizes can be increased or shrunk and we always have extra room. Our directions will also fill the allowable space to maximize the dedicated directions space.

As a pharmacist at an independent with 2 locations, we get calls for each other's locations all the time. It delays response from doctors and delays delivery to patients when the caller does not have the correct contact number. If we remove the pharmacy identifier, all chains become the same. It would begin a guessing game of who to call or where to send the prescription to.

If most patients are unaware of how to take their medications, how do we expect them to know the phone number of the pharmacy in which it was filled? With prescription transfers, the phone number IS the paper trail to transfer the prescription.

With poly-pharmacy becoming such a problem, between mail order and prescription shopping, imagine the struggle to conduct a medication reconciliation for a patient entering or leaving the hospital. If the tech had the bottle with the pharmacy phone number, they may reach out to get the last fill date or other clarification. Without it, they will not have the time to call all of the pharmacies of that chain in the area to get the information, leading to gaps in the record causing potential medication related complications resulting higher medical expense.

The focus of any change should be having a consistent sentence equation for the SIG, patient instructions. This has been studied over and over and found that even though a patient can read the directions, it differs from how they interpret them and take the medication. By changing the direction verbiage to a standard that has been studied and would be required to use for prescription directions, increasing consistency and clarity, this would reduce patient harm and errors.

I require all of my directions to be in the following order: Verb, # (number not in words), dosage form, route, frequency, with indication if known. (TAKE 1 TABLET BY MOUTH EVERY DAY FOR BLOOD PRESSURE).

I have transferred prescriptions from other pharmacies in which the sig was so poorly written, that I had to call the prescriber to understand how the patient was to take the medication or call the



pharmacy back to request the original hard copy for clarity. (Ex: B12 injection - take 1ml every 90 days) This was an injection in which the prescription should have been inject 1 ml intramuscularly every 30 days. Without requiring a route, the patient may have taken this orally and been off track by 60 days. This to me would be more important. However, if there was not a phone number on the patients label for me to call to get the correct information, how would I be able to track down the chain pharmacy in which this prescription was poorly dispensed?

I challenge you to take a look at your own prescription label and see if the phone number should be the focus of change.

Jenni Helmke, PharmD

CommentID: 80179

**Commenter:** John W Frye R.Ph. independent pharmacist

6/4/20 4:10 am

**Please deny this amendment to help frontline pharmacist's do their job**

Dear Sirs,

I respectfully request that the proposed amendment 18VAC 110-20-275 be emphatically denied for several good reasons.

This amendment does nothing to help protect public safety and in fact does the opposite and causes public harm.

It will cause more stress to front line retail pharmacists due to negatively impacting their workflow procedures by increasing the time it takes them to perform routine prescription transfers. This added stress which can be at high levels as it is, will add more distraction and thus create a greater potential for errors than if this process would be left alone as it stands.

The implication that more white space on the label is safer by eliminating the pharmacy phone number is untrue and a poor attempt at justification of a bad change in the regulations. I feel if you check with ISMP, they will not advocate nor appreciate the comments by CVS Caremark in that regard.

This amendment is a blatant attempt by CVS to manipulate the board of pharmacy and if passed, will demonstrate that Corporate Pharmacy Benefit Manager profits outweigh the need for public safety.

This amendment is all about increasing the practice of central filling to the detriment of local pharmacies both chain and independent. CVS management is seeking to cut hours and staffing and further lower pharmacist and pharmacy staff wages with this kind of practice. Is this for public safety?

I would note that that this amendment will lead to more Virginia prescriptions being filled out of state by a large mail order type operations which are not inspected by the board to insure the regulations of Virginia are being complied with as is the case with local pharmacies.

Mailed prescriptions are subject to temperature fluctuations that are outside of the labeling for the product and could thus be adulterated. This seems to be a risk to Virginia patient's lives that the board is not very concerned about. They have repeatedly denied regulations adding temperature-tracking devices to mailed prescriptions.

Let's be open and honest about this amendment. It is a corporate manipulation of the board of pharmacy disguised, as something needed which it is not. Historically, many employees of CVS have worked for or held positions on the board, and the companies interests seem to be represented with higher regard than the public good at times.

I would hereby request it be denied.

Thank you for your considerations in this matter,

John W. Frye R.Ph.  
Cedar Bluff, VA

CommentID: 80183

**Commenter:** Kelly H Kale

6/5/20 4:33 pm

**Amendment of 18 VAC 110-20-275**

Dear Board Members,

I am writing to you today in opposition to the proposed change to 18 VAC 110-20-275. This proposed change adds a layer of confusion to patients and ultimately could lead to delays in treatment and harm to patients. When a patient delivers and picks up a prescription medication from a pharmacy, they connect with that pharmacist. If that pharmacy is doing what it should be by law, that patient is seeing and talking to the providers of their care. When they get home and have a question, or are confused, or have a side effect from treatment and need to speak to their pharmacist they expect to talk to the person that was involved in their care at the pharmacy where they picked up their medication. The pharmacist that has been involved with and knows of all of their health issues.

With this proposed change you will effectively be taking that pharmacist out of the equation. The patient will no longer have the contact information readily available to them to speak to the pharmacist that just counseled them at the drug counter. And what happens when the information given at the drug counter at time of pick-up is different than the information given at some call in line in another state. Most patients I know will stop therapy until they can reach their Doctor, and what if that is over a weekend or holiday?

The patient deserves our best care. That best care is to provide them all of the information necessary to take their medication properly and to be able to contact THEIR pharmacist when there is a problem. If a pharmacy opts to conduct their business model in such a way as to move filling operations off site then they also bear the responsibility of insuring that the patient has access to ALL pertinent information related to the filling of that prescription and how to contact THEIR pharmacist. Where it was filled (address and phone number) and who filled it, as well as the information as to where the patient actually did business (address and phone number), was consulted by their pharmacist and where they can contact someone when help is needed all need to be provided to the patient.

I hope you will consider this a critical public health concern and do the right thing for our patients.

Thank you,

Kelly Kale

CommentID: 80185

**Commenter:** John W Hasty, Past Executive Director of the Dept of Health Professions

6/5/20 5:00 pm

**Opposition to amendment**

Fellow Pharmacists and Citizen Members of the Board,

I am not in favor of the proposed amendment to [18 VAC 110-20-275]. This amendment screams of big business ways to cut costs at the expense of the citizens of this Commonwealth. The citizens that you are appointed to protect.

The citizens that will be most affected are our Seniors. Those that take lots of medications, that have limited resources, that have mental health or dementia conditions and that have no support system to help them navigate this most confusing labeling situation that will be created if you proceed with this change.

I urge you to do what is right for our citizens. Do not cave to the wishes of big business and pad their pockets with the health and welfare of the people of this Commonwealth.

Thank you for allowing me to comment,

John W Hasty, RPh

Past Executive Director Virginia Department of Health Professions

CommentID: 80186

**Commenter:** Otto Wachsmann, Community Pharmacist

6/5/20 6:19 pm

### **Opposition to amendment**

I am opposed to amending the labelling requirements for prescription labels to delete the identification of the pharmacies involved with filling patient prescriptions.

When patients come into a pharmacy, they should be given information which properly identifies the pharmacies involved with processing their prescription. This critical information needs to be fully transparent.

Health care providers also need to have ready access to this information. Many caregivers and emergency services personnel are trained to bring patient's prescription bottles to the point of care. Not having the complete information on the label can create a delay when that patient's healthcare provider calls the information on the label only to discover that pharmacy does not have the complete information. In this instance that provider may have to hang up and dial another pharmacy. Once that occurs with several encounters, that provider is less likely to call to verify what can be critical information in treating that patient.

We already have violations on these labelling requirements which seem to go unchecked particularly with certain mail order pharmacies. Since Humana began sending Medicare Part D prescriptions into our state they have a pharmacy address and phone number on their label which is not the pharmacy number. Instead they provide the contact number to their customer services line. When we call for prescription transfers we have to first, call the number on the label and provide all of our information as well as the information to the customer services representative who then will transfer our phone call to the actual pharmacy. Once the call finally gets to the pharmacy, we have to reverify the information once again only to be transferred to the pharmacist to verify a third time and finally provide the transfer. This process can easily take 15 - 20 minutes. Doing that several times a day is quite time consuming and frustrating for a pharmacist who has to multi-task to remain anywhere close to profitable. Unfortunately this frustration can then lead to patient safety issues as the now stressed pharmacist becomes tainted by the frustration of getting the transfer and is less focused on the task at hand.

Pharmacy regulations are there for a reason. That reason is patient safety. Not having the complete information about the pharmacies associated with filling each prescription is not transparent to the patient and can delay patient care activities with the provider. CVS is asking for a resolution to a problem that they have created. They need to figure out how to comply with the existing patient safety related regulations.

I wish to thank the Board of Pharmacy for allowing us to comment on these important matters.

CommentID: 80187

**Commenter:** Virginia Breast Cancer Foundation

6/10/20 10:09 am

**Concerns with the proposed labeling amendments before the Board of Pharmacy**

On behalf of the Virginia Breast Cancer Foundation (VBCF), I am writing to share our concerns with the proposed labeling amendments before the Board of Pharmacy. VBCF is a statewide, state-based organization that is focused on education and advocacy for all Virginians affected by breast cancer. Medication plays an important role in the treatment of breast cancer and timely access to prescriptions and transparent labeling is vital. Patients should be able to easily identify the best person to contact if they have questions about a prescription. Therefore, attempts to alter pharmacy identifiers should be minimized. If breast cancer patients pick up products at a pharmacy that is serving as a depot for the products, they should be able to read the label information and contact the person who can help answer any related questions. There should be no questions about how a patient can speak with someone to obtain medical information. Please do not amend the current labeling system unless a change makes it easier, clearer, or more user-friendly to the patient.

Katy Sawyer, Executive Director, Virginia Breast Cancer Foundation

CommentID: 80222

**Commenter:** Richmond Academy of Medicine

6/11/20 12:59 pm

**Opposition to proposed amendments affecting the labeling of prescription medications [18 VAC 110-20]**

The Richmond Academy of Medicine (RAM) appreciates the opportunity to comment upon the proposed regulations affecting the labeling of prescription medications (18 VAC 110-20). The Academy represents more than 1900 physicians in the greater Richmond region.

While an initial reading of the proposed labeling changes sounds innocuous and could result in a less confusing label, the implications of this proposed change are significant, do not improve the health of Virginians, and have potentially devastating impacts upon not only our patients, but also pharmacies and physician practices.

First, we do not understand the rationale for the proposal. At a time when both citizens and legislators are asking for more transparency within the drug supply chain, it is inappropriate to decrease the ability of the prescription recipient to ask questions of or hold accountable the actual dispenser of the medication, not the final distribution point.

Second, anyone who has a question about a prescription would naturally call or speak with the person at the site where they picked up the prescription. If the pharmacist at the location did not actually fill the prescription, they may or may not be able to legitimately vouch for the information on the label, whether the prescription was actually filled correctly, or a number of other issues. If there is no data on the label to contact the actual dispenser to confirm the information, this places a potential significant liability on the distribution site employee and/or undue burden upon that person if they must then contact the pharmacy that actually filled the prescription. This creates additional unnecessary waste within our drug distribution system while creating an unfunded mandate upon the prescription distribution site.

Third, this proposed change opens the door for further limitation of prescription fulfillment from neighborhood and independent pharmacies to only chain pharmacies. We have seen in other states (i.e. Ohio) how national corporations have funneled business to their own pharmacies through spread pricing and other techniques. This business model has resulted in the closing of independent pharmacies. These closings are especially prevalent in areas where access to health care is already difficult - rural areas and inner cities. This proposal will allow national organizations to utilize their centralized pharmacies to fill prescriptions and have them delivered through their corporate network pharmacies, thereby cutting out neighborhood and independent pharmacies. We do not believe this will improve access to medications nor save money for the health care system. We fear it will result in profit mongering for these vertically integrated insurer/pharmacy benefit manager/pharmacy businesses at the expense of access to care.

Fourth, there is significant potential impact on physicians and their practices, especially those that prescribe specialty medications and/or infusion services. It will likely have a negative effect on independent infusion providers and hospital systems. This labeling proposal creates a means for insurers and/or pharmacy benefit managers to require that any medication that will be infused come from their national or specialty pharmacy. This so-called "white bagging" comes with a lack of validation by the infuser of how the medication was handled prior to being infused. It also creates an additional financial barrier to the provision by these localized infusion centers and/or a problem for the hospital if the infuser cannot "buy and bill" for these medications. The current financial strain on physician practices as well as hospital/regional health care systems means that this change in drug distribution/payment system could result in the closure of these providers. Again, the potential negative effects of this action would primarily affect the most vulnerable Virginians - those with chronic and/or disabling conditions as well as those who live in rural areas or inner cities.

Lastly, the Academy is concerned that the out-of-state filling of prescriptions could negatively affect to Commonwealth's revenue resulting in the loss of jobs and small businesses as an unintended consequence of this proposed regulation change.

For these reasons, on behalf of the 1,900+ physicians we represent and most importantly, the patients for whom they care, the Richmond Academy of Medicine respectfully opposes the proposed regulation changes to 18 VAC 110-20.

CommentID: 80227

**Commenter:** Kelly Waters, VHF and Brenda Bordelon, HACA

6/14/20 12:52 pm

### **Concerns with the proposed labeling amendments before the Board of Pharmacy**

As policy advocates for the Hemophilia Association of the Capital Area (HACA) and the Virginia Hemophilia Foundation (VHF), we are writing to express our concerns with the proposed labeling amendments before the Board of Pharmacy. Our members are individuals with inherited bleeding disorders and their family members. To achieve high quality of life, many individuals with inherited bleeding disorders receive clotting factor replacement therapy to treat bleeding episodes or prevent bleeding. The two main types of clotting factor concentrates are plasma-derived factor concentrates or recombinant factor concentrates. Other common treatment products include Hemlibra, DDAVP or Stimate, and Amicar.

Because medication is critically important in the treatment of inherited bleeding disorders, timely access to products is essential. And transparent labeling is vital. Persons should be able to determine who filled their prescriptions; therefore, attempts to alter pharmacy identifiers should be minimized. If we pick up products at a pharmacy that is serving as a depot for the products, we should be able to read the label information and contact the person who was responsible for filling the prescription. There should be minimal delays in obtaining this information, should we be obtaining a product that is to be used immediately to treat an emergent situation.

We recommend that you make no changes to current labeling requirements at this time.

Kelly Waters, MSW, LCSW  
Executive Director  
Virginia Hemophilia Foundation

Brenda Bordelon  
Executive Director  
Hemophilia Association of the Capital Area  
CommentID: 80268

6/14/20 3:52 pm

**Commenter:** Al Roberts, Remington Drug Company

**Opposition to proposed Amendment of 18 VAC 110-20-275**

I would like to thank the Virginia Board of Pharmacy for taking the time to review my comments on the proposed amendment of 18 VAC 110-20-275. My opposition is on several levels including but not limited to transparency, complete details on final product prior to final determination, patient choice, increased workflow stress in the pharmacy day to day operations, tracking and accountability for the filling process start to finish, and most importantly patient safety.

I can see how a patient would be concerned when a prescription label has an address different from the pick up address. Community pharmacists often get calls when product appearance changes even when the pharmacy has taken steps to alert the patient either in verbal or written form and this is also where the entire filling process took place. This could cause a patient to be concerned as to the accuracy of the finished product and potentially not take the medication. The amount of time and effort required to explain this in a fashion all patients, regardless of comprehension level, would be huge. It could not be accomplished with a piece of paper---what if they do not speak English or the document could not print in their native language. The bottom line is the patient believes the prescription has been filled where they are picking it up and that may not be the case and they may not know this if the amendment is accepted. Transparency is lost in this example.

I am confused to some degree as to what the label would look like if this amendment is accepted. Is the listed pharmacy on the label the filling pharmacy or the pharmacy where the pickup takes place or no pharmacy specific information at all on the label. The comment in the recent Virginia Pharmacists Association newsletter on this subject stated the following: "This means there would be no phone number or address on the label where the prescription was sold to the patient". From re-reading several times, it appears only the initial pharmacy processing the prescription would be listed, but I am not sure that is correct. What happens on refills, will it always be the pharmacy which initially processed the prescription the very first time?

This proposed amendment affects the patient's choice of where to fill their prescription. The patient is presenting a written prescription or a refill of an existing prescription at a pharmacy of their choice and the expectation is the prescription will be filled in that pharmacy and also picked up in that very same pharmacy each and every time. This amendment removes that piece of information related to remote processing/filling. While this may be done routinely, patients should be aware. A patient may have a reason for choosing a particular pharmacy and knowledge that the prescription may not always be processed/filled 100% at that location could determine which pharmacy is selected.

Without full disclosure of all pharmacies involved in the process, it will increase workflow time and work stress when transferring prescriptions. It is hard enough when a pharmacist knows which pharmacy to call to complete a transfer. Add in the infinite steps associated with mail order transfers and one could see that time lag becoming routine. It truly has taken our pharmacy 20 minutes to complete a transfer from a mail order facility. The analogy is similiar to what this amendment proposes since we often times call a remote call center which then routes the call or gives the pharmacist another number to call to complete the transfer. The workflow disruption and added stress on staff could affect how care is provided to the patient. This is assuming the patient can provide a starting point for the pharmacist and this is not always the case. It is sometimes challenging if we are just talking about two pharmacies in the same chain at different locations in the same community as in 2 Walgreens or 2 CVS ----- which one do we call when all we have is "Please call "?" and transfer my prescription". Without all necessary information related to the filling of a prescription, simple transfers can sometimes be difficult and time consuming.

With the recently enacted "track and trace" requirements related to pharmaceuticals, it seems odd as well as inappropriate to decrease the traceability of a prescription from start to finish. When a pharmacist is presented with another pharmacy's prescription bottle, the phone number listed should be the only one necessary to complete the transfer but in the event there is a problem all pharmacies information should be available if needed to resolve the concern. In independent

pharmacies this is never an issue because the prescription is handled 100% in that brick and mortar location from start to finish. Any issue related to the prescription can be traced from start to finish. The same should be true for chain, big box operations using offsite processing and filling.

I have saved the most important reason for opposing this amendment to discuss last and that reason is patient safety. What if the prescription is wrong---wrong drug, wrong strength, wrong person, or wrong directions. How is this potential harm caught, how is it corrected and at which pharmacy? If it is a new prescription, how is the patient to know? What if the directions are very complex and require detailed explanation? What if the prescription is for a device like an inhaler, an injectable insulin, or one of the new GLP-1 products like Ozempic. Who is responsible for being sure the patient has all the information necessary to properly and effectively use the medication? The proposed amendment reads like the final link in the process, the pharmacy holding the prescription for pick up, is only responsible for that which amounts to exchange of monies or the processing of a credit card and handing the prescription to the patient or authorized agent. The Institute for Safe Medication Practices (ISMP) has been cited in one comment as evidence for accepting this amendment. ISMP, in the second edition of **MEDICATION ERRORS**, devotes a full chapter to the patient's role in preventing medication errors. In this chapter the author highlights the importance of concise and accurate interpretation of the provider's directions for use on the prescription. With this amendment in place, if the patient has a question on the written directions, which pharmacy should be called--the one which processed or the one that delivered the prescription or should they both be accessible? The author also shares the six steps recommended by the American Medical Association for improving communication with patients thereby decreasing opportunities for errors. None of those six can be done by just handing a bag to a person and taking money or processing a card. They require a knowledgeable healthcare professional---that means one on one with a pharmacist.

Of the 10 comments to this point only two have supported this amendment. One is a student and the other is an employee of CVS Health neither of which has recently been involved in the intense everyday workflow experienced by pharmacists and technicians every single day. If this statement is not accurate, I apologize for jumping to this conclusion. I am aware one of the main functions of the Boards of Pharmacy is to be sure patients, our patients, are not harmed or exposed to unsafe pharmacy practices/procedures. I believe this amendment, if enacted/accepted, has the potential to adversely affect patient safety. It has the potential to allow the large pharmacy corporations to further reduce staff, increase employee workload, increase job related employee stress, mislead patients on where their prescriptions are filled, and negatively impact small independent pharmacies through more aggressive business efforts resulting in less patient choice when the independent pharmacy is forced to cease operations. The other 8 comments oppose this amendment and for good reasons--some repeated in this comment. While I have mentioned some major concerns, there are other like gaps in therapy due to formulary changes, step therapy requirements, prior authorizations, and expensive co-pays/coinsurance hurdles. Who handles those and when is the patient alerted? I am disappointed this amendment was even proposed and requiring valuable Board time when other items such as pharmacist's scope of practice have the ability to positively affect patient care once addressed and guidelines enacted.

Thank you again for reviewing my comments and concerns

Al Roberts, Remington Drug Company

CommentID: 80273

**Commenter:** Medical Society of Virginia

6/15/20 9:46 am

**Opposition to Proposed Change to Delivery of Dispense Prescriptions Labeling**

**Commenter:** The Medical Society of Virginia

**Opposition to the Proposed Change to Delivery of Dispense Prescriptions Labeling**

The Medical Society of Virginia (MSV) serves as the voice for more than 10,000 physicians, residents, medical students, physician assistants, and physician assistant students, representing all medical specialties in all regions of the Commonwealth. On behalf of these clinicians, I am writing you in opposition to the proposed amendments to section 275 of Chapter 20 pertaining to the procedure for identifying all pharmacies involved in the filling and dispensing of a prescription.

MSV recently became aware of the proposed changes which would no longer require a unique identifier for a pharmacy to be listed on the prescription label when a pharmacy was not involved in filling or dispensing functions. Such changes to the regulations would result in many patients with prescriptions no longer having quick access to the contact information of their local pharmacist. To ensure patient safety, it is essential that patients are provided with the contact information of their local pharmacist who can help address the concerns or questions they may have regarding their prescriptions. Many patients have become accustomed to having this resource posted on their prescription label and to remove this critical information for patients is simply improper patient care and not the standard for which should be accepted.

In addition to the detrimental effects to a patient's health, this change would further jeopardize independent pharmacies who have already been suffering, with many closing in our highest need communities. The proposal would essentially promote removing neighborhood and independent pharmacies from the pharmaceutical process by allowing national organizations to use their centralized pharmacies to fill prescriptions and their corporate network pharmacies to deliver prescription. Cutting out independent and community pharmacies that often reside in low-income and rural areas will do nothing to increase access or support affordability for patients. Rather, such proposal would put the profits of vertically integrated insurers, pharmacy benefit managers, and pharmacy corporations over patients.

Furthermore, MSV has concerns that such proposed changes could make it more difficult for physicians to identify a patient's local pharmacist and thus coordinate care. During visits, patients often may bring in a prescription which would typically include the number and/or address of a local pharmacist. This information, while essential for patients, is also helpful for physicians so that they can easily identify the pharmacist with whom to communicate to in the need of determining what other medications a patient may be taking and/or to discuss special needs of that patient. It also raises concerns around patient safety, if the physician is unable to verify the safety of drug supply chain, particularly for those patients that require infusions of specialty medications.

In summary, MSV feels the proposed changes, while may seem harmless, could result in numerous negative effects to patients, independent pharmacies, and the health care system at large.

We thank you for the opportunity to provide feedback on the proposed regulation change. If you have any questions, please do not hesitate to reach out to Clark Barrineau at [cbarrineau@msv.org](mailto:cbarrineau@msv.org) or 704.609.4948.

CommentID: 80286

**Commenter:** Randall Cole, Appalachian College of Pharmacy

6/15/20 9:56 am

### **Opposition to proposed Amendment of 18 VAC 110-20-275**

I am writing to voice my opposition to proposed amendment of 18 VAC 110-20-275. Simply put, as pharmacists and patient advocates, we all took an oath to serve and protect our patients' well-being. Please take a moment to put yourself into the shoes of your 85 year old grandfather who has CHF, on dialysis, and can hardly see anymore. Will these proposed labeling changes better serve and protect him when he has a medication issue? Will your grandfather want to speak to some stranger on an 800 number about his health conditions? If the proposed changes would better serve and protect him, then we would not be writing in opposition to these proposed labeling changes.



Lastly, I remember some words of wisdom from a preceptor when I was a student pharmacist. When we are faced with tough decisions, think of that patient as your grandfather and how your decisions would affect him. If it will negatively impact him, then don't do it! DO NO HARM

Sincerely,

Randall Cole, PharmD

CommentID: 80287

**Commenter:** Harry L Gewanter, MD, FAAP, MACR

6/16/20 4:36 pm

**Opposition to proposed Amendment of 18 VAC 110-20-275**

**From:** Harry L Gewanter, MD, FAAP, MACR

**Re: Opposition to proposed Amendment of 18 VAC 110-20-275**

As a pediatrician and pediatric rheumatologist I am writing in opposition to the Board's proposed amendments to 18 VAC 110-20-275. Beyond a lack of understanding for the concept of amending this regulation, I have serious and significant concerns regarding the proposed amendment's implications.

This change has the potential to seriously impair access to services for Virginians through the deference provided to chain pharmacies as compared to independent ones. The ability of an insurer/pharmacy benefit manager/specialty pharmacy to limit access to its clients/patients to its own pharmacies may be in the corporation's best interest, but it is not in the patient's best interest. As has been seen in other states, this type of forced choice through other means such as spread pricing has led to the financial failure and closure of these small businesses, especially in rural and inner city areas.

The lack of transparency that results from "increasing the amount of white on the label" is another concern. The patient will assume that the pharmacy where the prescription is obtained is the pharmacy that filled the prescription, thereby placing an inappropriate burden upon that pharmacy should the patient have any questions or issues. Further, I could easily conceive of a potential liability issue for that pharmacy and pharmacist since they are now part of the distribution chain but cannot vouch for the prescription or its handling during shipment, etc.

As a physician who has infused specialty medications for my patients, I am especially concerned about Part C of the proposed amendment.

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.

This amendment would allow an insurer/pharmacy benefit manager/specialty pharmacy to minimize my ability to provide my patients with the medications we have agreed are in their best interest. Similar to the distributing pharmacist, this places an undue burden and liability upon me to confirm and ensure the medication is as ordered, has been shipped and handled correctly, etc., with an inability to confirm these details. This "white bagging" system adds another layer of cost and complexity to an already overly complex and costly drug delivery system without adding any benefit to the patient, the ultimate payer.

While there are numerous other reasons to oppose this unnecessary amendment, I think these make the point that this proposal should be roundly defeated. It seems to only benefit the insurer/pharmacy benefit manager/specialty pharmacy component of the drug supply chain, but not the patient, pharmacist or any of the health care providers involved in the actual care of the patient.

Thank you for your consideration.

Harry L. Gewanter, MD, FAAP, MACR

Richmond, VA

CommentID: 80302

**Commenter:** American College of Rheumatology and Virginia Society of Rheumatologists

6/16/20 8:28 pm

### **Opposition to Proposed Change to Alternative Delivery Site Prescription Labeling**

The American College of Rheumatology (ACR) represents rheumatology professionals across the United States. The College routinely comments on proposed policy changes that could impact our members or the patients that they treat. The Virginia Society of Rheumatologists (VSR) represents rheumatology professionals across the state of Virginia and routinely comments on policy changes that would negatively impact our members and the patients they treat. The ACR and VSR are concerned that the proposed rule will have negative impacts on drug transparency that is vital to patient safety. The ACR urges the Board of Pharmacy to withdraw this proposed rule.

The drug supply chain is a complex system. When a prescription makes its way into the hands of the consumer it has been touched numerous times by many other people and entities along the way. To ensure adequate pharmacovigilance, the chain of custody once it reaches the pharmacy must be clear and transparent. This proposed rule would allow prescriptions to be filled at a specialty pharmacy then shipped to an alternative site for pickup, without requiring anything on the label to identify the pickup location. This substantially diminishes the drug transparency that patients deserve and that safety demands.

The ACR and VSR are concerned that this rule would further open the door for "white bagging" and "brown bagging" of pharmaceuticals. "White bagging" policies require providers to purchase medications through a specialty pharmacy, typically owned by the PBM or payer. "Brown bagging" refers to policies that require the dispensing of a medication from a specialty pharmacy directly to a patient, who then transports the medication to the physician's office for administration.

Our members frequently administer infusions. Increasingly payers are forcing patients to engage in the dubious practice of "brown bagging" to ensure that the payer's own specialty pharmacy is utilized to fill a prescription, instead of using the "buy and bill" system. The reason "buy and bill" is predominantly used in infusions goes to the heart of patient safety and chain of custody. Once a medication is delivered to a clinic, storage and handling is no longer an issue. With "brown bagging" handling and storage is especially a concern. Once the patient picks up the medication from a pharmacy, ensuring proper handling and storage is impossible.

It is worth noting that Board of Pharmacy already has a proposed rule on "white bagging" and "brown bagging" in its final stage of consideration. It is also particularly worth noting that the rule would add subsections F-G to the same

code sections being modified in this rule. <sup>[1]</sup> The sections contained in the other proposal prohibit the delivery of a dispensed drug to a patient's residence that requires special storage, compounding or reconstitution, and is to be subsequently taken by the patient to a clinic for administration. However, it would allow these drugs to be delivered to "alternative delivery sites," which includes another pharmacy. If this rule is adopted in conjunction with the other proposed rule, the pick-up pharmacy would not be on the drug label and would not just be hidden from the patient, but also from the administering physician.

In a "brown bagging" scenario, a physician must have as much information about the chain of custody as possible. Patient safety depends on the physician knowing how long the patient has had the drug, how it was stored, and where the drug was received from. The ACR and VSR do not endorse or condone "brown bagging." However, if this rule should move forward, it must exclude "brown bagged" medications from this label exemption, so that physicians have all the information necessary to determine the safety of the medication. That includes being able to contact the pharmacy where the prescription was picked up by the patient.

Finally, the ACR and VSR are a strong supporters of the rulemaking process and the transparency that it provides for physicians and patients. However, we strongly question the transparency of the rulemaking being undertaken here. While we do not question the Board's authority, modifying the same code section simultaneously with two different rules effectively hides the ball from interested parties. At a minimum this current proposal should be withdrawn until the other rule has a final disposition and interested parties can submit comments on the full implications of the changes proposed in this rule. We do not believe that the Board has undertaken this new rule with any ill intent. We simply believe it is an oversight driven by a petition for rulemaking that does not take into full account the implications of the proposed rule on patient safety and provider liability. We respectfully ask the Board to withdraw this rule.

We appreciate the opportunity to comment. If you have any additional questions please reach out to Joseph Cantrell at [jcantrell@rheumatology.org](mailto:jcantrell@rheumatology.org).

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[1] <https://townhall.virginia.gov/L/ViewXML.cfm?textid=14268>  
CommentID: 80304

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY  
PUBLIC HEARING FOR DELIVERY OF DISPENSED PRESCRIPTIONS;  
LABELING**

June 16, 2020  
Commonwealth Conference Center  
Third Floor  
Conference Room 5

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

**CALL TO ORDER:**

A Webex virtual public hearing was called to order at 9:04 a.m. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the Board convened a virtual meeting to consider such regulatory and business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

**PRESIDING:**

Cynthia Warriner, Chairman (on-site)

**MEMBERS PRESENT:**

James L. Jenkins, Jr. (On-Site)

**MEMBERS PARTICIPATING  
VIRTUALLY:**

Kristopher S. Ratliff, Vice Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
Ryan Logan  
Cheryl H. Nelson  
Patricia Richards-Spruill  
Rebecca Thornbury  
William Lee

**STAFF PRESENT:**

Caroline D. Juran, Executive Director (On-Site)  
James Rutkowski, Assistant Attorney General (On-Site)  
Kiara Christian, Executive Assistant (On-Site)

**STAFF PARTICIPATING  
VIRTUALLY:**

Annette Kelley, Deputy Executive Director  
Beth O' Halloran, Deputy Executive Director  
Ellen B. Shinaberry, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP  
Barbara Allison-Bryant, MD, Chief Deputy, DHP

**CALL FOR PUBLIC COMMENT:**

The Board intends to amend section 275 of Chapter 20 pertaining to the procedure for identifying all pharmacies involved in the filling and dispensing of a prescription. The amendment would specify that a unique identifier on the prescription label 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.

PUBLIC COMMENT:

Lauren Paul, Sr. Director, Pharmacy Regulatory Affairs, CVS Caremark thanked the board for opportunity to comment. Petition was submitted in Sep 2017 to make changes to labeling when picking up a prescription from a pharmacy that was filled by a different pharmacy. She commented that this hearing is the sixth discussion through meetings, third formal comment period. She offered support of the amendment, and has spoken to the board multiple times. She pointed out in the Economic Impact Analysis provided by the Department of Planning and Budget in response to this petition that older adults and adults with visual impairments prefer larger size print on labels.

Christina Barrille, Executive Director, VPhA, thanked the board for the opportunity to provide comment. She referred to comment provided by Virginia pharmacists on the Regulatory Town Hall Website. She shared concerns regarding patient safety, if the chance for counseling from a pharmacist may be taken away and that senior citizens will be greatly impacted. Healthcare providers need to have access to information, having the complete information on the label will help if a provider needs to contact the pharmacy. She commented that the proposed amendment takes away a patient's choice of where to fill their pharmacy. She shared concerns from the Richmond Academy of Medicine indicating that pharmacists are not the only providers impacted by this change.

Mark Hickman representing the Virginia Society of Health-System Pharmacists asked the board to take context of the various situation of delivery sites and potential impact to pharmacist-patient relationship into consideration during their decision-making. He shared that VSHP will provide additional comment later if the Board approves the petition for rulemaking.

ADJOURN:

The public hearing adjourned at 9:21 am.

\_\_\_\_\_  
Cynthia Warriner, Chairman

\_\_\_\_\_  
Caroline D. Juran, Executive Director

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date



## Proposed Text

[highlight](#)**Action:** Delivery of dispensed prescriptions; labeling**Stage:** Proposed

1/29/20 8:05 AM [latest] ▼

18VAC110-20-275

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~~ pick-up 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. A unique identifier on the prescription label 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;

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~~ Procedure for assuring confidentiality of patient information; and

e. ~~The procedure~~ 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 that cannot be easily moved and that 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.

## § 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;
2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;
3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, **a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.**

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed. If the prescription is for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.
2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.



**A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.** However, if the pharmacist dispenses a Schedule III through VI drug or device for expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, the prescription shall state "Expedited Partner Therapy" or "EPT" in lieu of the full name and address of the contact patient.

**Agenda Item: Adoption of Exempt Regulations for Collaborative Practice Agreements**

**Included in package:**

- Copy of HB1506 as passed by the 2020 General Assembly
- Draft amendments to regulations

**Board action:**

- Motion to amend sections of 18VAC110-40-20., as presented in the agenda package

# HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Introduced by: Mark D. Sickles | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED: (all summaries)

**Pharmacists; prescribing, dispensing, and administration of controlled substances.** Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, to promulgate emergency regulations to implement the provisions of the bill, and to convene a work group to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

### CHAPTER 731

[H 1506]

Approved April 6, 2020

Be it enacted by the General Assembly of Virginia:

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement*. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~ B. A patient who *meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure* shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by

contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

*C.* Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

*D.* Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

*E.* Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

# HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Introduced by: Mark D. Sickles | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED: (all summaries)

**Pharmacists; prescribing, dispensing, and administration of controlled substances.** Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, to promulgate emergency regulations to implement the provisions of the bill, and to convene a work group to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

### CHAPTER 731

[H 1506]

Approved April 6, 2020

Be it enacted by the General Assembly of Virginia:

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement*. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~ B. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by

contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

*C.* Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

*D.* Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

*E.* Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

## Draft Regulations for Collaborative Practice Agreements

### 18VAC110-40-20. Signed Authorization for an Agreement.

A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a single physical location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. ~~Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.~~ A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure.

1. The patient may decline to participate or withdraw from participation at any time.
2. ~~Prior to giving consent to participate, the~~ The patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.
3. ~~As part of the informed consent, the~~ The practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

**Agenda Item: Adoption of Fast-track Regulations for use of industrial hemp by pharmaceutical processors**

**Included in your agenda package are:**

Copy of HB1670 passed by the 2020 General Assembly that authorizes such use

Copy of proposed amendments to Chapter 60

**Board action:**

Adoption of amendments to section 280 by a fast-track action



# HB 1670 Pharmaceutical processors; cannabidiol oil, permit to operate processor.

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## SUMMARY AS PASSED HOUSE: (all summaries)

**Board of Pharmacy; pharmaceutical processors; cannabis oil.** Allows pharmaceutical processors to acquire industrial hemp grown and processed in Virginia from a registered industrial hemp dealer or processor and allows a pharmaceutical processor to process and formulate industrial hemp with cannabis plant extract into an allowable dosage.

### CHAPTER 928

*An Act to amend and reenact §§ 54.1-3408.3, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to Board of Pharmacy; pharmaceutical processors; cannabidiol oil; industrial hemp.*

[H 1670]

Approved April 9, 2020

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 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 any formulation of processed Cannabis plant extract, *which may include oil from industrial hemp extract acquired by a pharmaceutical processor pursuant to § 54.1-3442.6*, 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 five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol.

"Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, *unless it has been acquired and formulated with cannabis plant extract by a pharmaceutical processor.*

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

"THC-A oil" means any formulation of 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 five milligrams of tetrahydrocannabinol acid per dose 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 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 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. A 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, may designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.

H. 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, his registered agent, 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.

I. 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, his registered agent, or, if such patient is a

minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

§ 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, his registered agent, 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; (x) the secure disposal of plant remains; (xi) a process for registering a cannabidiol oil and THC-A oil product; (xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; and (xiii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors; and (xiv) a process for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabidiol oil.

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

G. No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, 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 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor.

H. Every pharmaceutical processor shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

*I. A pharmaceutical processor may acquire oil from industrial hemp extract processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A pharmaceutical processor may process and formulate such oil extract with cannabis plant extract into an allowable dosage of cannabidiol oil. Oil from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in compliance with state law. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before oil from industrial hemp may be acquired.*

§ 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, (ii) such patient's registered agent, or (iii) 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 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, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, registered agent, 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, registered agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's 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 a pharmaceutical processor permitted by the Board *or cannabidiol oil that has been formulated with oil from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6.* A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

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, registered agents, 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. The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and shall establish a stability testing schedule of THC-A oil.

**18VAC110-60-280. Cultivation and production of cannabidiol oil or THC-A oil.**

A. No cannabis 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, cannabis oil not in compliance with this section shall be deemed adulterated.

D. A pharmaceutical processor may acquire oil from industrial hemp extract for the purpose of formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil provided:

1. The pharmaceutical processor acquires the oil from industrial hemp extract processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor;

2. The oil from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements applicable to cannabis plant extract as verified by testing performed by a laboratory located in Virginia and in compliance with state law; and

3. The industrial hemp dealer or processor provides such third-party testing results to the pharmaceutical processor before oil from industrial hemp is acquired.

E. A pharmaceutical processor acquiring oil from industrial hemp extract shall ensure receipt of a record of the transaction that shows the date of distribution, the names and addresses of the registered industrial hemp dealer or processor distributing the product and the pharmaceutical processor receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the pharmaceutical processor with its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years.

F. A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of oil from industrial hemp extract, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

**Agenda Item: Petition for rulemaking:**

**Included in your package are:**

Copy of Notice on Townhall

Copy of petition from the Virginia Medical Cannabis Coalition

Copy of Comments on the petition

Copy of sections of regulations for which amendments requested

**Board action:**

**The Board has the option to:**

- 1) Initiate rulemaking with publication of a NOIRA, or**
- 2) Deny the petitioner's request, or**
- 3) Decline to initiate rulemaking and refer consideration of changes to the Regulation Committee.**

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Secretariat Health and Human Resources

Agency Department of Health Professions

Board Board of Pharmacy

[Edit Petition](#)

Petition 328

## Petition Information

<b>Petition Title</b>	Changes to requirements for pharmaceutical processors
<b>Date Filed</b>	7/15/2020 <a href="#">[Transmittal Sheet]</a>
<b>Petitioner</b>	Virginia Medical Cannabis Coalition
<b>Petitioner's Request</b>	<p>18VAC110-60-170: Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor</p> <p>18VAC110-60-220(F,G): Visitors Policy: Remove the requirement that the Board must approve or waive all visitors. Also, allow younger minor children to accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues.</p> <p>18VAC110-60-230(A)(1), (B): Inventory: Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct.</p> <p>18VAC110-60-290: Product Label: Remove requirements for duplicative information between the product label and patient label.</p> <p>18VAC110-60-290(B)(2)(e): Expiration Dates: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months</p> <p>18VAC110-60-300(F): Remediation: Allow for remediation if a sample does not pass testing requirements.</p> <p>18VAC110-60-310(A)(1): VCPRL: Allow non-licensed personnel to access the VCPRL to allow access to the processor.</p> <p>18VAC110-60-310(C): Patient Labels: Remove requirements for duplicative information between the product label and patient label (same request as product label).</p>
<b>Agency's Plan</b>	<p>In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on August 3, 2020. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at <a href="http://www.townhall.virginia.gov">www.townhall.virginia.gov</a>; comment will be requested until August 25, 2020.</p> <p>Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in</p>

Regulations Governing Pharmaceutical Processors. This matter will be on the Board's agenda for its meeting scheduled for September 9, 2020, and the petitioner will be informed of the Board's decision after that meeting.

<b>Comment Period</b>	<p>◆ <b><u>In Progress!</u></b></p> <p><b><u>Ends 8/25/2020</u></b></p> <p><b><u>Currently 1 comments</u></b></p>
<b>Agency Decision</b>	Pending
<b>Contact Information</b>	
<b>Name / Title:</b>	Caroline Juran, RPh / <i>Executive Director</i>
<b>Address:</b>	9960 Mayland Drive Suite 300 Richmond, 23233
<b>Email Address:</b>	<a href="mailto:caroline.juran@dhp.virginia.gov">caroline.juran@dhp.virginia.gov</a>
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# COMMONWEALTH OF VIRGINIA

## Board of Pharmacy

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

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

### Petition for Rule-making

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

<b>Please provide the information requested below. (Print or Type)</b>		
Petitioner's full name (Last, First, Middle initial, Suffix,) Virginia Medical Cannabis Coalition		
Street Address PO Box 3632	Area Code and Telephone Number 804-901-8785	
City N. Chesterfield	State Virginia	Zip Code 23235
Email Address (optional)	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.

- Title 18. Professional and Occupational Licensing: Pharmaceutical Processor Employee Licenses and Registrations.  
• 18VAC110-60-170
- Title 18. Professional and Occupational Licensing: Pharmaceutical Processor Prohibitions.  
• 18VAC110-60-220(F,G)
- Title 18. Professional and Occupational Licensing: Inventory Requirements.  
• 18VAC110-60-230(A)(1), (B)
- Title 18. Professional and Occupational Licensing: Labeling of Batch of Cannabidiol Oil or Thc-A Oil Products  
• 18VAC110-60-290  
• 18VAC110-60-290(B)(2)(e)
- Title 18. Professional and Occupational Licensing Laboratory Requirements: Testing.  
• 18VAC110-60-300(F)
- Title 18. Professional and Occupational Licensing: Dispensing of Cannabidiol Oil or Thc-A Oil.  
• 18VAC110-60-310(A)(1)  
• 18VAC110-60-310(C)

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

- Title 18. Professional and Occupational Licensing: Pharmaceutical Processor Employee Licenses and Registrations.
- 18VAC110-60-170:
- Request: Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor
- Rationale: Commercial pharmacies currently may hire any pharmacy technician without experience restrictions. We ask that this be the same for pharmaceutical processors; all of our employees must be specifically trained upon hiring for our industry regardless of prior experience. Furthermore, it is especially difficult to recruit and hire pharmacy technicians in some areas of the Commonwealth. Finally, experienced pharmacy technicians are typically seeking increased pay which adds costs to operation, and therefore patient costs, when such experience is not necessary for the job.
  
- Title 18. Professional and Occupational Licensing: Pharmaceutical Processor Prohibitions.
- 18VAC110-60-220(F,G): Visitors Policy
- Request: Remove the requirement that the BOP must approve or waive all visitors. Also, allow younger minor children to accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues.
- Rationale: The current visitor approval process delays and interrupts processor operations, as the processors need to allow visitor access on a regular basis to contractors and other individuals that need to do work on the premises. Visitors should still be required to be escorted, badged, and logged as is currently required. The Board of Pharmacy may wish to look to states such as Massachusetts, Maryland, and New York for their visitor policies for the medical cannabis programs. Currently only registered patients, legal guardians, or registered agents can enter the dispensary area to pick up medication. This is a concern as a parent would be forced to illegally leave their child in the car in order to come in to get medication. We are also concerned that someone with mobility issues may need someone to escort them in. That caregiver may not be registered and would currently not legally be allowed entry. States such as Maryland allow minor children to accompany registered patients when necessary and also permit someone to assist a registered patient as long as they are properly logged as a visitor.
  
- Title 18. Professional and Occupational Licensing: Inventory Requirements
- 18VAC110-60-230(A)(1), (B): Inventory
- Request: Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct.
- Rationale: Processor facilities require inventory on multiple levels: cultivation related inventory, processing related inventory, and dispensary related inventory. Requiring a pharmacist or pharmacy technician to conduct all of these inventories throughout the day is overly burdensome and will increase patient costs. Inventory activities can safely be performed by non-licensed employees under video surveillance with verification by a pharmacist or pharmacy technician. As every part of a processor where cannabis is located is required to be videoed at all times, any discrepancies can easily be accessed via video surveillance logs.
  
- Title 18. Professional and Occupational Licensing: Labeling of Batch of Cannabidiol Oil or Thc-A Oil Products
- 18VAC110-60-290: Product Label
- Request: Remove requirements for duplicative information between the product label and patient label.
- Rationale: Each product will have both product label (manufacturer's label) and patient label. So long as the information is included on the product label, such information should not be required to also be on the patient label. The information required on both labels is duplicative when taken together and will cause processors to utilize font that will be too small for patients to read. See the attached label examples.
  
- Title 18. Professional and Occupational Licensing: Labeling of Batch of Cannabidiol Oil or Thc-A Oil Products.
- 18VAC110-60-290(B)(2)(e): Expiration Dates
- Request: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months.
- Rationale: Current regulations are unclear about stability testing processes, and recent conversations with Board staff suggest no product may be sold until aged product has been stability tested. If enforced this way, patient access to product would be delayed by months, if not years. In other medical markets such as Ohio and Massachusetts, expiration dates are set at a maximum of 12 months, which is used as the default in the early years of the program. In New York, testing on past formulations has been done and expiration dates have been set at 6 to 12 months. Processors in those markets are then allowed to provide shorter expiration dates based on stability testing conducted on product over time. Additionally, USP standards for compounding sets a 6-month expiration date for nonaqueous formulations. This compromise of 6 to 12 months ensures patient access early on in the program while quality assurance measures take place for long term success of the program.

- Title 18. Professional and Occupational Licensing Laboratory Requirements: Testing.
- 18VAC110-60-300(F): Remediation
- Request: Allow for remediation if a sample does not pass testing requirements.
- Rationale: In the event a sample of product does not pass laboratory testing, the pharmaceutical processor should be permitted to reprocess the lot and submit a reprocessed sample for retesting. Reprocessed samples that satisfy all testing requirements should not be subject to disposal. Such methods of remediation can be utilized to produce a safe and effective product without destroying an entire batch. Requiring the disposal of an entire batch without allowing for remediation creates unnecessary waste of product which increases processor costs and thus patient costs.

- Title 18. Professional and Occupational Licensing: Dispensing of Cannabidiol Oil or Thc-A Oil.
- 18VAC110-60-310(A)(1): VCPRL
- Request: Allow non-licensed personnel to access the VCPRL to allow access to the processor.
- Rationale: VCPRL does not contain patient protected data. Allow an employee, such as a receptionist in the lobby, to simply perform a patient look-up to determine that the person can access the building.

- Title 18. Professional and Occupational Licensing: Dispensing of Cannabidiol Oil or Thc-A Oil.
- 18VAC110-60-310(C): Patient Labels
- Request: Remove requirements for duplicative information between the product label and patient label (same request as product label).
- Rationale: Each product will have both product label (manufacturer's label) and patient label. So long as the information is included on the product label, such information should not be required to also be on the patient label. The information required on both labels is duplicative when taken together and will cause processors to utilize font that will be too small for patients to read. See the attached label examples.

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

§54.1-3442.6 ( C )

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities. 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 dispensing and delivering in person cannabis oil to a registered patient, his registered agent, 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) dosage limitations, which shall provide that each dispensed dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the transfer of cannabis oil products between pharmaceutical processors and between a pharmaceutical processor and a cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed products; (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification; and (xiii) a process for acquiring oil from industrial hemp extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis oil; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) the secure disposal of plant remains; and (d) a process for registering cannabis oil products.

Signature: **Katie Hellebush, Executive Director, Virginia Medical Cannabis Coalition**

Date: 7.15.20

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**Agency** Department of Health Professions

**Board** Board of Pharmacy

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

2 comments

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**Commenter:** Cynthia Hites

8/9/20 2:47 am

**I fully support this petition**

Everything in this petition is right on. I fully, wholeheartedly agree and support every single point encompassed in this document. START LISTENING TO INDIVIDUALS who actually know and understand the complexities and real-life scenerios.

VOTE YES AND SUPPORT THIS PETITION. Your salaries are paid by myself and other constituents.

Vote in favor of this petition, or I'll see for your mini-swamp is drained.

POWER TO THE PEOPLE

CommentID: 84205

**Commenter:** Todd Gathje, Ph.D., The Family Foundation

8/25/20 5:57 pm

**Don't Allow Minors Into Cannabis Dispensaries**

I am Todd Gathje, Director of Government Relations for The Family Foundation, and I'm writing to express opposition to the proposed petition to change 18VAC110-60-220(F,G) regarding the visitors policy to allow minor children to accompany their parent into the dispensing area.

The reasons for not allowing minors into a cannabis dispensary are well documented. For example, children could find and ingest edible products, including any left inadvertently by a dispensary customer or employee. It also contributes to desensitizing more teenagers to cannabis products and leads to increases in marijuana use. Allowing minors into these facilities will only lead to more unhealthy and irresponsible exploratory behavior.

It is insightful that 18VAC110-60-210 provides that states: "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."

Clearly, the fact that cannabidiol oil and other products must be in a container that a child cannot open implies the potential harm this can cause if ingested by a minor. We should maintain a separation of these products from children in all the policies regulating them.

We strongly urge the Board to reject this petition given the potential harm this could have on impressionable and curious children.

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

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 or the registered agent; and
8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; 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. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has 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 pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

H. 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.

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

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

K. 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 unless such license or registration has been reinstated and is current and unrestricted.

**18VAC110-60-220. Pharmaceutical processor prohibitions.**

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or 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, except for the wholesale distribution of cannabidiol oil or THC-A oil products between pharmaceutical processors;
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 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;
5. Product information and pricing; and
6. 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, or a registered agent 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 an authorized 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 that shall include the date, time, and purpose of the visit and that shall be available to the board.
4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor 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 or a registered agent or an agent of the processor may deliver cannabidiol oil or THC-A oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or 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, that 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, that 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; the registered patient, parent, or legal guardian or the registered agent 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. The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, or legal guardian or the registered agent to whom the cannabidiol oil or THC-A oil was sold; the kind and quantity of cannabidiol oil or THC-A oil sold or disposed of; and the method of disposal.



D. 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.

E. 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.

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

G. 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.

**18VAC110-60-290. Labeling of batch of cannabidiol oil or THC-A oil products.**

A. Cannabidiol oil or THC-A oil produced as a batch shall not be adulterated.

B. Cannabidiol oil or THC-A oil produced as a batch shall be:

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

2. Labeled with:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285;

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

d. The date of testing and packaging;

e. The expiration date based on stability testing;

f. The quantity of cannabidiol oil or THC-A oil contained in the batch;

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

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD); and

(4) Cannabidiolic acid (CBDA); and

h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis.

**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 (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

B. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

C. From the time that a batch of cannabidiol oil or THC-A oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor sell a cannabidiol oil or THC-A oil product ] prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any cannabidiol oil or THC-A oil products and materials upon the completion of any testing, use, or research.

F. If a sample of cannabidiol oil or THC-A oil product 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 sample of cannabidiol oil or THC-A oil product 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 G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabidiol oil or THC-A oil product 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.

5. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:

- a. Tetrahydrocannabinol (THC);
- b. Tetrahydrocannabinol acid (THC-A);

- c. Cannabidiols (CBD); and
- d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopoeia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

G. If a sample of cannabidiol oil or THC-A oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

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, residual solvents, 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 or registered agents 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 or to a registered agent for a specific patient.

1. 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, legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three 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, legal guardian, or registered agent 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 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian or registered agent shall receive more than a 90-day supply of cannabidiol oil or THC-A oil for a patient in a 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 that contains:

1. A serial number assigned to the dispensing of the oil;
2. The brand name of cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-60-285 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;
6. A terpenes profile and a list of all active ingredients, including:
  - a. Tetrahydrocannabinol (THC);
  - b. Tetrahydrocannabinol acid (THC-A);
  - c. Cannabidiol (CBD); and
  - d. Cannabidiolic acid (CBDA);
7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;
8. The name and registration number of the registered patient;
9. The name and registration number of the certifying practitioner;
10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. The name or initials of the dispensing pharmacist;
12. Name, address, and telephone number of the pharmaceutical processor;
13. Any necessary cautionary statement; and
14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. 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.

E. The 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).

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

G. 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.

H. 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 diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. 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 or registered agent if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian or registered agent may have negative health or safety consequences for the registered patient or the public.

## Frequently Asked Questions regarding Pesticides and the Assigning of Expiration Dates for Cannabis Oil Products

**Q: Under what conditions may a pharmaceutical processor use pesticides during the cultivation, extraction, production, or manufacturing process of cannabis oil?**

**A:** Per Regulation 18VAC110-60-280, a pharmaceutical processor may only use pesticides for the purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

When a pesticide is used, the pharmaceutical processor should immediately notify the board office and maintain a record on its premises of the following information:

- a. The name, signature and applicator certification number, issued by the Virginia Department of Agriculture and Consumer Services; if applicable, of the individual who applied the pesticide;
- b. The date and time of the application;
- c. The U.S. Environmental Protection Agency (EPA) registration number or, if exempt from EPA's registration process under Section 25(b) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Chemical Abstract Service (CAS) number of the pesticide applied;
- d. Active ingredients of the pesticide applied;
- e. Brand name and product name of the pesticide applied;
- f. The restricted entry interval from the product label of any pesticide applied;
- g. The radio-frequency identification (RFID) tag number of the cannabis plant(s) that the pesticide was applied to or if applied to all plants throughout the pharmaceutical processor, a statement to that effect and principle pests to be controlled; and
- h. The amount of pesticide concentrate and amount of diluent, by weight or volume, in mixture applied.

The pharmaceutical processor should have the original label for all pesticide used to address an infestation that could result in catastrophic loss.

**Q: What pesticides does the board authorize a pharmaceutical processor to use to address an infestation that could result in a catastrophic loss of Cannabis crops?**

**A:** The Board authorizes pharmaceutical processors to use a pesticide, to address an infestation that could result in a catastrophic loss of Cannabis crops, which satisfies the following criteria:

- It is listed on the Oregon [“Guide List for Pesticides and Cannabis”](#) and is used consistent with any directions or indications as found on this document; and,
- The pesticide is registered with the Virginia Department of Agriculture and Consumer Services. Search Virginia registered pesticides [here](#).

The pharmaceutical processor is responsible for determining which pesticides can be used on its crops in accordance with the above criteria and assumes all risk associated with the use, including possible crop loss. This information is not an endorsement of any product and shall not be considered a guaranty of efficacy or without risk of harm to the crop on which it is applied.

**Q: What criteria will the Board use to determine compliance with the pesticide chemical residue testing requirements for pharmaceutical processors?**

**A:** Per 18VAC110-60-300, for purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide 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. Pesticide chemical residue testing shall include, but not be limited to, testing for carbamates, organochlorines, and organophosphates.

**Q: What criteria will the Board use to determine compliance with assigning an expiration date for cannabis oil products?**

**A:** Per Regulation 18VAC110-60-300, a pharmaceutical processor shall assign an expiration date to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

A pharmaceutical processor may assign an expiration date not to exceed 6-months from the date of production. The expiration date may be extended if validated stability testing supports such extension.



**Agenda Item: Adoption of Protocols – Pharmacists initiating treatment**

**Included in your agenda package are:**

Copy of the summary of legislation passed in the 2020 General Assembly

Amendment to Code in HB1506

Copy of the Statewide Protocols as recommended by the Workgroup (see minutes from the Workgroup meetings on August 4, 2020 and August 17, 2020 in agenda package)

**Board action:**

Adoption of Protocols (Board should review all protocols and adopt in a block unless there are amendments to one or more of the protocols).

# HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Introduced by: Mark D. Sickles | all patrons ... notes | add to my profiles

## SUMMARY AS PASSED: (all summaries)

**Pharmacists; prescribing, dispensing, and administration of controlled substances.** Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, to promulgate emergency regulations to implement the provisions of the bill, and to convene a work group to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

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

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

- 1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;*
- 2. Epinephrine;*
- 3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;*
- 4. Prenatal vitamins for which a prescription is required;*
- 5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and*
- 6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.*

*B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient*

*consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.*

**2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.**

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, *Helicobacter pylori* bacteria, urinary tract infection, and group A *Streptococcus* bacteria; (v) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Naloxone Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

### PATIENT INCLUSION CRITERIA

Patients eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

### PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age or older;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law. Refer patient to primary care provider to determine if naloxone appropriate.

### COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and ~~he or she shall~~ counsel the patient or the patient's agent on how

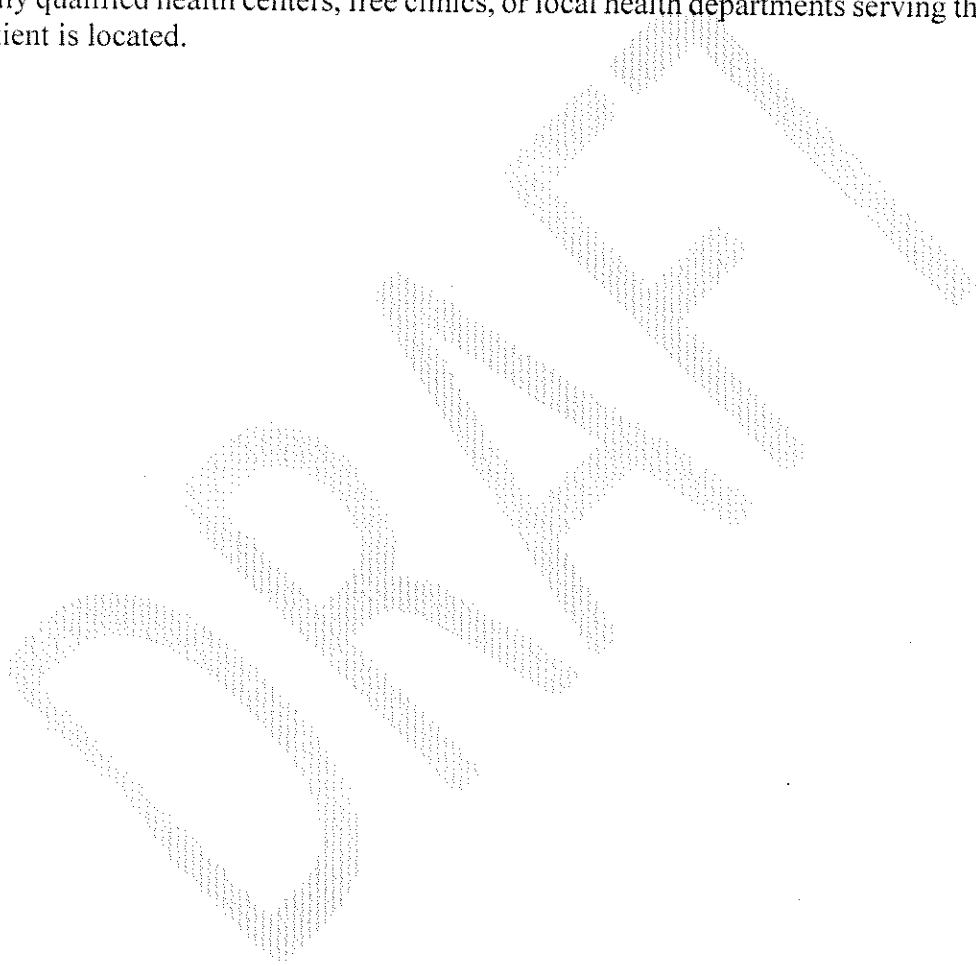
to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

**RECORDKEEPING**

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

**NOTIFICATION OF PRIMARY CARE PROVIDER**

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.



# VIRGINIA BOARD OF PHARMACY

## Pharmacist Epinephrine Statewide Protocol

Consistent with the epinephrine manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Epinephrine auto-injector; or,
- Injectable epinephrine, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such epinephrine.

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognition and management of anaphylaxis.

### PATIENT INCLUSION CRITERIA

Patients eligible for epinephrine under this protocol:

- Any person, 18 years of age or older, demonstrating signs and symptoms of anaphylaxis or at risk for experiencing anaphylaxis, e.g., patients reporting having previously been prescribed epinephrine for treatment of possible anaphylaxis or reporting a diagnosis of allergies that may result in anaphylaxis.

### COUNSELING

The pharmacist shall counsel the patient or the patient's agent on how to properly recognize and manage anaphylaxis, including proper administration of the epinephrine.

### RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

### NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Hormonal Contraceptive Statewide Protocol (Excluding Emergency Contraception)

Consistent with the hormonal contraceptive manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

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

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering injectable or self-administered hormonal contraceptive under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited educational training program related to the prescribing of contraceptives by a pharmacist.

### PATIENT INCLUSION CRITERIA

Patients eligible for injectable or self-administered hormonal contraceptives approved by the FDA under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire\** and who the pharmacist has determined is eligible for a hormonal contraceptive, consistent with the most cost version of the Centers for Disease Control and Prevention *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use*, i.e., the prescribed drug is assessed at a "1" or "2" for all conditions applicable to the patient.

\*Note: A pharmacy may create and use an electronic routine hormonal contraceptive self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

### PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

1. Obtain from each new patient and, at a minimum of every twelve months for each returning patient, a completed *Virginia Self-Screening Risk Assessment Questionnaire*; and,
2. Utilize and follow the *Virginia Standard Procedures Algorithm for Prescribing Contraceptives* to perform the patient assessment.

### PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for a hormonal contraceptive as indicated by the *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* and the *Virginia Standard Procedures Algorithm for Prescribing Contraceptives* shall be referred to a healthcare

practitioner and may not receive a hormonal contraceptive under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

### **FURTHER CONDITIONS**

1. For each new patient requesting a contraceptive service a participating pharmacist must provide the patient with a visit summary.
2. A pharmacist shall not:
  - a. Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit. Such evidence may be obtained by the response on the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire* regarding the date of the patient's last women's health clinical visit.
  - b. Prescribe in instances that the Virginia Standard Procedures Algorithm requires referral to a provider.

### **DRUG INCLUSION CRITERIA**

The following drug formulations approved by the FDA to prevent pregnancy are included in this statewide protocol:

- injectable depot medroxyprogesterone acetate;
- transdermal patches;
- vaginal rings; and,
- contraceptives intended to be taken orally.

### **RECORDKEEPING**

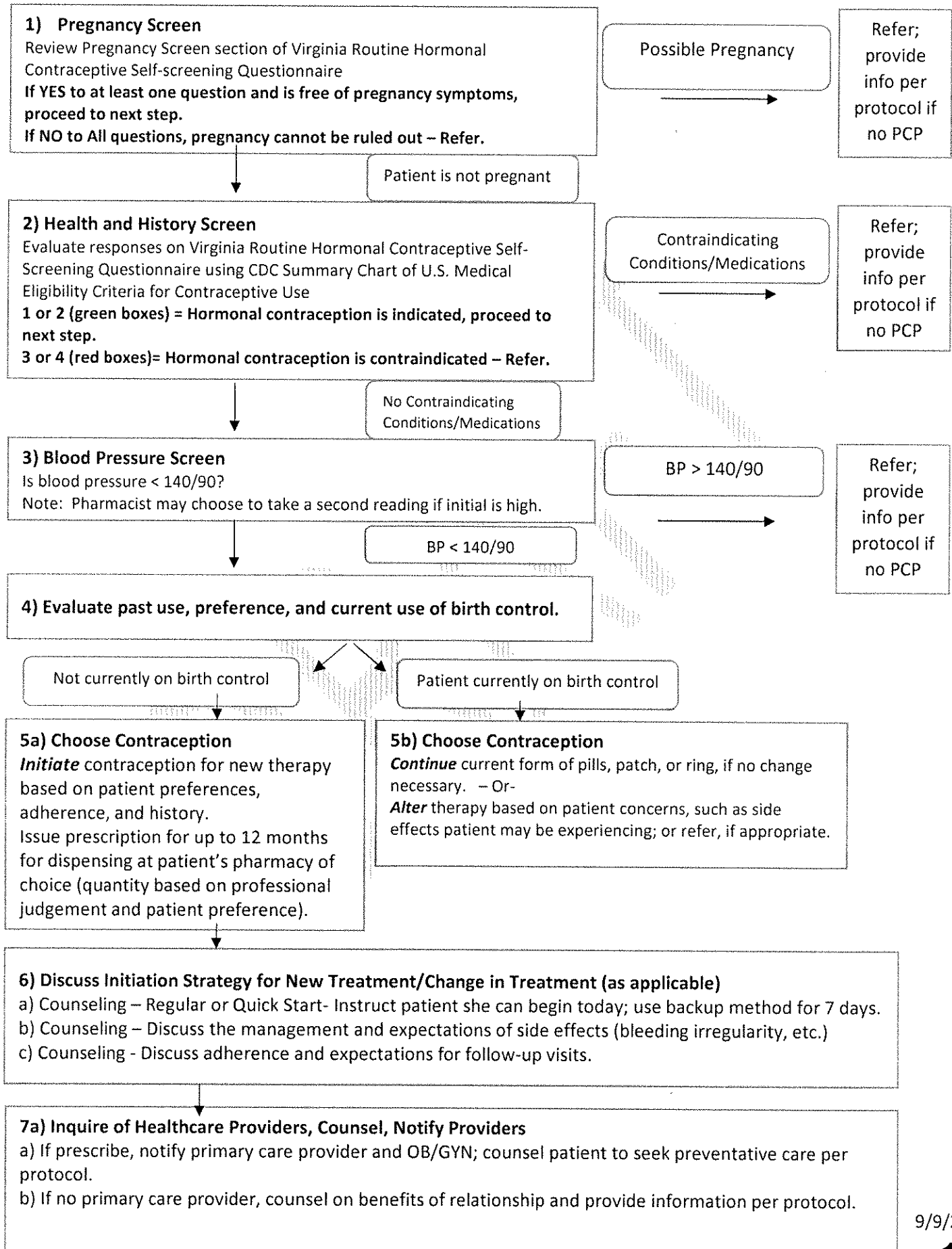
The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

### **NOTIFICATION OF PRIMARY CARE PROVIDER; COUNSELING**

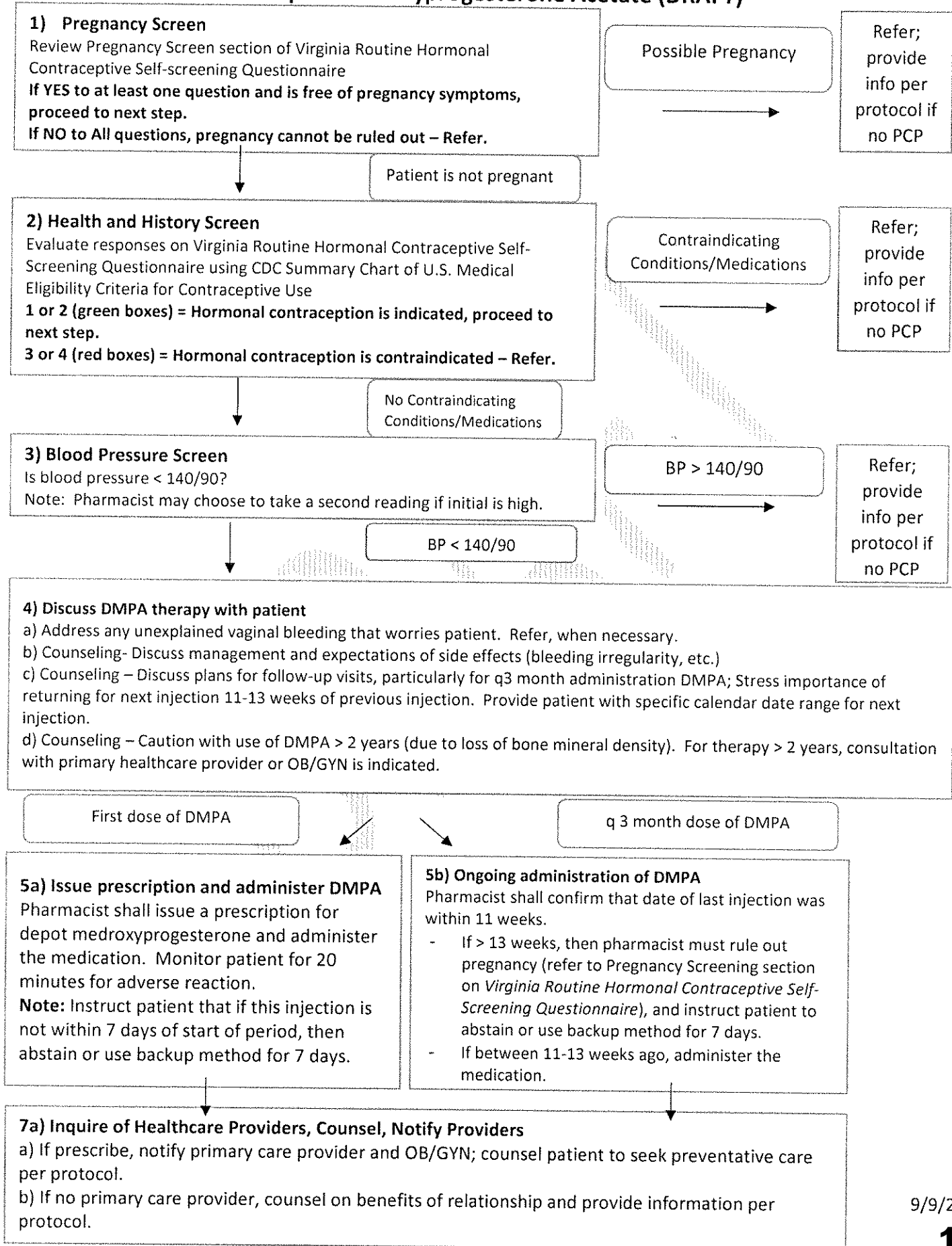
1. If the pharmacist initiates treatment with or dispenses or administers a hormonal contraceptive, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider or obstetrician/gynecologist (OB/GYN), the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,
2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.



# Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives (DRAFT)



## Virginia Algorithm for Pharmacists to Prescribe & Administer Depot Medroxyprogesterone Acetate (DRAFT)



# VIRGINIA ROUTINE HORMONAL CONTRACEPTIVE SELF-SCREENING QUESTIONNAIRE (DRAFT)

Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_ Weight: \_\_\_\_\_

Date of Birth: \_\_\_\_\_ Age: \_\_\_\_\_ Healthcare Provider's Name: \_\_\_\_\_

Healthcare Provider's Telephone, Fax, or Email: \_\_\_\_\_

What was the date of your last women's health clinical visit? \_\_\_\_\_

Any Allergies to Medications? *Yes / No* If yes, list them here: \_\_\_\_\_

**Pregnancy Screen:**

1.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, <i>AND</i> have you had no menstrual period since the delivery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
2.	Have you had a baby in the last 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3.	Did you have a miscarriage or abortion in the last 7 days?	____/____/____	
4.	Did your last menstrual period start within the past 7 days?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6.	Have you been using a reliable contraceptive method consistently and correctly?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

***If you answered NO to ALL of the questions above, you may stop here and consult with the pharmacist. If you answered YES to at least one of the questions above, please proceed with completing this form.***

**Additional Information:**

7.	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8.	Have you used emergency contraception within the last 5 days?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9.	What was the first day of your last menstrual period?	____/____/____	
10.	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11.	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12.	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13.	- If yes, what kind of reaction occurred?		
14.	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15.	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16.	- If yes, which one do you use? (List here)		
17.	Do you have a preferred method of birth control that you would like to use? (check box)		
	<input type="checkbox"/> A pill that you take daily <input type="checkbox"/> A patch that you change weekly <input type="checkbox"/> A vaginal ring that you change monthly		
	<input type="checkbox"/> An injection that you receive every 3 months		

**Medical History**

**Smoking:**

18.	Do you smoke cigarettes or vape nicotine?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19.	-If yes, number or equivalent number of cigarettes per day either smoked or vaped.	____ /day	

**Postpartum (nonbreastfeeding women)/Breastfeeding:**

20.	Have you given birth within 21 days? If yes, how long ago?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
21.	Are you currently breastfeeding?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

**Diabetes:**

22.	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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**Headaches:**

23.	Do you get migraine headaches?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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24.	- If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Hypertension, History of high blood pressure during pregnancy:</b>			
25.	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Deep venous thrombosis (DVT)/Pulmonary embolism (PE), Ischemic heart disease, Known thrombogenic mutations, Multiple risk factors for atherosclerotic cardiovascular disease, Peripartum cardiomyopathy, Stroke, Valvular heart disease:</b>			
26.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
27.	Have you ever had a blood clot?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
28.	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
29.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>History of bariatric surgery:</b>			
30.	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Breast disease:</b>			
31.	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Cirrhosis, Gallbladder disease, History of cholestasis, Liver tumors, Viral hepatitis:</b>			
32.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Rheumatoid arthritis, Systemic lupus erythematosus:</b>			
33.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
<b>Epilepsy, HIV, Tuberculosis, Drug Interactions (Antiretrovirals, Anticonvulsant, Antimicrobial therapy):</b>			
34.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
35.	- If yes, list them here:		
<b>Other information:</b>			
36.	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
37.	- If yes, list them here:		
38.	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>

**Internal use only**

Verified DOB with valid photo ID      BP Reading \_\_\_\_\_/\_\_\_\_\_

Drug Prescribed: \_\_\_\_\_  
 Sig: \_\_\_\_\_  
 Pharmacist Name: \_\_\_\_\_  
 Pharmacy Name and Address: \_\_\_\_\_  
 Pharmacy Phone: \_\_\_\_\_

Patient Referred

Reason(s): \_\_\_\_\_

Notes: \_\_\_\_\_

# Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



Condition	Sub-Condition	Cu-IUD			LNG-IUD			Implant			DMPA			POP			CHC		
		I	C	I	I	C	I	I	C	I	I	C	I	I	C	I	I	C	I
Age		Menarche to <20 yrs: 2			Menarche to <20 yrs: 2			Menarche to <18 yrs: 1			Menarche to <18 yrs: 2			Menarche to <18 yrs: 1			Menarche to <40 yrs: 1		
		≥20 yrs: 1			≥20 yrs: 1			18-45 yrs: 1			18-45 yrs: 2			18-45 yrs: 1			≥40 yrs: 2		
Anatomical abnormalities	a) Distorted uterine cavity	4	4	4	4	4	4												
	b) Other abnormalities	2	2	2	2	2	2												
Anemias	a) Thalassemia	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Sickle cell disease†	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Benign ovarian tumors	c) Iron-deficiency anemia (including cysts)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Breast disease	a) Undiagnosed mass	1	2	2*	1	2	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	b) Benign breast disease	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	c) Family history of cancer	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	d) Breast cancer†																		
	i) Current	1	4	4	1	4	4	4	4	4	4	4	4	4	4	4	4	4	4
	ii) Past and no evidence of current disease for 5 years	1	3	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Breastfeeding	a) <21 days postpartum							2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	b) 21 to <30 days postpartum							2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	i) With other risk factors for VTE							1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	ii) Without other risk factors for VTE							1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	c) 30-42 days postpartum																		
	i) With other risk factors for VTE							1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	ii) Without other risk factors for VTE							1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	d) >42 days postpartum	4	2	2	4	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Cervical cancer	Awaiting treatment	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Cervical ectropion		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Cervical intraepithelial neoplasia		1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Cirrhosis	a) Mild (compensated)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Severe† (decompensated)	1	3	3	1	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Cystic fibrosis†		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Deep venous thrombosis (DVT)/pulmonary embolism (PE)	a) History of DVT/PE, not receiving anticoagulant therapy																		
	i) Higher risk for recurrent DVT/PE	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	ii) Lower risk for recurrent DVT/PE	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	b) Acute DVT/PE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	c) DVT/PE and established anticoagulant therapy for at least 3 months																		
	i) Higher risk for recurrent DVT/PE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	ii) Lower risk for recurrent DVT/PE	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	d) Family history (first-degree relatives)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	e) Major surgery																		
	i) With prolonged immobilization	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	ii) Without prolonged immobilization	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	f) Minor surgery without immobilization	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Depressive disorders		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**Key:**  
**1** No restriction (method can be used)  
**2** Advantages generally outweigh theoretical or proven risks  
**3** Theoretical or proven risks usually outweigh the advantages  
**4** Unacceptable health risk (method not to be used)

Condition	Sub-Condition	Cu-IUD			LNG-IUD			Implant			DMPA			POP			CHC		
		I	C	I	I	C	I	I	C	I	I	C	I	I	C	I	I	C	I
Diabetes	a) History of gestational disease	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Nonvascular disease																		
	i) Non-insulin dependent	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	ii) Insulin dependent	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	c) Nephropathy/retinopathy/neuropathy†	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	d) Other vascular disease or diabetes of >20 years' duration†	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Dysmenorrhea	Severe	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Endometrial cancer†		4	2	2	4	2	2	1	1	1	1	1	1	1	1	1	1	1	1
Endometrial hyperplasia		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Endometriosis		2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Epilepsy†	(see also Drug Interactions)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Gallbladder disease	a) Symptomatic																		
	i) Treated by cholecystectomy	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	ii) Medically treated	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	iii) Current	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	b) Asymptomatic	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
Gestational trophoblastic disease†	a) Suspected GTD (immediate postevacuation)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	i) Uterine size first trimester	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	ii) Uterine size second trimester	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	b) Confirmed GTD																		
	i) Undetectable/non-pregnant β-hCG levels	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	ii) Decreasing β-hCG levels	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	iii) Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	iv) Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4	2	2	4	2	2	1	1	1	1	1	1	1	1	1	1	1	1
Headaches	a) Nonmigraine (mild or severe)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Migraine																		
	i) Without aura (includes menstrual migraine)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	ii) With aura	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
History of bariatric surgery†	a) Restrictive procedures	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Malabsorptive procedures	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
History of cholestasis	a) Pregnancy related	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Past COC related	1	2	2	1	2	2	2	2	2	2	2	2	2	2	2	2	2	2
History of high blood pressure during pregnancy		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
History of Pelvic surgery		1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
HIV	a) High risk for HIV	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) HIV infection																		
	i) Clinically well receiving ARV therapy	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	ii) Not clinically well or not receiving ARV therapy†	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1

**Abbreviations:** ARV = antiretroviral; C=continuation of contraceptive method; CHC=combined hormonal contraceptive (pill, patch, and ring); COC=combined oral contraceptive; Cu-IUD=copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; I=initiation of contraceptive method; LNG-IUD=levonorgestrel-releasing intrauterine device; NA=not applicable; POP=progestin-only pill; P/R=patch/ring; SSR=selective serotonin reuptake inhibitor; † Condition that exposes a woman to increased risk as a result of pregnancy. \*Please see the complete guidance for a clarification to this classification. [https://www.cdc.gov/epp/products/etwhealth/contraception/contraception\\_guidance.html](https://www.cdc.gov/epp/products/etwhealth/contraception/contraception_guidance.html).

# Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use



Condition	Sub-Condition	Cu-IUD			LNG-IUD			Implant			DMPA			POP			CHC		
		I	C	I	I	C	I	I	C	I	I	C	I	I	C	I	I	C	I
Hypertension	a) Adequately controlled hypertension	1*	1*	1*	1*	1*	1*	1*	1*	1*	2*	2*	2*	1*	1*	1*	3*	3*	3*
	b) Elevated blood pressure levels (properly taken measurements)																		
	i) Systolic 140-159 or diastolic 90-99	1*	1*	1*	1*	1*	1*	1*	1*	1*	2*	2*	2*	1*	1*	1*	3*	3*	3*
Inflammatory bowel disease	ii) Systolic ≥160 or diastolic ≥100†	1*	1*	1*	1*	1*	1*	1*	1*	1*	3*	3*	3*	2*	2*	2*	4*	4*	4*
	c) Vascular disease	1*	1*	1*	1*	1*	1*	1*	1*	1*	3*	3*	3*	2*	2*	2*	4*	4*	4*
	(Ulcerative colitis, Crohn's disease)	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2/3*	2/3*	2/3*
Ischemic heart disease†	Current and history of	1	1	1	1	1	1	1	1	1	3	3	3	2	2	2	3	3	3
	Known thrombogenic mutations†	1*	1*	1*	1*	1*	1*	1*	1*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	Liver tumors																		
Malaria	a) Benign																		
	i) Focal nodular hyperplasia	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	ii) Hepatocellular adenoma†	1	1	1	1	1	1	1	1	1	3	3	3	3	3	3	4	4	4
Multiple risk factors for atherosclerotic cardiovascular disease	b) Malignant† (hepatoma)	1	1	1	1	1	1	1	1	1	3	3	3	3	3	3	4	4	4
	(e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	3	3	3
	Multiple sclerosis	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2
Obesity	a) With prolonged immobility	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	b) Without prolonged immobility	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	a) Body mass index (BMI) ≥30 kg/m²	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Ovarian cancer†	b) Menarche to <18 years and BMI ≥30 kg/m²	1	1	1	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2
	a) Nulliparous	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Parous	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Past ectopic pregnancy	a) Past	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	i) With subsequent pregnancy	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	ii) Without subsequent pregnancy	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1
Pelvic inflammatory disease	b) Current	4	4	4	4	4	4	4	4	4	2	2	2	2	2	2	1	1	1
	a) Normal or mildly impaired cardiac function																		
	i) <6 months	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	4	4	4
Peripartum cardiomyopathy†	ii) ≥6 months	2	2	2	2	2	2	2	2	2	1	1	1	1	1	1	3	3	3
	b) Moderately or severely impaired cardiac function	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	4	4	4
	a) First trimester	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
Postabortion	b) Second trimester	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	c) Immediate postseptic abortion	4	4	4	4	4	4	4	4	4	1	1	1	1	1	1	1*	1*	1*
	a) <21 days																		
Postpartum (nonbreastfeeding women)	b) 21 days to 42 days																		
	i) With other risk factors for VTE																		
	ii) Without other risk factors for VTE																		
Postpartum (in breastfeeding or non-breastfeeding women, including cesarean delivery)	c) >42 days																		
	a) <10 minutes after delivery of the placenta	1*	1*	1*	1*	1*	1*	1*	1*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	i) Breastfeeding																		
St. John's wort	ii) Nonbreastfeeding	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	b) 10 minutes after delivery of the placenta to <4 weeks	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	c) ≥4 weeks	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	d) Postpartum sepsis	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4

Condition	Sub-Condition	Cu-IUD			LNG-IUD			Implant			DMPA			POP			CHC		
		I	C	I	I	C	I	I	C	I	I	C	I	I	C	I	I	C	I
Pregnancy	a) On immunosuppressive therapy	4*	4*	4*	4*	4*	4*	4*	4*	4*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*	NA*
	Rheumatoid arthritis	2	1	2	1	2	1	1	1	1	2/3*	2/3*	2/3*	1	1	1	2	2	2
	b) Not on immunosuppressive therapy	1	1	1	1	1	1	1	1	1	2	2	2	1	1	1	2	2	2
Schistosomiasis	a) Uncomplicated	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Fibrosis of the liver†	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2*	4	2*	4	2*	1	1	1	1	1	1	1	1	1	1	1	1
Sexually transmitted diseases (STDs)	b) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	c) Other factors relating to STDs	2*	2*	2*	2*	2*	2*	1	1	1	1	1	1	1	1	1	1	1	1
	a) Age <35	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Smoking	b) Age ≥35, <15 cigarettes/day	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	c) Age ≥35, ≥15 cigarettes/day	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Complicated	3	2	3	2	3	2	2	2	2	2	2	2	2	2	2	2	2	2
Solid organ transplantation†	b) Uncomplicated	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2
	a) History of cerebrovascular accident	1	1	1	1	1	1	1	1	1	3	3	3	2	2	2	4	4	4
	a) Varicose veins	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Superficial venous disorders	b) Superficial venous thrombosis (acute or history)	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Positive (or unknown) antiphospholipid antibodies	1*	1*	3*	1*	3*	3*	3*	3*	3*	3*	3*	3*	3*	3*	3*	4*	4*	4*
	b) Severe thrombocytopenia	3*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
Systemic lupus erythematosus†	c) Immunosuppressive therapy	2*	1*	2*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	d) None of the above	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	Simple goiter/ hyperthyroid/hypothyroid	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Thyroid disorders	a) Nonpelvic	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Pelvic	4	3	4	3	4	3	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*	1*
	Unexplained vaginal bleeding	4*	2*	4*	2*	4*	2*	3*	3*	3*	3*	3*	3*	2*	2*	2*	2*	2*	2*
Uterine fibroids	a) Uncomplicated	2	2	2	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1
	b) Complicated†	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Irregular pattern without heavy bleeding	1	1	1	1	1	1	2	2	2	2	2	2	2	2	2	2	2	2
Valvular heart disease	b) Heavy or prolonged bleeding	2*	1*	2*	1*	2*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	a) Acute or flare	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Carrier/Chronic	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Vaginal bleeding patterns	a) Uncomplicated	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Complicated†	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Irregular pattern without heavy bleeding	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Viral hepatitis	b) Heavy or prolonged bleeding	2*	1*	2*	1*	2*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*	2*
	a) Acute or flare	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Carrier/Chronic	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
Drug Interactions	Fosamprenavir (FPV)																		
	All other ARVs are 1 or 2 for all methods.	1/2*	1*	1/2*	1*	1/2*	1*	2*	2*	2*	2*	2*	2*	2*	2*	2*	3*	3*	3*
	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	1	1	1	1	1	1	1	1	1	1*	1*	1*	3*	3*	3*	3*	3*	3*
Antimicrobial therapy	b) Lamotrigine	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	a) Broad spectrum antibiotics	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	b) Antifungals	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
SSRIs	c) Antiparasitics	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1
	d) Rifampin or rifabutin therapy	1	1	1	1	1	1	1	1	1	1*	1*	1*	3*	3*	3*	3*	3*	3*
	St. John's wort	1																	

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Emergency Contraception Statewide Protocol

A pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Self-administered hormonal emergency contraception (EC) provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, or dispensing of a self-administered hormonal EC under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or standard protocol and shall have completed at least one hour of continuing education specific to the prescribing of EC.

### PATIENT INCLUSION CRITERIA

Patients eligible for self-administered hormonal EC under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Emergency Contraception Self-Screening Questionnaire* indicating the last day of unprotected intercourse was within the previous 5 days (120 hours) and who the pharmacist has determined is eligible for a hormonal emergency contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *US Medical Eligibility Criteria for Contraceptive Use, Classifications for Emergency Contraception*.

### PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for EC shall be referred to a healthcare practitioner and may not receive EC under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

### DRUG INCLUSION CRITERIA

The following drug formulations are included in this EC statewide protocol:

#### Dedicated Approved EC – One Tablet Regimens

Plan B One-Step	1 tablet	1.5mg levonorgestrel	OTC
Levonorgestrel	1 tablet	1.5mg levonorgestrel	OTC
Next Choice One Dose	1 tablet	1.5mg levonorgestrel	OTC
Ella	1 tablet	30mg ulipristal	Rx only

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed.

## Oral Contraceptive Pills

Brand	Tablets per dose (2 doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*	Status
Alesse	5 pink tablets	100	0.50	Rx only
Aviane	5 orange tablets	100	0.5	Rx only
Levlen	4 light-orange tablets	120	0.6	Rx only
Levlite	5 pink tablets	100	0.5	Rx only
Levora	4 white tablets	120	0.60	Rx only
Lo/Ovral	4 white tablets	120	0.60	Rx only
Low-Ogestrel	4 white tablets	120	0.60	Rx only
Nordette	4 light-orange tablets	120	0.60	Rx only
Ogestrel	2 white tablets	100	0.50	Rx only
Ovral	2 white tablets	100	0.50	Rx only
Tri-Levlen	4 yellow tablets	100	0.50	Rx only
Triphasil	4 yellow tablets	120	0.50	Rx only
Trivora	4 pink tablets	120	0.50	Rx only
Ovrette	20 yellow tablets	0	0.75	Rx only

\*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrol, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrol in each dose is twice the amount of levonorgestrel.

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed. Estrogen containing regimens are not preferred and should be used only when other options are not available.

### Anti-nausea Treatment Options for use with EC

Drug	Dose	Timing of Administration	Status
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours	OTC
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours	OTC



## **ADDITIONAL PRESCRIBING AND DISPENSING CONSIDERATIONS**

- For women who weigh more than 165 lbs, levonorgestrel may be less effective than ulipristal acetate.\*
- Levonorgestrel may be preferable for women who need EC due to missed or late pills, patch, or ring.\*
- Starting hormonal birth control immediately after taking ulipristal acetate may make it ineffective.\*
- For women with prescription insurance coverage, OTC drugs may be covered by the health carrier when prescribed for the patient.\*
- Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse.
- Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.

## **RECORDKEEPING**

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

## **NOTIFICATION OF PRIMARY CARE PROVIDER AND COUNSELING**

1. If the pharmacist initiates treatment with or dispenses or administers a self-administered hormonal EC, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,
2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

\*Per the American Society for Emergency Contraception.

# Virginia Emergency Contraception Self-Screening Questionnaire

Timing is an essential element of the effectiveness of emergency contraception (EC). EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) after unprotected intercourse.

Patient's Name \_\_\_\_\_ Date \_\_\_\_\_

Healthcare Provider's Name \_\_\_\_\_

Healthcare Provider's Telephone or Email address \_\_\_\_\_

Date of Birth \_\_\_\_\_ Age \_\_\_\_\_ Weight \_\_\_\_\_

What was the date of your last women's health clinical visit? \_\_\_\_\_

Any allergies to medications? \_\_\_\_\_

Number of hours/days since last unprotected intercourse \_\_\_\_\_

### *Internal use only*

Verified DOB with valid photo ID BP Reading \_\_\_\_\_ / \_\_\_\_\_

Drug Prescribed: \_\_\_\_\_

Sig: \_\_\_\_\_

Pharmacist's Name: \_\_\_\_\_

Pharmacy's Name and Address: \_\_\_\_\_

Pharmacy's Phone: \_\_\_\_\_

Patient Referred

Reason(s): \_\_\_\_\_

Notes: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Prenatal Vitamin Statewide Protocol

Consistent with the prenatal vitamin manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Prenatal vitamins for which a prescription is required.

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering prenatal vitamins under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and evidence-based guidelines.

### PATIENT INCLUSION CRITERIA

Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, who is considering pregnancy, attempting to become pregnant, or pregnant.

### RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

### NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Dietary Fluoride Supplement Statewide Protocol

The American Dental Association does not recommend the prescribing of dietary fluoride supplements for persons 18 years of age or older whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services, therefore pharmacists are not currently authorized to initiate treatment with, dispense, or administer dietary fluoride supplements under a pharmacist statewide protocol.



# VIRGINIA BOARD OF PHARMACY

## Pharmacist Statewide Protocol to Lower Out-of-Pocket Expense

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

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

### PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering medications under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

### PATIENT INCLUSION CRITERIA

Patients eligible for medications under this protocol:

- An individual, 18 years of age or older, whose over-the-counter medication is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed drug is lower than the out-of-pocket cost to purchase the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter medication would cost more out-of-pocket than a prescribed prescription-only medication that is a therapeutically equivalent drug product<sup>1</sup>, as defined in § 54.1-3401, as the over-the-counter medication.

### RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

### NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Drug Control Act, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

<sup>1</sup>"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.", § 54.1-3401.

**Agenda Item: Adoption of Recommendations from Drug Disposal Workgroup**

**Included in your agenda package:**

Copy of HB 1531 passed during the 2020 General Assembly Session

Refer to July 21, 2020 Drug Disposal Workgroup minutes (included in the minutes portion of agenda package)

**Board action:**

Consider and adopt recommendations offered by the Drug Disposal Workgroup, as presented or amended.

## 2020 SESSION

**VIRGINIA ACTS OF ASSEMBLY -- CHAPTER**

*An Act to require the Board of Pharmacy to develop public awareness of proper methods of drug disposal.*

[H 1531]

Approved

Be it enacted by the General Assembly of Virginia:

**1.** § 1. *That the Board of Pharmacy shall determine methods to enhance public awareness of proper drug disposal methods, which may include requirements for pharmacies or hospitals or clinics with an on-site pharmacy to provide such information to customers and the public through the provision of informative pamphlets, the posting of signs in public areas of the pharmacy, and the posting of information on public-facing websites. The Board of Pharmacy shall also assemble a group of stakeholders to develop strategies to increase the number of permissible drug disposal sites and options for the legal disposal of drugs, including pharmacies and hospitals and clinics with an on-site pharmacy that are authorized collectors and other sites legally permitted for drug disposal, and the legal return of unused drugs by mail. Such stakeholders shall include the Virginia Pharmacists Association, the Virginia Association of Free Clinics, the Virginia Hospital and Healthcare Association, the Virginia Society of Health System Pharmacists, the Virginia Association of Drug Stores, and any other relevant stakeholders. Strategies developed by the Board of Pharmacy and stakeholders shall take into account the geographic proximity and availability of drug disposal sites in localities across the Commonwealth and existing resources. The Board shall report its findings and recommendations to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than November 15, 2020.*

**Agenda Item: Amendment to bylaws – delegation of authority**

**Included in your agenda package are:**

A copy of amended bylaws – Guidance document 110-12

*Staff Note: The Board voted on June 16 (see minutes in agenda package) to amend bylaws to add delegation of exception to the requirement for a PIC to have 2 years of experience. The amendment was not provided to the Board in advance of the meeting, so the action has to be taken at the September meeting.*

**Board action:**

To adopt the amendment (#17) in Delegation of Authority in the Bylaws



## **BYLAWS OF THE VIRGINIA BOARD OF PHARMACY**

### **ARTICLE I: GENERAL**

The organizational year for the Board shall be from July 1<sup>st</sup> through June 30<sup>th</sup>. At the last meeting before July 1, the Board shall elect from its members, a chairman and a vice chairman. The term of office shall be one year and shall begin on July 1. A person shall not serve as chairman or vice chairman for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

### **ARTICLE II: OFFICERS OF THE BOARD**

- A. The officers of the Board shall be the chairman and the vice chairman.
- B. The chairman presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The chairman shall appoint all committees unless otherwise ordered by the Board.
- C. The vice chairman shall act as chairman in the absence of the chairman.
- D. In the absence, or inability to serve, of both the chairman and vice chairman, the chairman shall appoint another board member to preside at the meeting and/or formal administrative hearing.
- E. The executive director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

### **ARTICLE III: ORDER OF BUSINESS MEETINGS**

The order of business shall be as follows:

- 1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.
- 2. Approval of Agenda
- 3. Public comment received
- 4. Approval of Minutes
- 5. The remainder of the agenda shall be established by the executive director in consultation with the chairman.

**ARTICLE IV: COMMITTEES**

A. There shall be the following standing committees:

- Special Conference Committees
  - Inspection Special Conference Committee
- Item Review Committee
- Regulation Committee
- Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. A special conference committee may also review information regarding a non-routine applicant for whom there may be cause to deny or restrict and may issue a final Order to grant or deny the application or to issue a license, registration or permit with terms and conditions. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The chairman may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chairman shall appoint committees as needed to expedite the adjudication of cases.
2. Item Review Committee. This committee shall consist of at least six pharmacists, to include one board member and the executive director, holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of approving content to assemble the Virginia Multistate Pharmacy Jurisprudence Examination (MPJE) form(s) which shall be accomplished through writing, reviewing, and selecting items for the VA MPJE item pool.
3. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board’s Public Participation Guidelines and any Executive Order of the Governor, and any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.
4. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and any matters related to such programs.

B. Ad Hoc Committees.

The chairman shall also name such other committees as may be deemed necessary.

C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.

**ARTICLE V: GENERAL DELEGATION OF AUTHORITY**

The Board delegates the following functions:

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.
2. The Board delegates to the executive director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.
3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.
4. The Board delegates to the Department of Health Professions' inspectors the authority to issue summaries of inspection deficiencies upon completion of an inspection, and the Board delegates to the executive director the authority to issue letters regarding reported deficiencies to the facilities or licensee.
5. The Board delegates to the executive director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.
6. The Board delegates to the executive director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.
7. The Board delegates to the executive director, in consultation with the chairman, the review and approval of applications for special or limited use pharmacy permits. If the executive director and chairman do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.
8. The Board delegates to the executive director, in consultation with the chairman, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the executive director and the chairman not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.
9. The Board delegates to the executive director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the chairman. Should the executive director and chairman not reach agreement, the matter shall be referred to a special conference committee.
10. The Board delegates to the chairman, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.
11. The Board delegates the approval of continuing education programs to the executive director in consultation with one member of the Board.
12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with § 54.1-2408.1, to the executive director or deputy executive director. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with § 54.1-2400 (13), to the executive director or deputy executive director. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent

agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the executive director or deputy executive director.

13. The Board delegates to the chairman, or the vice chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with § 54.1-3307.3.
14. The Board delegates to the executive director, in accordance with § 54.1-3434.1(A)(2), the authority to accept an inspection report or other documentation for a non-resident pharmacy from an entity that may not be listed on the Board's guidance document, or to request an inspection by an agent of the Board.
15. The Board delegates to the executive director the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.
16. The Board delegates to the executive director, in consultation with the chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses. A waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.
17. The Board delegates to the executive director, in consultation with the chairman, the ability to approve or deny a request for an exception to the two-year pharmacist eligibility requirement to serve as the pharmacist-in-charge, with the ability for the applicant to request an informal conference if denied.

#### **ARTICLE VI: AMENDMENTS**

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date: July 1, 1997  
Latest revision: September 9, 2020

**Agenda Item: Information for license renewal notification regarding dispensing of naloxone per request from Joint Commission on Health Care**

**Included in your agenda package:**

Copy of request from Joint Commission on Health Care

Draft language for inclusion on pharmacist and pharmacy technician license renewal notifications

**Board action:**

Adopt language for inclusion on pharmacist and pharmacy technician license renewal notifications, as presented or amended.



Joint Commission on Health Care  
Senator George L. Barker, Interim Chair

February 10, 2020

David E. Brown, D.C., Director  
Department of Health Professions  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico, Virginia 23233-1463

Dear Director Brown:

On behalf of the Joint Commission on Health Care, I respectfully request that the Board of Pharmacy include in its next pharmacy profession license renewal communication information about Virginia laws and regulations making naloxone available without a patient-specific prescription.

During the 2019 study "Naloxone Public Access and Storage," JCHC staff documented that some pharmacies still provide members of the public incorrect information on Virginia laws and regulations regarding the dispensing of naloxone. Specifically, in a statewide survey based on a representative sample of over 300 community retail pharmacies, almost one-quarter of respondents (23%) did not accurately indicate that a patient-specific prescription is *not* a requirement for an individual to purchase naloxone. Also significant, only 50 percent of respondents from independent pharmacies provided accurate information on obtaining naloxone without a patient-specific prescription, compared to 87 percent of chain pharmacies. In the upcoming license renewal communication, a clear statement of Virginia laws and regulations regarding pharmacy-based dispensing of naloxone would help ensure that all Board-regulated pharmacists have up-to-date and accurate information that they also can share with pharmacy staff.

Thank you for your consideration of this request. Michele Chesser and Andrew Mitchell are happy to discuss any questions or concerns you or your staff may have. They may be reached at [mchesser@jchc.virginia.gov](mailto:mchesser@jchc.virginia.gov), [amitchell@jchc.virginia.gov](mailto:amitchell@jchc.virginia.gov), and 804-786-5445.

Sincerely,

George L. Barker

## **Information to include regarding Naloxone for pharmacist and technician renewal at end of 2020**

Per a request from the Joint Commission on Health Care, pharmacists and pharmacy technicians are reminded that Virginia Health Commissioner M. Norman Oliver, MD, issued a standing order in March 2020 authorizing pharmacists to dispense naloxone to anyone requesting it. No patient specific prescription is required to dispense naloxone to a person. Based on recent media reports, it appears that not all pharmacists are aware of the standing order despite ongoing educational efforts on this subject. Please assist the Board in communicating this allowance to both peers and the public. Additionally, please ensure all pharmacy staff members, including all cashiers, are aware of this allowance in law. The Board is aware of circumstances wherein pharmacy cashiers have turned away customers requesting naloxone, because they believed a prescription was necessary for obtaining the drug. Pharmacists should review and become familiar with Guidance Document 110-44 – Protocol for Prescribing and Dispensing of Naloxone.

In addition to the statewide standing order, another option for a pharmacist to prescribe and dispense naloxone is the Pharmacist Naloxone Statewide Protocol. The 2020 General Assembly passed a bill to add §54.1-3303.1 to the Drug Control Act to allow a pharmacist to initiate treatment with, dispense, or administer naloxone in addition to certain other drugs and devices to persons 18 years of age or older in accordance with a statewide protocol. This protocol may be found at [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy).

Pharmacist questions regarding the use of the Commissioner's standing order or the prescribing and dispensing under the naloxone statewide protocol should be directed to [pharmbd@dhp.virginia.gov](mailto:pharmbd@dhp.virginia.gov).

Virginia Board of Pharmacy  
 Inspection Report  
 September 9, 2020  
 Licenses Issued

	3/1/19-4/20/19	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	2/1/20-4/30/20	5/1/20-7/30/20	License Count 8/3/2020
Business CSR	19	36	32	23	25	28	1,437
CE Courses	0	0	0	0	0	2	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	11
Medical Equipment Supplier	1	3	7	1	4	5	229
Nonresident Manufacturer	8	11	11	10	7	6	196
Nonresident Medical Equipment Supplier	5	30	12	14	9	5	350
Non-resident Outsourcing Facility	0	1	0	1	0	3	31
Non-resident Pharmacy	22	27	18	21	33	22	809
Non-resident Third Party Logistics Provider	8	58	42	17	14	5	141
Non-resident Warehouse	6	10	16	6	19	5	59
Non-resident Wholesale Distributor	3	22	13	8	8	11	626
Non-restricted Manufacturer	1	2	0	0	1	1	32
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor				1	1	1	3
Pharmacist	134	316	328	187	120	309	15,711
Pharmacist Volunteer Registration	0	2	1	0	0	0	0
Pharmacy	7	13	10	11	10	12	1,770
Pharmacy Intern	74	65	225	43	160	76	1,584
Pharmacy Technician	249	426	433	485	345	333	13,349
Pharmacy Technician Training Program	2	3	3	1	0	2	123
Physician Selling Controlled Substances	7	25	18	23	28	22	642
Physician Selling Drugs Location	3	7	4	3	6	5	174
Pilot Programs	2	1	0	1	0	1	22
Registered Physician For CBD/THC-A Oil	25	52	59	39	58	68	442
Repackaging Training Program	1	0	0	0	0	0	2
Restricted Manufacturer	0	1	0	0	1	1	44
Third Party Logistics Provider	0	1	0	0	1	0	6
Warehouse	0	0	1	3	2	1	111
Wholesale Distributor	0	1	3	0	0	2	66
<b>Total</b>	<b>577</b>	<b>1,113</b>	<b>1,236</b>	<b>898</b>	<b>852</b>	<b>926</b>	<b>37,979</b>



Virginia Board of Pharmacy  
 Inspection Report  
 September 9, 2020

Inspections Completed

License Type	3/1/19-4/30/19	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	2/1/20-4/30/20	5/1/20-7/31/20
					Total	Virtual
Controlled Substances Registration	83	145	177	111	145	153
Medical Equipment Supplier	11	21	19	36	33	21
Non-restricted Manufacturer	1	3	0	0	1	2
Permitted Physician	0	0	0	1	0	0
Physician Selling Drugs Location	11	39	30	39	18	9
Restricted Manufacturer	0	1	0	0	2	1
Third Party Logistics Provider	0	1	2	0	3	0
Warehouse	7	10	7	11	16	27
Wholesale Distributor	2	11	7	5	5	15
Pharmacy	207	348	284	274	184	73
Pilot	1	0	0	0	6	8
Pharmaceutical Processor				6	1	4
<b>Total</b>	<b>323</b>	<b>579</b>	<b>526</b>	<b>483</b>	<b>414</b>	<b>179</b>

Pharmacy (0201) Inspections	3/1/19-4/30/19	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	2/1/20-4/30/20	5/1/20-7/31/20
Change of Location	0	7	5	5	4	6
New	6	13	10	10	9	11
Reinspection	4	9	15	10	7	8
Remodel	38	53	49	39	42	14
Routine	159	253	193	207	121	15
Focus	0	2	3	2	1	2
Federal Agency	0	11	9	0	0	0
Compliance	0	0	0	1	0	1
Pilot	0	0	0	0	0	0
<b>Total</b>	<b>207</b>	<b>348</b>	<b>284</b>	<b>274</b>	<b>184</b>	<b>73</b>

Pharmacy Routine Inspections	3/1/19-4/30/19	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	2/1/20-4/30/20	5/1/20-7/31/20
No Deficiency	53	98	64	73	42	7
Deficiency	47	76	66	70	34	3
Deficiency & IPHCO	59	79	63	64	45	5
<b>Total</b>	<b>159</b>	<b>253</b>	<b>193</b>	<b>207</b>	<b>121</b>	<b>15</b>

Virginia Board of Pharmacy

June 16, 2020

Frequently Cited Deficiencies

March 2019 - July 2020

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	106
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54
14. No incoming change of Pharmacist-in-Charge in 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)	37
7. Change of location or remodel of pharmacy without submitting application or Board approval	29
20. Pharmacist not checking and documenting repackaging or bulk packaging	26
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)	23
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)	23
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	22
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	22
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	21
<b>Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)</b>	<b>Cumulative Total</b>
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)	140
123. Engaging in remote processing not in compliance	87
127. Repackaging records and labeling not kept as required or in compliance	87
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.	72
130a. Compounded products not properly labeled	57
108. Emergency access alarm code/key not maintained in compliance	56
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	56
124. Labels do not include all required information	48
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	43
119. Not properly documenting partial filling of prescriptions	41

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies 1 - 100  
(Formerly Major Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20 Repeat	Cumulative Repeat
<b>Routine Inspections Completed</b>	159	253	193	207	121	73	1006	0	266
<b>Total Deficiencies</b>	101	123	119	111	74	8	536	0	266
<b>Average Deficiencies per Inspection</b>	0.6	0.5	0.6	0.5	0.6	0.1	0.5		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	0	0	4	1	0	7		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	12	14	7	15	6	0	54		3
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	5	1	4	4	2	0	16		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	1	1	0	0	0	0	2		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	0	2	6	5	2	0	15		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	1	0	1	0	0	2		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	5	11	4	2	5	2	29		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	1	0	0	3	0	0	4		1
9. Alarm not operational or not being set	1	0	0	1	1	0	3		
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)	3	2	11	5	1	1	23		1

Virginia Board of Pharmacy  
 Inspection Report  
 September 9, 2020

Deficiencies 1 - 100  
 (Formerly Major Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	4	2	7	3	0	0	16		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	2	3	1	3	2	0	11		
12. Storage of prescription drugs not in the prescription department	3	5	5	3	1	1	18		11
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)	4	3	2	4	0	0	13		4
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	8	5	4	3	0	23		5
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)	9	6	7	8	6	1	37		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	31	19	17	18	2	106		119
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	4	4	5	3	6	0	22		4
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)	1	0	3	0	2	0	6		
18. Records of dispensing not maintained as required	2	1	4	1	0	0	8		1
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	0	2	3	2	1	0	8		3

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies 1 - 100  
(Formerly Major Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
20. Pharmacist not checking and documenting repackaging or bulk packaging	3	10	5	5	3	0	26		18
20a. Pharmacist not documenting final verification of non-sterile compounding	5	5	1	2	2	0	15		4
20b. Pharmacist not documenting final verification of sterile compounding	3	1	3	4	0	0	11		16
21. No clean room	0	0	0	0	0	1	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	0	0	1	0	1	0	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	0	0	0	1	0	1		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	0	0	0		
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	0	0	0	0		2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	1	0	0	0	1		1
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies 1 - 100  
(Formerly Major Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
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.	3	4	5	6	3	0	21		33
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	1	0	0	1	0	0	2		1
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	1	1	2	0	0	0	4		1
29. Unlawful compounding for further distribution by other entities	0	1	1	0	1	0	3		
30. Security of after-hours stock not in compliance	0	0	0	0	1	0	1		
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	4	4	6	4	4	0	22		22
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	1	0	1	0	2		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	0	0	0	1	0	0	1		1

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies Above 100  
(Formerly Minor Deficiency)

Routine Inspections Completed	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
	159	253	193	207	121	73	1006	Repeat	Repeat
<b>Total Deficiencies</b>	150	238	239	208	97	5	932	0	376
<b>Average Deficiencies per Inspection</b>	0.9	0.9	1.2	1.0	0.8	0.1	0.9		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	0	1	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.	1	3	1	3	2	0	10		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	0	1	0	4	1	0	6		7
106. Prescription department substantially not clean and sanitary and in good repair	0	2	0	0	0	0	2		2
107. Current dispensing reference not maintained	4	2	2	2	0	0	10		11
108. Emergency access alarm code/key not maintained in compliance	9	20	10	11	4	2	56		18
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)	23	31	38	37	11	0	140		53
110. Storage of paraphernalia/Rx devices not in compliance	0	0	0	0	0	0	0		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	2	0	0	0	0	0	2		2
112. Biennial taken late but within 30 days	2	2	0	1	0	0	5		
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.	14	21	16	15	6	0	72		63

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies Above 100  
(Formerly Minor Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	0	1	2	0	3	0	6		
115. Other records of distributions not maintained as required	2	0	0	1	1	0	4		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	7	12	11	7	5	1	43		2
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	0	1	1	0	0	0	2		
119. Not properly documenting partial filling of prescriptions	3	13	10	11	4	0	41		28
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	0	0	0	0	0	0	0		
122. Engaging in alternate delivery not in compliance	5	3	13	6	4	0	31		11
123. Engaging in remote processing not in compliance	11	25	23	14	14	0	87		10
124. Labels do not include all required information	5	12	14	12	5	0	48		15
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	4	8	10	7	2	1	32		10
126. Special packaging not used or no documentation of request for non-special packaging	0	2	1	0	0	0	3		5
<b>Repackaging, specialty dispensing, compounding:</b>									
127. Repackaging records and labeling not kept as required or in compliance	17	20	20	19	10	1	87		38
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	0	0	0	0	1		
130. Required compounding/dispensing/distribution records not complete and properly maintained	6	9	8	9	2	0	34		16
130a. Compounded products not properly labeled	9	14	14	15	5	0	57		17



Virginia Board of Pharmacy  
 Inspection Report  
 September 9, 2020

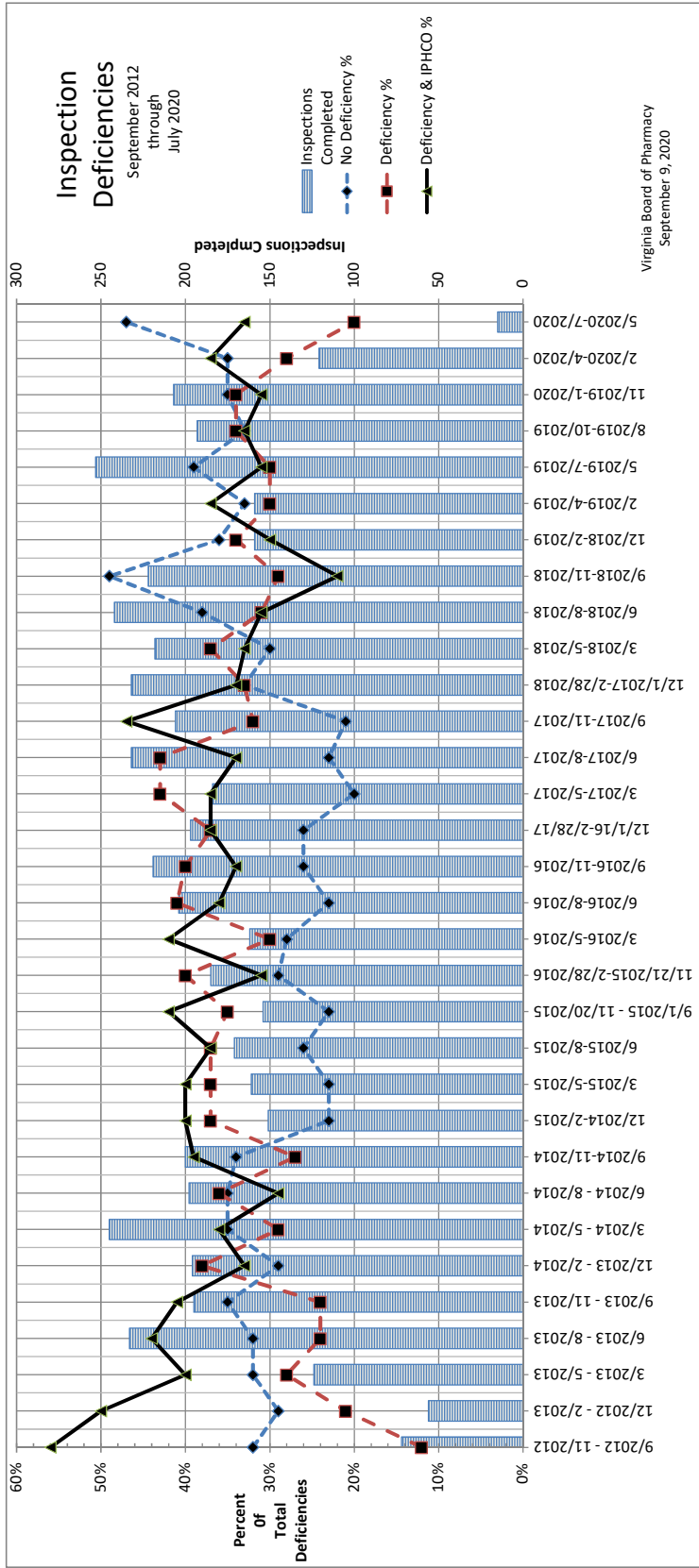
Deficiencies Above 100  
 (Formerly Minor Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	1	1	7	7	2	0	18		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	8	7	8	6	0	0	29		8
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1.-3410.2	0	0	1	0	0	0	1		
<b>Hospital specific or long-term care specific:</b>						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	1	0	0	1		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	0	1	0	1	0	2		2
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	3	2	3	0	1	0	9		1
139. Emergency medical services procedures or records not in compliance	0	1	2	2	0	0	5		5
140. Emergency kit or stat-drug box procedures or records not in compliance	1	0	3	2	1	0	7		7
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	10	14	14	12	6	0	56		20
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	0	0	0	0	0	0		

Virginia Board of Pharmacy  
Inspection Report  
September 9, 2020

Deficiencies Above 100  
(Formerly Minor Deficiency)

	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	5/20-7/20	Total	5/20-7/20	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)	0	0	0	0	0	0	0		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	0	0	0	0	0	0		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)	0	0	0	0	0	0	0		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	0	0	1	0	1	0	2		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)	2	11	4	4	6	0	27		3



Virginia Board of Pharmacy  
September 9, 2020

**Pharmaceutical Processors Report-September 9, 2020**

- Dalitso, LLC (Manassas) was awarded their pharmaceutical processor permit on August 18, 2020
- The pharmaceutical processor PICs received training on the patient verification system
- Legislative changes are being addressed through emergency regulatory procedures
- 3 of the 4 pharmaceutical processors are actively cultivating cannabis; 1 has product ready for testing
- The Board is receiving, on average, 200 patient applications per week

Pharmaceutical Processors Program-By the Numbers  
As of 5/22/2020

Registered Practitioners	479
Registered Patients	4727
Registered Parents/Guardians	59
Registered Agents	6

# Discipline Program Report

Open Cases as of 8-28-2020:

	PC	APD	Investigation	FH	IFC	Entry	Pending Closure	TOTALS
<b>Patient Care Cases</b>	67	12	56	4	17	0	0	156
<b>Non-Patient Care Cases</b>	69	5	34	5	10	3	12	138
						<b>TOTAL:</b>		<b>294</b>

Notes:

- 1) Patient care cases:
  - We have sixty-seven (67) patient care cases at Probable Cause which is equal to the number reported for June 2020. Twenty-one (21) of these cases are pending an IFC or FH.
  - We have only five (5) fewer cases compared to June 2020.
  
- 2) Non-patient care cases (inspection cases or compliance related cases):
  - The number of cases is 20% less than reported in June 2020.
  
- 3) Cases greater than 250 work days = Forty-two (42)

Upcoming Disciplinary Proceedings:

September 23, 2020	IFC-B	Patricia Richards-Spruill/Bill Lee
October 5, 2020	Pilot	Kris Ratliff/Bill Lee
October 7, 2020	Formal	All Board members
October 14, 2020	IFC-A	Glenn Bolyard/Cheryl Nelson
October 20, 2020	IFC-B	Patricia Richards-Spruill/Bill Lee
November 3, 2020	IFC-A	Glenn Bolyard/Cheryl Nelson
November 12, 2020	Formal	All Board members
December 9, 2020	IFC-B	Patricia Richards-Spruill/Bill Lee

## **Executive Director's Report** – September 9, 2020

### *Newly Appointed Board Members:*

- ❖ Sarah Melton, PharmD
- ❖ Dale St. Clair, Jr., PharmD

### *Recent Meetings:*

- ❖ COVID-19 Pharmacy Services Subcommittee of the Healthcare Coordination Committee Call – *ongoing*
- ❖ COVID Partner Call – *ongoing*
- ❖ NABP monthly executive director call – *ongoing*
- ❖ NABP Executive Committee Call - *quarterly*
- ❖ NABP Board of Managers Call - *quarterly*
- ❖ DHP executive director call - *monthly*
- ❖ Marijuana Legalization Workgroup meetings – *ongoing*
- ❖ Medical Cannabis Workgroup – *ongoing*
- ❖ JLARC cannabis study - *ongoing*
- ❖ Forensic Science Board meeting - *quarterly*
- ❖ Virginia's State Telehealth Plan meetings – *ongoing*
- ❖ New Board Member Orientation meeting

### *Presentations:*

- ❖ Virginia General Assembly, HWI Committee – Prescription Drug Supply Chain
- ❖ VPhA annual meeting – Law Update
- ❖ VDH Telehealth Subcommittee – Telehealth and Prescribing

### *Upcoming Presentations:*

- ❖ Academy of Medical Cannabis – Pharmaceutical Processor Update
- ❖ Rx Partnership – Law Update

### *Upcoming Meetings:*

- ❖ September 21, 2020 and October 2, 2020, Statewide Protocols Workgroup
- ❖ November 12, 2020, Regulation Committee
- ❖ See website for Special Conference Committee and Formal Hearing dates

### *Staffing:*

- ❖ Continuing to telework with limited hours on-site
- ❖ Offer extended and accepted for vacant licensing administrative assistant position

# Attachment 1

**DRAFT**

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## *Virginia's Pharmacist Workforce: 2019*

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Healthcare Workforce Data Center

January 2020

Virginia Department of Health Professions  
Healthcare Workforce Data Center  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico, VA 23233  
804-367-2115, 804-527-4466(fax)  
E-mail: [HWDC@dhp.virginia.gov](mailto:HWDC@dhp.virginia.gov)

Follow us on Tumblr: [www.vahwdc.tumblr.com](http://www.vahwdc.tumblr.com)

Get a copy of this report from:

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

*14,415 Pharmacists voluntarily participated in this survey. Without their effort, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for your ongoing cooperation.*

***Thank You!***

***Virginia Department of Health Professions***

**David E. Brown, DC**  
*Director*

**Barbara Allison-Bryan, MD**  
*Chief Deputy Director*

*Healthcare Workforce Data Center Staff:*

Elizabeth Carter, PhD  
*Director*

Yetty Shobo, PhD  
*Deputy Director*

Laura Jackson, MSHSA  
*Operations Manager*

Rajana Siva, MBA  
*Data Analyst*

Christopher Coyle  
*Research Assistant*



## **The Board of Pharmacy**

### ***Chair***

Cynthia Warriner  
*Chester*

### ***Vice-Chair***

Kristopher S. Ratliff  
*Marion*

### ***Members***

Glenn Bolyard  
*Glen Allen*

Melvin L. Boone, Sr.  
*Chesapeake*

James L. Jenkins, Jr.  
*Mechanicsville*

William Lee  
*Radford*

Ryan K. Logan  
*Fairfax*

Cheryl H. Nelson  
*Richmond*

Patricia Lynn Richards-Spruill  
*Suffolk*

Rebecca Thornbury  
*Grundy*

### **Executive Director**

Caroline D. Juran

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# The Pharmacist Workforce: At a Glance:

## The Workforce

Licenses:	15,875
Virginia's Workforce:	8,734
FTEs:	7,137

## Background

Rural Childhood:	33%
HS Degree in VA:	48%
Prof. Degree in VA:	49%

## Current Employment

Employed in Prof.:	91%
Hold 1 Full-time Job:	71%
Satisfied?:	84%

## Survey Response Rate

All Licenses:	91%
Renewing Practitioners:	97%

## Education

Baccalaureate:	34%
Pharm.D./Professional:	66%

## Job Turnover

Switched Jobs in 2019:	5%
Employed over 2 yrs:	62%

## Demographics

Female:	66%
Diversity Index:	52%
Median Age:	44

## Finances

Median Inc.: \$120k-\$130k	
Health Benefits:	70%
Under 40 w/ Ed debt:	74%

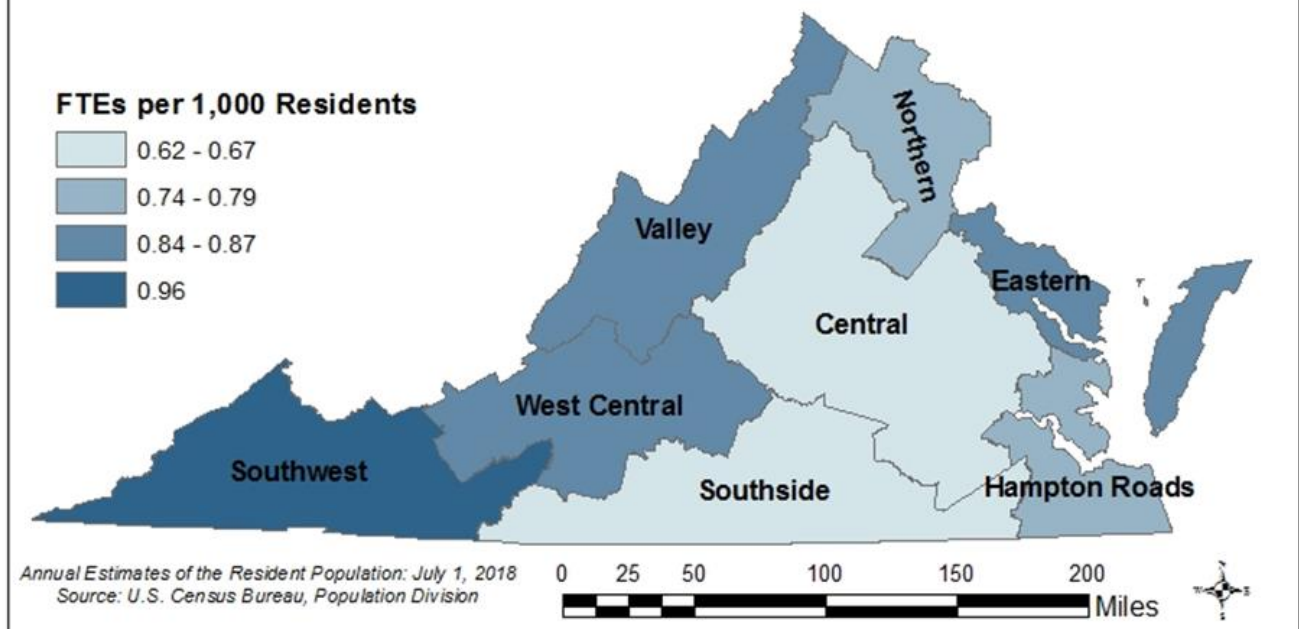
## Primary Roles

Patient Care:	75%
Administration:	7%
Education:	1%

Source: Va. Healthcare Workforce Data Center

## Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Virginia Performs Regions

Source: Va Healthcare Workforce Data Center



## Results in Brief

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A total of 14,415 pharmacists voluntarily took part in the 2019 Pharmacist Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacists. These survey respondents represent 91% of the 15,875 pharmacists who are licensed in the state and 97% of renewing practitioners. The HWDC estimates that 8,734 pharmacists participated in Virginia's workforce during the survey period and they provided 7,137 full-time equivalency units (FTE).

The majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. About one-third of pharmacists grew up in a rural area, and nearly one-quarter of these professionals currently work in non-metro areas of the state. Overall, 11% of Virginia's pharmacists work in a non-metro area. Around 66% of Virginia's pharmacist workforce have earned a doctorate or other professional degree as their highest educational attainment. About 43% of pharmacists currently carry educational debt, including nearly three-quarters of those under the age of 40. The median debt for those pharmacists with educational debt is between \$110,000 and \$120,000.

Nine out of every ten pharmacists are currently employed in the profession, with 71% holding one full-time position. Over the past year, 3% of pharmacists were involuntarily unemployed, while another 3% were underemployed. The typical pharmacist earned between \$120,000 and \$130,000 in 2019. Around 84% of all pharmacists are satisfied with their current employment situation, including 44% who indicated that they are "very satisfied".

About 91% of all pharmacists work in the private sector, including 65% 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 27% of all professionals. Hospital systems and smaller pharmacies were also common employers. About 4 in 10 pharmacists expect to retire by the age of 65 and 7% of the current workforce expect to retire in the next two years. Half of the current workforce expect to retire by 2044.

## Summary of Trends

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The total number of licensed pharmacists has grown by 29% since 2013. Of these, the number working in the state workforce has also increased but the increase of 12% is more modest by comparison. However, the 1.2% increase in FTE provided by pharmacists in the same period is even a more modest increase.

The diversity index of Virginia's pharmacists increased from 47% in 2013 to 52% in 2019. The percentage of pharmacist who are female also continues to inch up by about one percent every year, from 62% in 2013 to 66% in the current report. Median age has been relatively stable between 44 to 45 years in the past seven surveys. Even the percent under age 40, which increased from 37% in 2013 to 40% in 2016, has stayed at 40% in the past three years.

Educational attainment continues to increase among the pharmacist workforce. In 2013, only 51% had a pharmacy doctorate compared to 66% in 2019. Not surprisingly, the percent reporting educational debt has also increased annually from 35% in 2013 to 43% in 2019. Meanwhile, the median educational debt, which increased from \$90K-\$100K in 2013 to \$110K-\$120K in 2018, stayed the same in 2019.

The labor market was a bit slack for pharmacists in the past year; 3% reported being involuntarily unemployed compared to the 1% involuntary employment rate in nearly all pre-2017 surveys. However, around 91% still reported being employed in the profession and the current involuntary unemployment rate in December 2019, when the survey took place, was 2%. Median income has been stable at \$120K to \$130K between 2016 and 2019 after increasing from \$110K-\$120K in 2013. However, the percent earning above \$140,000 increased from 17% in 2016 to 22% in 2019; only 12% earned in that income range in 2013. Job satisfaction dropped precipitously in the past year, from 87% in 2018 to 84% in 2019; pharmacists who reported being very satisfied with their job also declined from 47% to 44% in the period.

Pharmacists intending to retire in the next decade increased from 22% in the pre-2017 surveys to 23% in 2017; it has stayed at 23% since then. The percent planning to retire in the next two years increased from 6% in 2013 to 7% in recent years. Regarding future plans, only 10% intended to pursue additional education in 2019 compared to 13% in 2013.

**A Closer Look:**

Licensee Counts		
License Status	#	%
<b>Renewing Practitioners</b>	14,114	89%
<b>New Licensees</b>	1,012	6%
<b>Non-Renewals</b>	749	5%
<b>All Licensees</b>	<b>15,875</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

*HWDC surveys tend to achieve very high response rates. 97% of renewing pharmacists submitted a survey. These represent 91% of pharmacists who held a license at some point in 2019.*

Statistic	Response Rates		Response Rate
	Non Respondents	Respondent	
<b>By Age</b>			
<b>Under 30</b>	149	895	86%
<b>30 to 34</b>	205	2,327	92%
<b>35 to 39</b>	206	2,259	92%
<b>40 to 44</b>	165	1,831	92%
<b>45 to 49</b>	142	1,768	93%
<b>50 to 54</b>	123	1,635	93%
<b>55 to 59</b>	118	1,287	92%
<b>60 and Over</b>	352	2,413	87%
<b>Total</b>	<b>1,460</b>	<b>14,415</b>	<b>91%</b>
<b>New Licenses</b>			
<b>Issued in 2019</b>	284	728	72%
<b>Metro Status</b>			
<b>Non-Metro</b>	103	1,040	91%
<b>Metro</b>	589	7,925	93%
<b>Not in Virginia</b>	767	5,449	88%

Source: Va. Healthcare Workforce Data Center

**At a Glance:**

**Licensed Pharmacists**

Number:	15,875
New:	6%
Not Renewed:	5%

**Survey Response Rates**

All Licensees:	91%
Renewing Practitioners:	97%

Source: Va. Healthcare Workforce Data Center

**Response Rates**

<b>Completed Surveys</b>	14,415
<b>Response Rate, all licensees</b>	91%
<b>Response Rate, Renewals</b>	97%

Source: Va. Healthcare Workforce Data Center

**Definitions**

- The Survey Period:** The survey was conducted in December 2019.
- Target Population:** All pharmacists who held a Virginia license at some point in 2019.
- 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 2019.

## At a Glance:

### Workforce

Pharmacist Workforce: 8,734  
 FTEs: 7,137

### Utilization Ratios

Licensees in VA Workforce: 55%  
 Licensees per FTE: 2.22  
 Workers per FTE: 1.22

Source: Va. Healthcare Workforce Data Center

Virginia's Pharmacist Workforce		
Status	#	%
Worked in Virginia in Past Year	8,466	97%
Looking for Work in Virginia	269	3%
Virginia's Workforce	<b>8,734</b>	<b>100%</b>
Total FTEs	<b>7,137</b>	
Licensees	<b>15,875</b>	

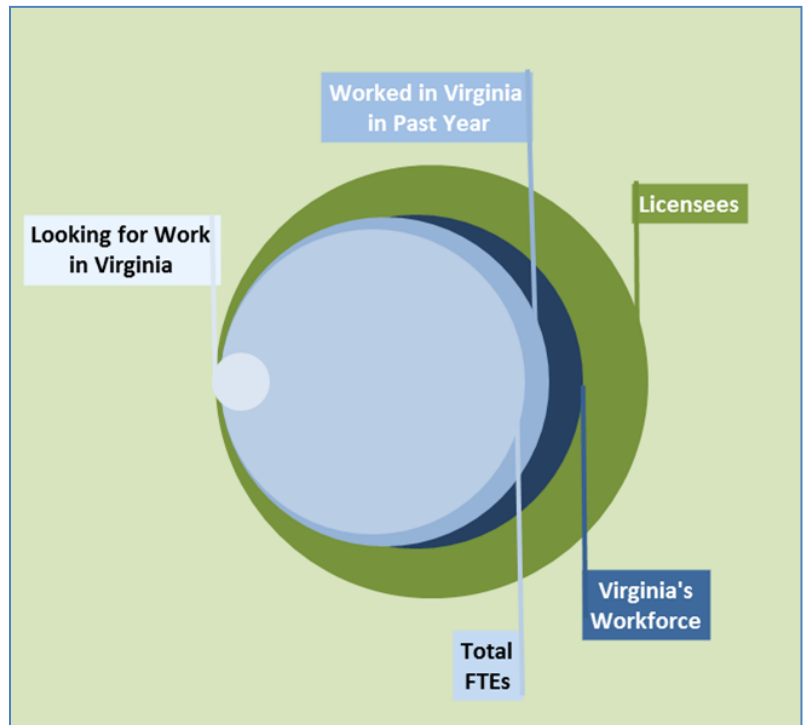
Source: Va. Healthcare Workforce Data Center

*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](http://www.dhp.virginia.gov/hwdc)

## Definitions

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



Source: Va. Healthcare Workforce Data Center

**A Closer Look:**

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	176	28%	448	72%	624	9%
30 to 34	385	31%	842	69%	1,227	17%
35 to 39	283	28%	727	72%	1,010	14%
40 to 44	252	30%	594	70%	846	12%
45 to 49	210	26%	593	74%	803	11%
50 to 54	256	33%	533	68%	789	11%
55 to 59	208	34%	411	66%	619	9%
60 +	693	56%	548	44%	1,241	17%
<b>Total</b>	<b>2,464</b>	<b>34%</b>	<b>4,696</b>	<b>66%</b>	<b>7,160</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	61%	4,732	66%	1,717	60%
Black	19%	816	11%	373	13%
Asian	7%	1,275	18%	606	21%
Other Race	0%	106	1%	39	1%
Two or more races	3%	108	2%	71	2%
Hispanic	10%	112	2%	57	2%
<b>Total</b>	<b>100%</b>	<b>7,149</b>	<b>100%</b>	<b>2,863</b>	<b>100%</b>

\*\* 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, 2018. Source: Va. Healthcare Workforce Data Center

**At a Glance:**

**Gender**

% Female: 66%  
% Under 40 Female: 70%

**Age**

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

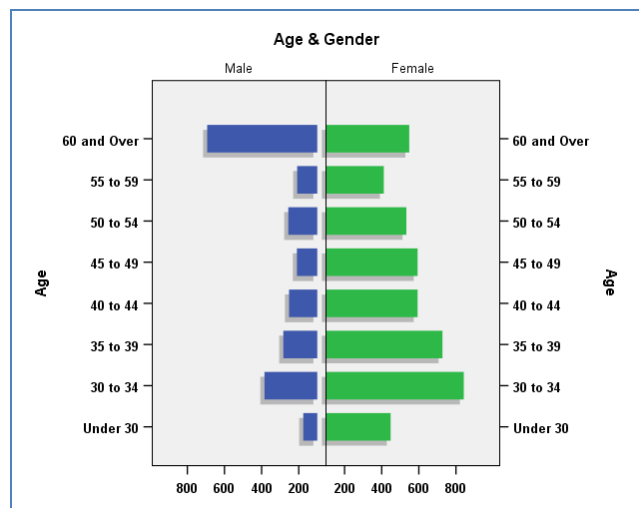
**Diversity**

Diversity Index: 52%  
Under 40 Div. Index: 58%

Source: Va. Healthcare Workforce Data Center

*In a chance encounter between two pharmacists, there is a 52% 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 57%.*

*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: 48%  
Prof. Education in VA: 49%  
HS/Prof. Educ. in VA: 57%

### Location Choice

% Rural to Non-Metro: 23%  
% Urban/Suburban to Non-Metro: 5%

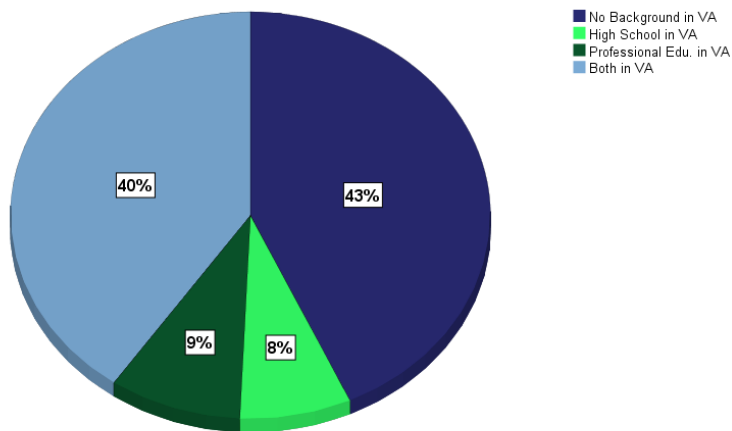
Source: Va. Healthcare Workforce Data Center

## A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
<b>Metro Counties</b>				
1	Metro, 1 million+	22%	58%	20%
2	Metro, 250,000 to 1 million	53%	40%	8%
3	Metro, 250,000 or less	42%	45%	13%
<b>Non-Metro Counties</b>				
4	Urban pop 20,000+, metro adjacent	56%	32%	13%
6	Urban pop, 2,500-19,999, metro adjacent	63%	26%	11%
7	Urban pop, 2,500-19,999, non adjacent	90%	8%	2%
8	Rural, metro adjacent	54%	43%	4%
9	Rural, non adjacent	57%	31%	12%
<b>Overall</b>		<b>33%</b>	<b>51%</b>	<b>17%</b>

Source: Va. Healthcare Workforce Data Center

Educational Background in Virginia



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 work in non-metro counties.

Source: Va. Healthcare Workforce Data Center



## Top Ten States for Pharmacy Recruitment

Rank	All Pharmacists			
	High School	#	Professional School	#
1	Virginia	3,375	Virginia	3,434
2	Outside U.S./Canada	776	Pennsylvania	471
3	Pennsylvania	435	North Carolina	300
4	New York	355	Outside U.S./Canada	291
5	Maryland	223	New York	269
6	North Carolina	189	Maryland	234
7	West Virginia	186	West Virginia	193
8	New Jersey	148	Massachusetts	188
9	Ohio	131	Washington, D.C.	186
10	Florida	116	Ohio	133

Source: Va. Healthcare Workforce Data Center

*48% of Virginia's pharmacists received their high school degree in Virginia, and 49% received their initial professional degree in the state.*

*Among pharmacists who have been licensed in the past five years, 42% received their high school degree in Virginia, and 45% received their initial professional degree in the state.*

Rank	Licensed in the Past 5 Years			
	High School	#	Professional School	#
1	Virginia	769	Virginia	814
2	Outside U.S./Canada	198	Pennsylvania	114
3	Pennsylvania	115	North Carolina	99
4	New York	111	Maryland	92
5	Maryland	75	New York	78
6	North Carolina	71	Tennessee	62
7	Florida	47	Outside U.S./Canada	56
8	New Jersey	34	West Virginia	48
9	Ohio	32	Florida	43
10	West Virginia	29	Massachusetts	42

Source: Va. Healthcare Workforce Data Center

*45% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2019. 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

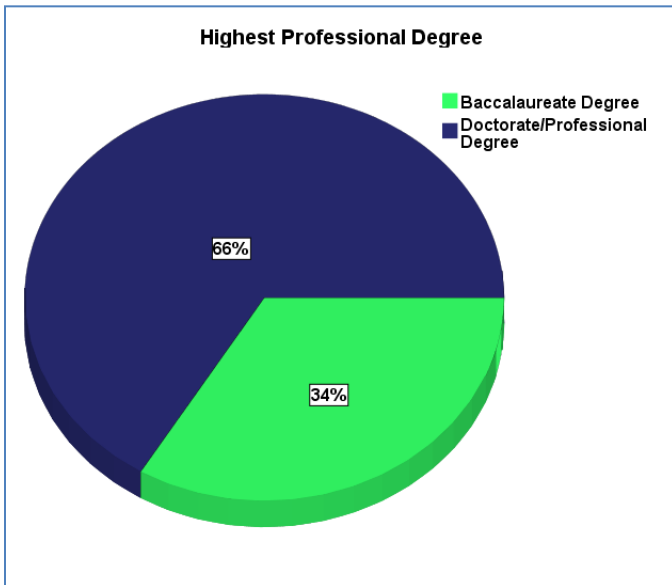
Total:	7,139
% of Licensees:	45%
Federal/Military:	7%
VA Border State/DC:	19%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	2,322	34%
Pharm.D.	4,581	66%
<b>Total</b>	<b>6,903</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Education**

B.S. Pharmacy: 34%

Pharm.D.: 66%

**Educational Debt**

Carry debt: 43%

Under age 40 w/ debt: 74%

Median debt: \$110k-\$120k

Source: Va. Healthcare Workforce Data Center

66% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a Bachelor's degree in Pharmacy.

43% of pharmacists currently have educational debt, including 74% of those under the age of 40. For those with educational debt, the median debt is between \$110,000 and \$120,000. Among those under the age of 40 with debt, median is \$150,000 to \$160,000.

Educational Debt				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
<b>None</b>	3,373	57%	613	26%
<b>\$20,000 or less</b>	195	3%	77	3%
<b>\$20,001-\$40,000</b>	190	3%	83	4%
<b>\$40,001-\$60,000</b>	211	4%	103	4%
<b>\$60,001-\$80,000</b>	228	4%	112	5%
<b>\$80,001-100,000</b>	225	4%	146	6%
<b>\$100,001-\$120,000</b>	211	4%	145	6%
<b>\$120,001-\$140,000</b>	155	3%	116	5%
<b>\$140,001-\$160,000</b>	164	3%	135	6%
<b>\$160,001-\$180,000</b>	156	3%	133	6%
<b>\$180,001-\$200,000</b>	144	2%	119	5%
<b>Over \$200,000</b>	621	11%	537	23%
<b>Total</b>	<b>5,873</b>	<b>100%</b>	<b>2,319</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

A Closer Look:

At a Glance:

**Top Specialties**

Immunization:	16%
Community Pharmacy:	8%
Ambulatory Care:	4%

**Top Board Certifications**

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

**Top Residencies (PGY1)**

Pharmacy Practice (Post 1993):	10%
Community Pharmacy:	5%
Pharmacy Practice (Pre 1993):	4%

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	916	10%
Community Pharmacy	415	5%
Pharmacy Practice (Pre 1993)	317	4%
Managed Care Pharmacy	40	<1%
Other	0	0%
<b>Total</b>	<b>1,688</b>	<b>19%</b>
PGY2		
Ambulatory Care	105	1%
Critical Care	64	1%
Internal Medicine/Cardiology	44	1%
Drug Information	39	<1%
Infectious Disease	32	<1%
Pediatrics	28	<1%
Oncology	27	<1%
Health-system Pharmacy Administration	25	<1%
Geriatrics	23	<1%
Psychiatry	22	<1%
Managed Care Pharmacy Systems	16	<1%
Pharmacotherapy	15	<1%
Informatics	15	<1%
Other	167	2%
<b>At Least One</b>	<b>622</b>	<b>7%</b>

Source: Va. Healthcare Workforce Data Center

**Board Certifications**

Certification	#	%
BPS-Pharmacotherapy	485	6%
BPS-Ambulatory Care	93	1%
BCGP-Geriatrics	85	1%
BPS-Oncology	30	<1%
BPS- Psychiatric	22	<1%
BPS- Nutrition	12	<1%
BPS-Nuclear Pharmacy	12	<1%
ABAT-Applied Toxicology	1	0%
Other Board Certification	211	2%
<b>At Least One Certification</b>	<b>857</b>	<b>10%</b>

Source: Va. Healthcare Workforce Data Center

10% of pharmacists hold a board certification, including 6% who hold a certification in Pharmacotherapy. 33% also have a self-designated specialty area, including 16% who have a specialization in immunization.

## At a Glance:

**Top Services**

Immunization: 32%  
 Medication Management: 29%  
 Compounding: 25%

**Disease Management**

Anticoagulation: 15%  
 Diabetes: 3%

Source: Va. Healthcare Workforce Data Center

### A Closer Look:

Disease Management in Collaborative Practice		
	#	%
Anticoagulation	79	15%
Diabetes	16	3%
Hypertension, Hypercholesterolemia, Anticoagulation, Diabetes	15	3%
Anticoagulation, Diabetes	14	3%
Hypertension, Hypercholesterolemia, Asthma, Anticoagulation, Diabetes	13	2%
Hypertension, Diabetes	11	2%
Hypertension, Hypercholesterolemia, Asthma, Diabetes	13	2%
Hypertension, Anticoagulation	4	1%
Hypertension, Asthma, Anticoagulation, Diabetes	4	1%
Hypertension	3	1%
Hypertension, Hypercholesterolemia, Asthma	3	1%
Hypertension, Hypercholesterolemia	2	0%
Asthma, Diabetes	1	0%
Asthma, Tobacco cessation	1	0%
Hypercholesterolemia	1	0%
Hypercholesterolemia, Asthma	1	0%
Hypertension, Asthma, Tobacco cessation, Diabetes	1	0%
Hypertension, Asthma, Tobacco cessation, Travel medications	1	0%
Hypertension, Asthma, Travel medications, Diabetes	1	0%
Hypertension, Hypercholesterolemia, Anticoagulation	1	0%
<b>Other</b>	<b>343</b>	<b>66%</b>
<b>Total</b>	<b>528</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

Services Provided				
Services	Primary		Secondary	
	#	%	#	%
Primary Service, Immunization	2,800	32%	2,800	32%
Primary Service, Medication Management	2,539	29%	274	3%
Primary Service, Compounding	2,225	25%	227	3%
Primary Service, Central Filling	1,188	14%	155	2%
Primary Service, Remote Order Processing	937	11%	84	1%
Primary Service, Collaborative Practice Agreement	580	7%	74	1%
<b>At Least One</b>	<b>4,679</b>	<b>54%</b>	<b>3,044</b>	<b>35%</b>

Source: Va. Healthcare Workforce Data Center

## At a Glance:

### Employment

Employed in Profession: 91%  
 Involuntarily Unemployed: 2%

### Positions Held

1 Full-time: 71%  
 2 or More Positions: 8%

### Weekly Hours:

40 to 49: 48%  
 60 or more: 4%  
 Less than 30: 14%

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	5	0%
Employed in a pharmacy-related capacity	6,307	91%
Employed, NOT in a pharmacy-related capacity	208	3%
Not working, reason unknown	0	0%
Involuntarily unemployed	117	2%
Voluntarily unemployed	177	3%
Retired	128	2%
<b>Total</b>	<b>6,941</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

*91% of Virginia’s pharmacists are currently employed in the profession, and 2% of all pharmacy professionals are involuntarily unemployed at the moment. 71% of the state’s pharmacist workforce have one full-time job, while 8% of pharmacists have multiple positions. 48% 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	422	6%
One Part-Time Position	993	15%
Two Part-Time Positions	134	2%
One Full-Time Position	4,876	71%
One Full-Time Position & One Part-Time Position	349	5%
Two Full-Time Positions	8	0%
More than Two Positions	39	1%
<b>Total</b>	<b>6,821</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	422	6%
1 to 9 hours	194	3%
10 to 19 hours	247	4%
20 to 29 hours	477	7%
30 to 39 hours	1,390	21%
40 to 49 hours	3,256	48%
50 to 59 hours	515	8%
60 to 69 hours	146	2%
70 to 79 hours	82	1%
80 or more hours	38	1%
<b>Total</b>	<b>6,767</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

**A Closer Look:**

Income		
Annual Income	#	%
<b>Volunteer Work Only</b>	55	1%
<b>\$50,000 or less</b>	459	9%
<b>\$50,001-\$60,000</b>	128	3%
<b>\$60,001-\$70,000</b>	116	2%
<b>\$70,001-\$80,000</b>	136	3%
<b>\$80,001-\$90,000</b>	158	3%
<b>\$90,001-\$100,000</b>	244	5%
<b>\$100,001-\$110,000</b>	514	10%
<b>\$110,001-\$120,000</b>	661	13%
<b>\$120,001-\$130,000</b>	880	17%
<b>\$130,001-\$140,000</b>	738	14%
<b>\$140,001-\$150,000</b>	501	10%
<b>More than \$150,000</b>	612	12%
<b>Total</b>	<b>5,204</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Annual Income**  
Median Income: \$120k-130k

**Benefits**  
Employer Health Insurance: 66%  
Employer Retirement: 67%

**Satisfaction**  
Satisfied: 84%  
Very Satisfied: 44%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
<b>Very Satisfied</b>	2,957	44%
<b>Somewhat Satisfied</b>	2,641	39%
<b>Somewhat Dissatisfied</b>	718	11%
<b>Very Dissatisfied</b>	384	6%
<b>Total</b>	<b>6,700</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

*The typical pharmacist earned between \$120,000 and \$130,000 in 2019. Among pharmacists who received either an hourly wage or a salary as compensation at their primary work location, 70% received health insurance and 70% also had access to a retirement plan.*

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
<b>Paid Vacation Leave</b>	4,750	75%	79%
<b>Retirement</b>	4,235	67%	70%
<b>Health Insurance</b>	4,191	66%	70%
<b>Dental Insurance</b>	4,058	64%	68%
<b>Paid Sick Leave</b>	3,643	58%	61%
<b>Group Life Insurance</b>	3,068	49%	52%
<b>Signing/Retention Bonus</b>	394	6%	7%
<b>Received At Least One Benefit</b>	<b>5,051</b>	<b>80%</b>	<b>83%</b>

\*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?	222	3%
Experience Voluntary Unemployment?	269	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	299	3%
Work two or more positions at the same time?	636	7%
Switch employers or practices?	397	5%
<b>Experienced at least 1</b>	<b>1,486</b>	<b>17%</b>

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Unemployment Experience**  
 Involuntarily Unemployed: 3%  
 Underemployed: 3%

**Stability**  
 Switched: 5%  
 New Location: 21%  
 Over 2 years: 62%  
 Over 2 yrs, 2<sup>nd</sup> location: 48%

**Employment Type**  
 Salary or Wage: 93%  
 Hourly Wage: 72%

Source: Va. Healthcare Workforce Data Center

*3% of Virginia's pharmacists were involuntary unemployed at some point in 2019. For comparison, Virginia's average monthly unemployment rate was 2.8%.<sup>1</sup>*

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
<b>Not Currently Working at this Location</b>	168	3%	76	9%
<b>Less than 6 Months</b>	608	9%	128	15%
<b>6 Months to 1 Year</b>	523	8%	95	11%
<b>1 to 2 Years</b>	1,137	18%	157	18%
<b>3 to 5 Years</b>	1,411	22%	180	21%
<b>6 to 10 Years</b>	968	15%	109	12%
<b>More than 10 Years</b>	1,604	25%	129	15%
<b>Subtotal</b>	<b>6,419</b>	<b>100%</b>	<b>874</b>	<b>100%</b>
<b>Did not have location</b>	320		7,822	
<b>Item Missing</b>	1,995		39	
<b>Total</b>	<b>8,734</b>		<b>8,734</b>	

Source: Va. Healthcare Workforce Data Center

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

*62% of pharmacists have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.*

Employment Type		
Primary Work Site	#	%
<b>Salary/ Commission</b>	2,888	50%
<b>Hourly Wage</b>	2,550	44%
<b>By Contract</b>	78	1%
<b>Business/ Practice Income</b>	279	5%
<b>Unpaid</b>	36	1%
<b>Subtotal</b>	<b>5,832</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

<sup>1</sup> As reported by the US Bureau of Labor Statistics, the non-seasonally adjusted monthly unemployment rate fluctuated from a low of 2.4% to a high of 3.2%. At the time of publication, the unemployment rate from November 2019 was still preliminary, and the unemployment rate from December 2019 was not available.

## At a Glance:

### Concentration

Top Region:	26%
Top 3 Regions:	70%
Lowest Region:	2%

### Locations

2 or more (2019):	10%
2 or more (Now*):	12%

Source: Va. Healthcare Workforce Data Center

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

## A Closer Look:

Regional Distribution of Work Locations				
Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	1,661	26%	162	19%
Eastern	116	2%	12	1%
Hampton Roads	1,190	19%	155	18%
Northern	1,614	25%	194	22%
Southside	216	3%	27	3%
Southwest	364	6%	68	8%
Valley	410	6%	60	7%
West Central	724	11%	102	12%
Virginia Border State/DC	32	1%	39	4%
Other US State	42	1%	51	6%
Outside of the US	0	0%	3	0%
<b>Total</b>	<b>6,369</b>	<b>100%</b>	<b>873</b>	<b>100%</b>
<b>Item Missing</b>	<b>2,045</b>		<b>39</b>	

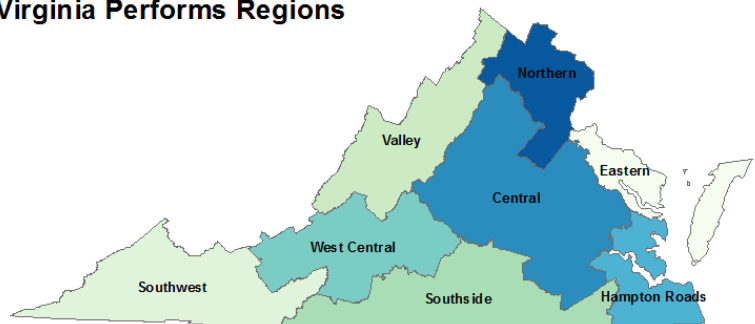
Source: Va. Healthcare Workforce Data Center

Number of Work Locations				
Locations	Work Locations in 2019		Work Locations Now*	
	#	%	#	%
0	316	4%	406	6%
1	7,508	86%	5,461	82%
2	465	5%	436	7%
3	296	3%	258	4%
4	28	0%	25	0%
5	15	0%	9	0%
6 or More	105	1%	80	1%
<b>Total</b>	<b>8,734</b>	<b>100%</b>	<b>6,675</b>	<b>100%</b>

\*At the time of survey completion, December 2019.

Source: Va. Healthcare Workforce Data Center

### Virginia Performs Regions



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



**A Closer Look:**

Sector	Location Sector			
	Primary Location		Secondary Location	
	#	%	#	%
<b>For-Profit</b>	3,892	65%	572	70%
<b>Non-Profit</b>	1,532	26%	188	23%
<b>State/Local Government</b>	237	4%	35	4%
<b>Veterans Administration</b>	131	2%	4	0%
<b>U.S. Military</b>	119	2%	17	2%
<b>Other Federal Gov't</b>	64	1%	6	1%
<b>Total</b>	<b>5,975</b>	<b>100%</b>	<b>822</b>	<b>100%</b>
<b>Did not have location</b>	320		7,822	
<b>Item Missing</b>	2,439		91	

Source: Va. Healthcare Workforce Data Center

## At a Glance: (Primary Locations)

**Sector**

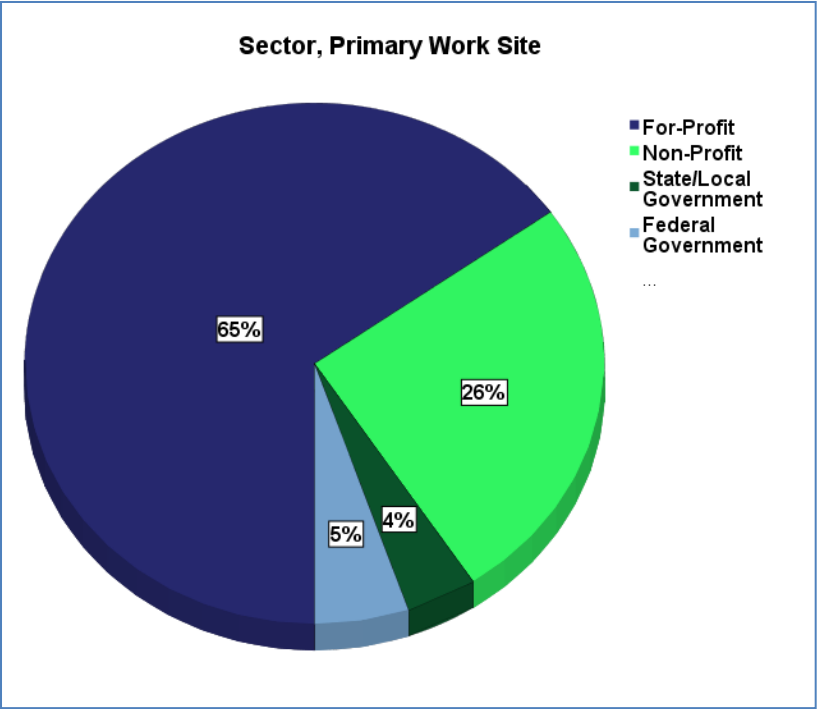
For Profit:	65%
Federal:	5%

**Top Establishments**

Large Chain Pharmacy: (11+ Stores)	27%
Hospital/Health System: (Inpatient)	25%
Independent Pharmacy: (1-4 Stores)	9%

Source: Va. Healthcare Workforce Data Center

91% of all pharmacists work in the private sector, including 65% 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.

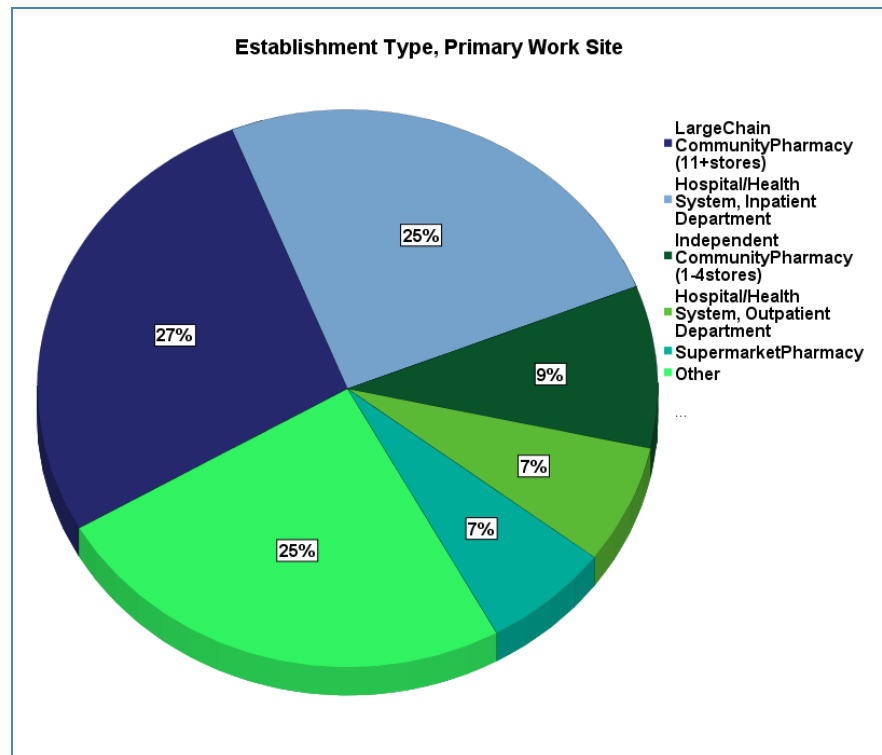


Source: Va. Healthcare Workforce Data Center

Top Location Types				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy	1,599	27%	172	21%
Hospital/Health System, Inpatient Department	1,473	25%	156	19%
Independent Community Pharmacy	552	9%	119	15%
Hospital/Health System, Outpatient Department	405	7%	46	6%
Supermarket Pharmacy	391	7%	36	4%
Mass Merchandiser (i.e. Big Box Store)	253	4%	30	4%
Nursing Home/Long-Term Care	205	3%	46	6%
Clinic-Based Pharmacy	202	3%	61	8%
Benefit Administration	147	3%	9	1%
Academic Institution	106	2%	36	4%
Home Health/Infusion	82	1%	12	1%
Mail Service Pharmacy	61	1%	9	1%
Manufacturer	45	1%	4	0%
Small Chain Community Pharmacy	29	0%	5	1%
Wholesale Distributor	4	0%	1	0%
Other	312	5%	65	8%
<b>Total</b>	<b>5,866</b>	<b>100%</b>	<b>807</b>	<b>100%</b>
<b>Did Not Have a Location</b>	320		7,822	

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

Source: Va. Healthcare Workforce Data Center



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

Source: Va. Healthcare Workforce Data Center

## At a Glance: (Primary Locations)

### Typical Time Allocation

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

### Roles

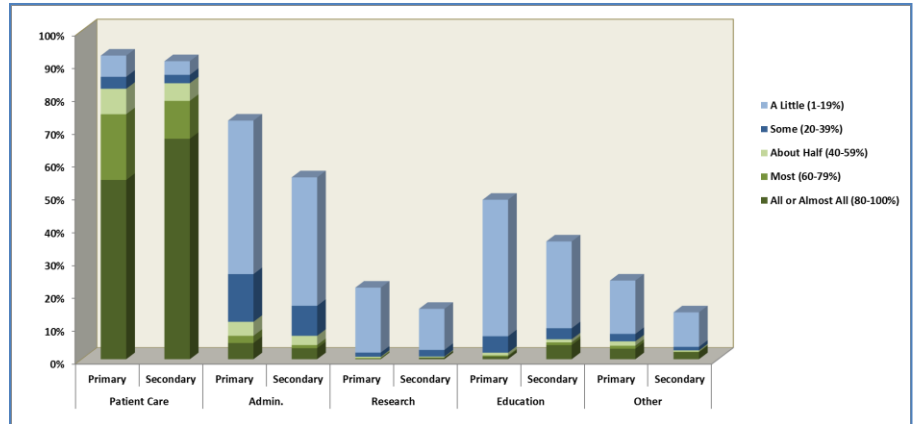
Patient Care: 75%  
Administration: 7%  
Education: 1%

### Patient Care Pharmacists

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

Source: Va. Healthcare Workforce Data Center

## A Closer Look:



Source: Va. Healthcare Workforce Data Center

*A typical pharmacist spends most of her time in patient care activities. In fact, 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
<b>All or Almost All (80-100%)</b>	55%	67%	5%	3%	0%	1%	1%	4%	3%	2%
<b>Most (60-79%)</b>	20%	12%	2%	1%	0%	0%	0%	1%	1%	0%
<b>About Half (40-59%)</b>	8%	5%	4%	3%	0%	0%	1%	1%	1%	0%
<b>Some (20-39%)</b>	4%	3%	15%	9%	1%	2%	5%	3%	2%	1%
<b>A Little (1-20%)</b>	6%	4%	47%	39%	20%	13%	42%	26%	16%	10%
<b>None (0%)</b>	8%	9%	27%	45%	78%	85%	51%	64%	76%	86%

Source: Va. Healthcare Workforce Data Center

**A Closer Look:**

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
<b>Under age 50</b>	174	3%	-	-
<b>50 to 54</b>	206	4%	0	0%
<b>55 to 59</b>	589	11%	121	6%
<b>60 to 64</b>	1,356	25%	493	24%
<b>65 to 69</b>	1,996	36%	841	41%
<b>70 to 74</b>	600	11%	326	16%
<b>75 to 79</b>	176	3%	100	5%
<b>80 or over</b>	80	1%	39	2%
<b>I do not intend to retire</b>	329	6%	136	7%
<b>Total</b>	<b>5,506</b>	<b>100%</b>	<b>2,056</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

**At a Glance:**

**Retirement Expectations**

**All Pharmacists**

Under 65: 42%

Under 60: 18%

**Pharmacists 50 and over**

Under 65: 30%

Under 60: 5%

**Time until Retirement**

Within 2 years: 7%

Within 10 years: 23%

Half the workforce: By 2044

Source: Va. Healthcare Workforce Data Center

42% of Virginia’s pharmacists expect to retire before the age of 65, while 21% plan on working until at least age 70. Among pharmacists who are age 50 and over, 30% 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% plan on increasing the number of hours that they devote to patients.

**Future Plans**

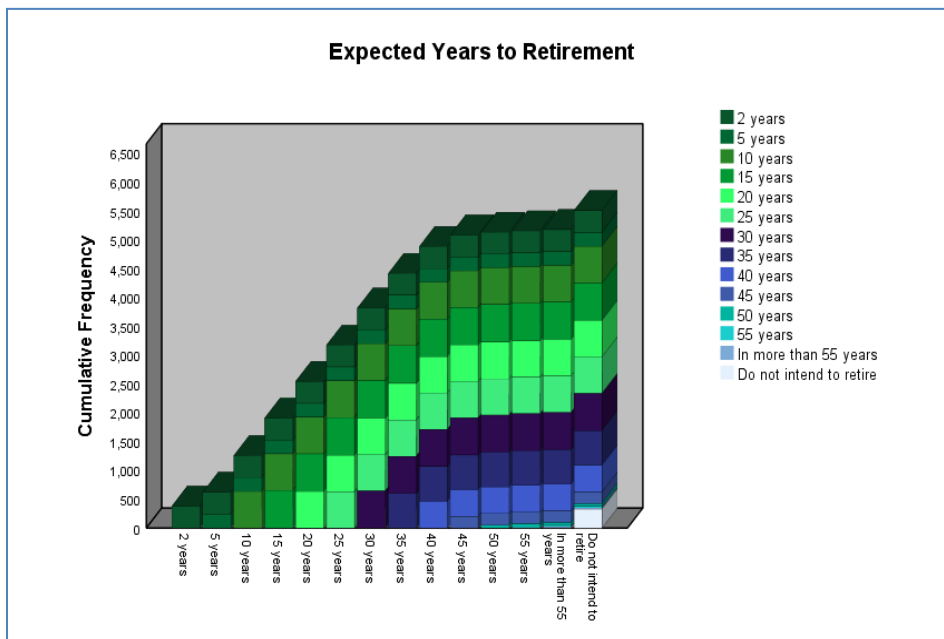
2 Year Plans:	#	%
<b>Decrease Participation</b>		
<b>Leave Profession</b>	169	2%
<b>Leave Virginia</b>	231	3%
<b>Decrease Patient Care Hours</b>	224	3%
<b>Decrease Teaching Hours</b>	28	0%
<b>Increase Participation</b>		
<b>Increase Patient Care Hours</b>	678	8%
<b>Increase Teaching Hours</b>	395	5%
<b>Pursue Additional Education</b>	849	10%
<b>Return to Virginia’s Workforce</b>	125	1%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacists. Only 7% of pharmacists plan on retiring in the next two years, while 23% plan on retiring in the next ten years. Half of the current pharmacist workforce expect to retire by 2044.

Time to Retirement			
Expect to retire within . . .	#	%	Cumulative %
<b>2 years</b>	379	7%	7%
<b>5 years</b>	242	4%	11%
<b>10 years</b>	635	12%	23%
<b>15 years</b>	652	12%	35%
<b>20 years</b>	635	12%	46%
<b>25 years</b>	630	11%	58%
<b>30 years</b>	643	12%	69%
<b>35 years</b>	601	11%	80%
<b>40 years</b>	465	8%	89%
<b>45 years</b>	201	4%	92%
<b>50 years</b>	49	1%	93%
<b>55 years</b>	24	0%	94%
<b>In more than 55 years</b>	21	0%	94%
<b>Do not intend to retire</b>	329	6%	100%
<b>Total</b>	<b>5,506</b>	<b>100%</b>	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2029. Retirement will peak at 12% of the current workforce around the same time before declining to under 10% of the current workforce again around 2059.

## At a Glance:

### FTEs

Total: 7,137  
 FTEs/1,000 Residents<sup>2</sup>: 0.838  
 Average: 0.85

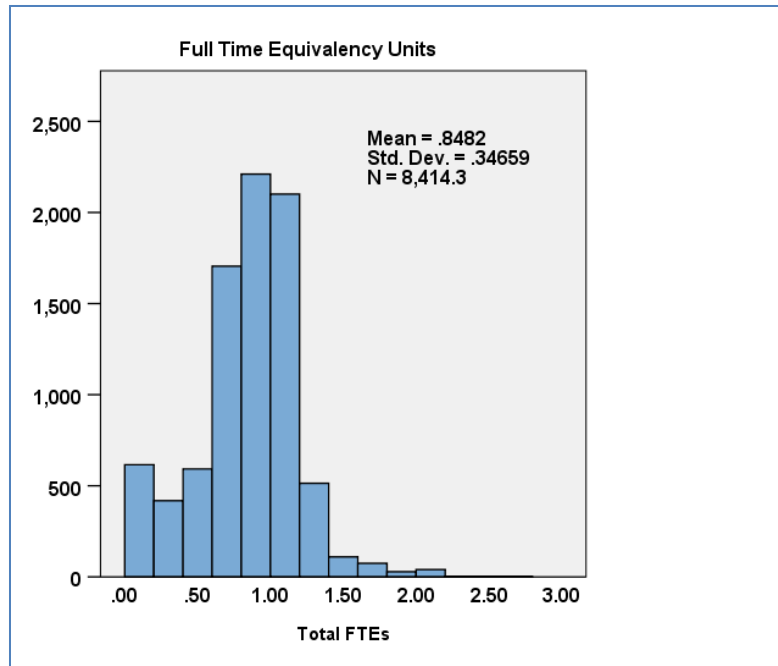
### Age & Gender Effect

Age, Partial Eta<sup>3</sup>: Small  
 Gender, Partial Eta<sup>3</sup>: Negligible

*Partial Eta<sup>3</sup> Explained:*  
 Partial Eta<sup>3</sup> is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

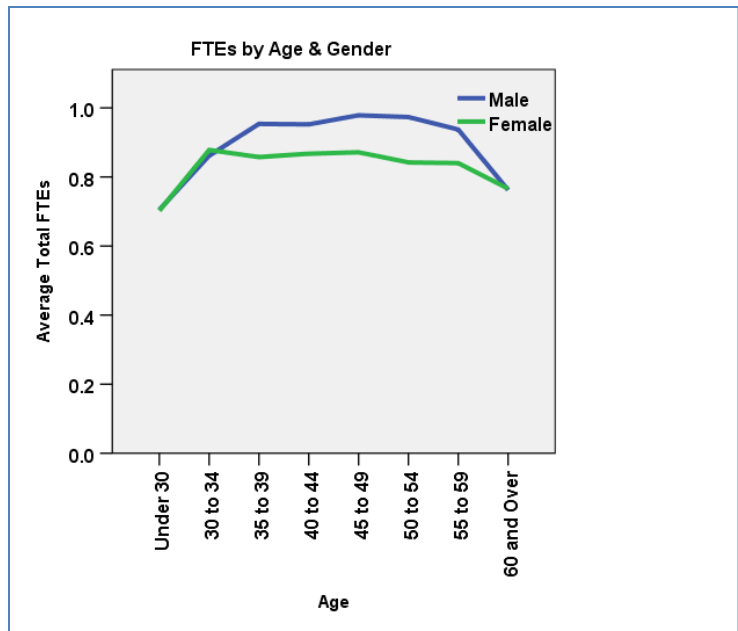


Source: Va. Healthcare Workforce Data Center

*The typical pharmacist provided 0.92 FTEs in 2019, 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.<sup>3</sup>*

Full-Time Equivalency Units		
	Average	Median
<b>Age</b>		
<b>Under 30</b>	0.70	0.65
<b>30 to 34</b>	0.88	0.95
<b>35 to 39</b>	0.87	0.83
<b>40 to 44</b>	0.90	0.92
<b>45 to 49</b>	0.91	0.95
<b>50 to 54</b>	0.86	0.84
<b>55 to 59</b>	0.85	0.83
<b>60 and Over</b>	0.77	0.80
<b>Gender</b>		
<b>Male</b>	0.87	0.96
<b>Female</b>	0.84	0.93

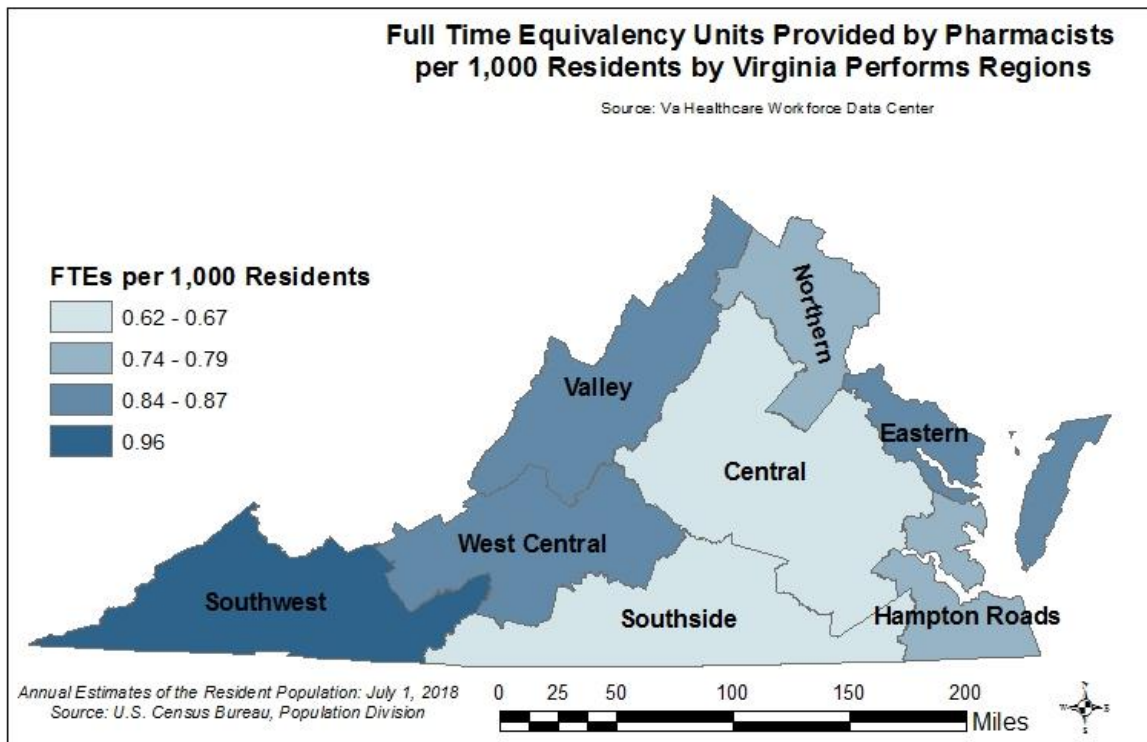
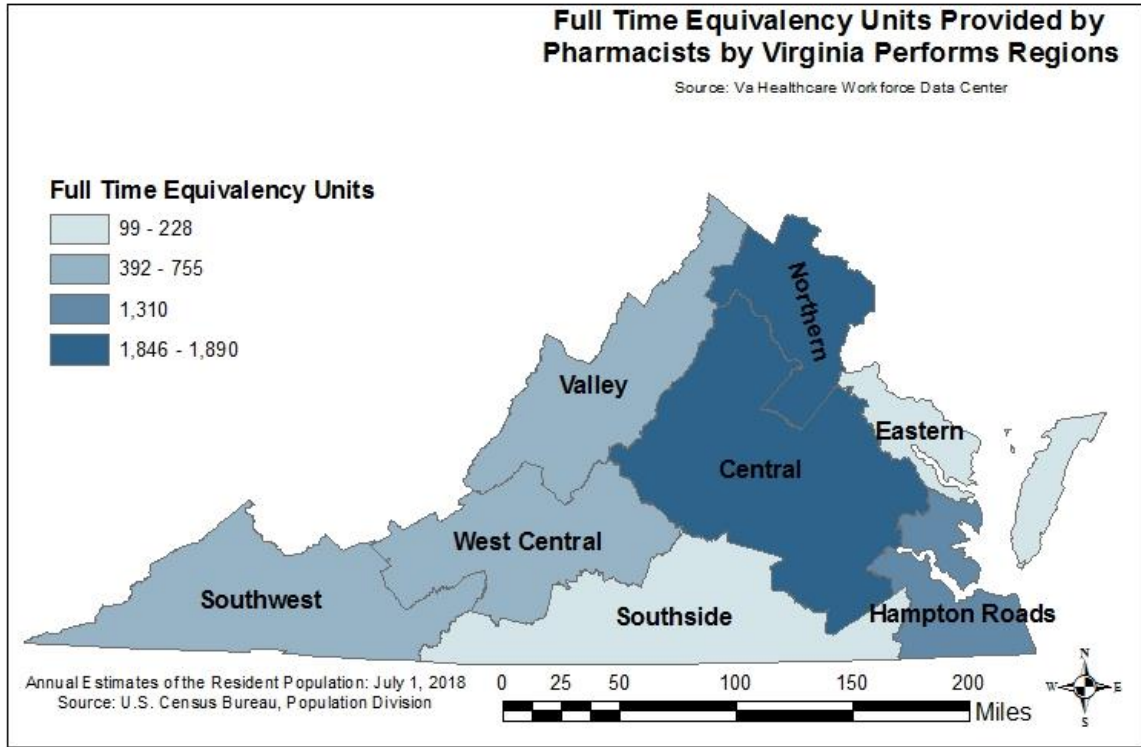
Source: Va. Healthcare Workforce Data Center



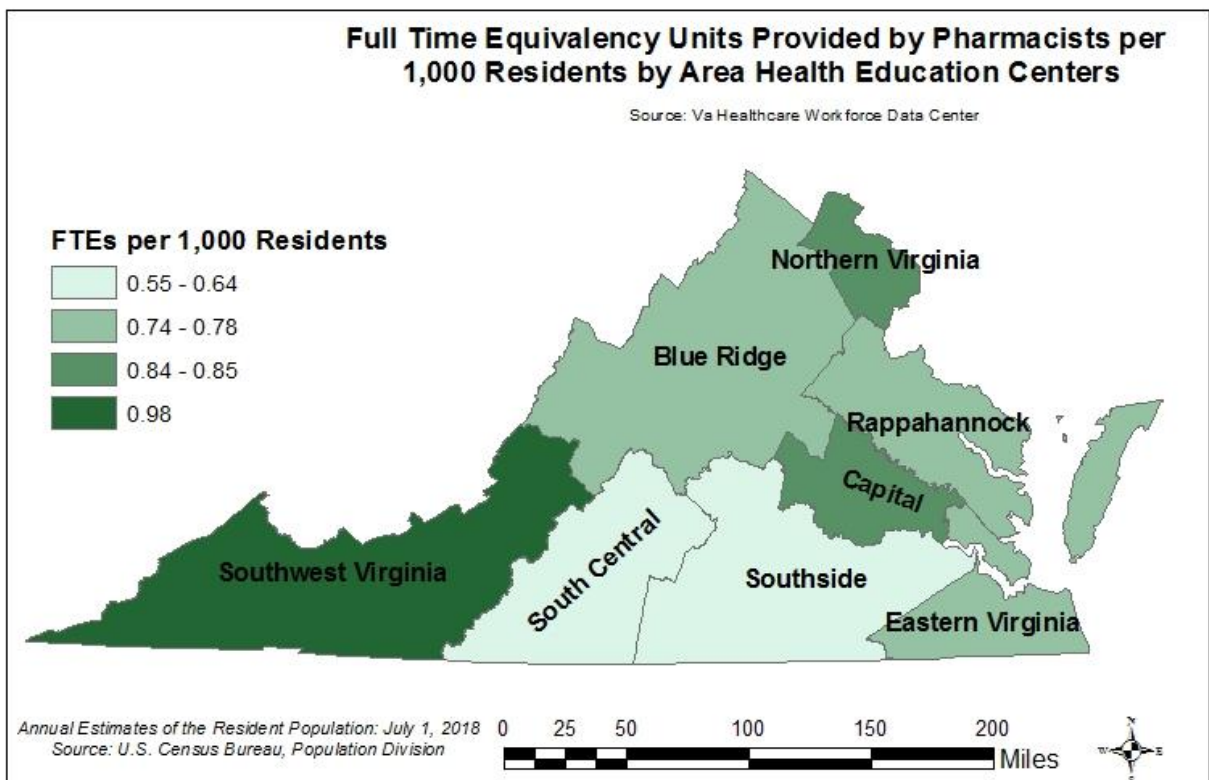
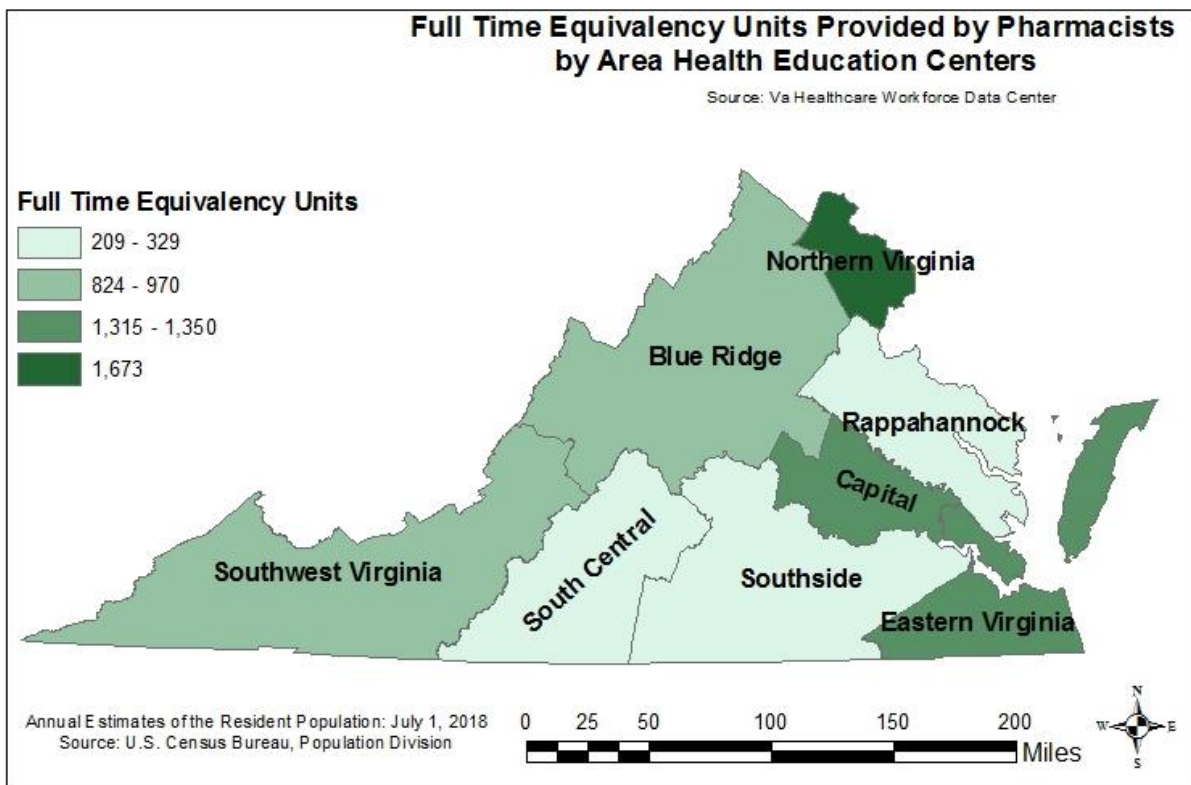
Source: Va. Healthcare Workforce Data Center

<sup>2</sup> Number of residents in 2018 was used as the denominator.

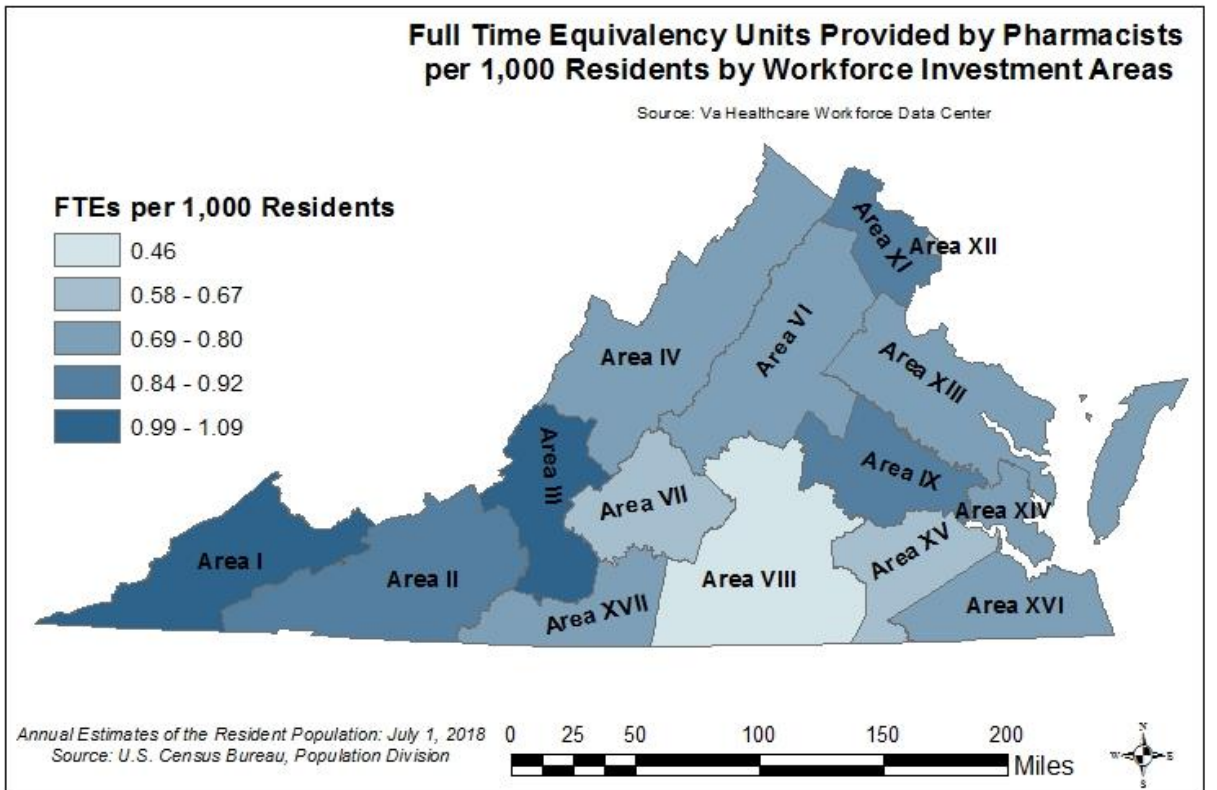
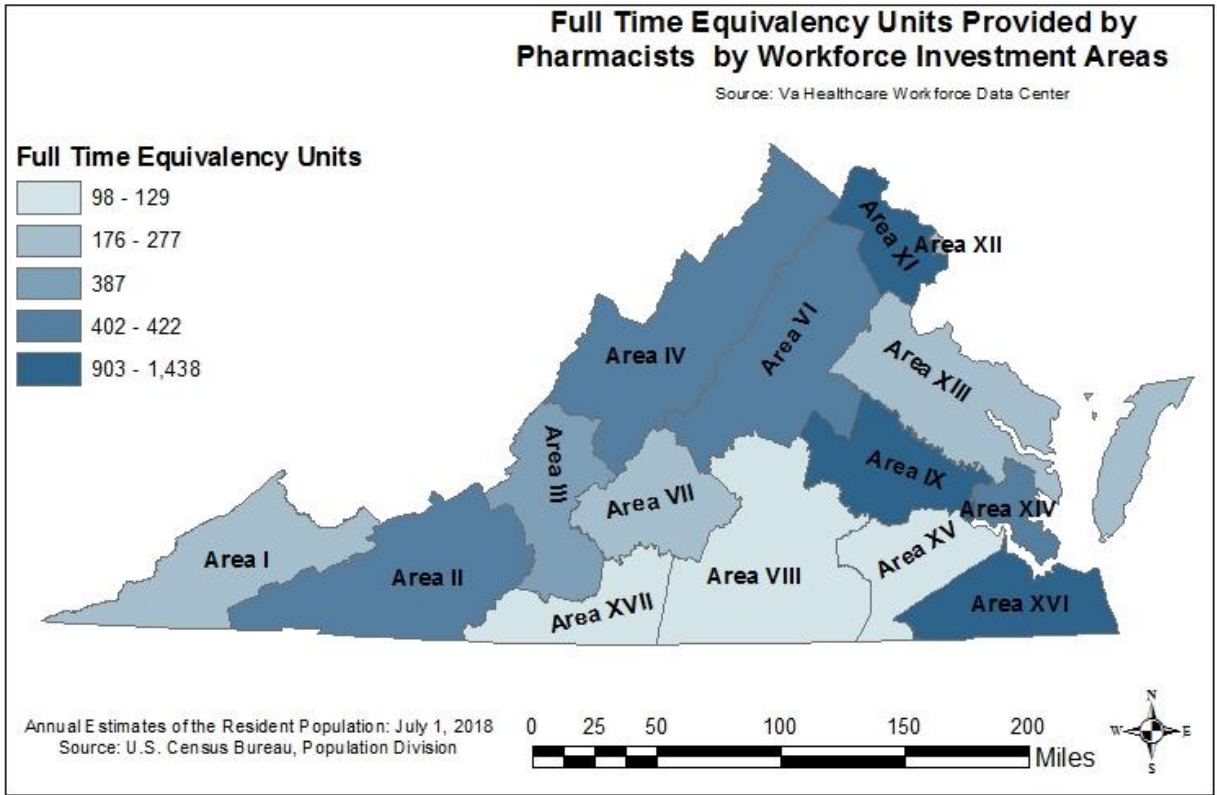
<sup>3</sup> Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

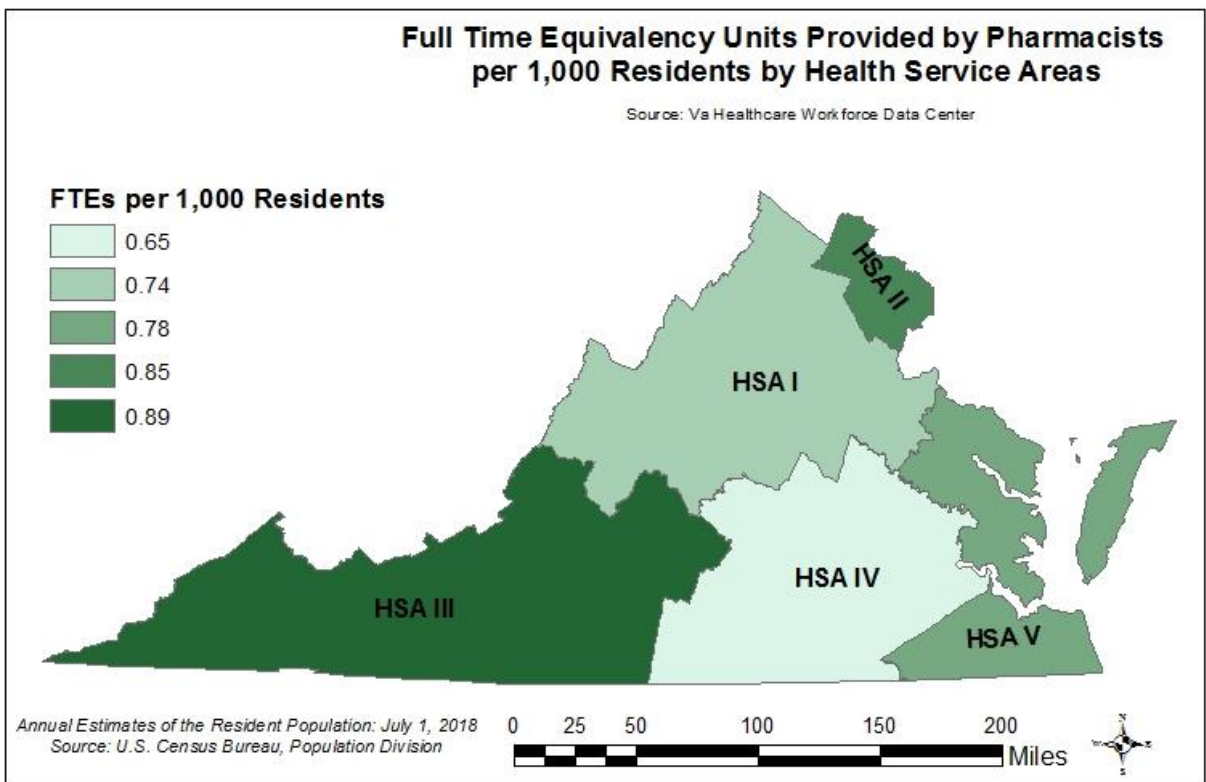
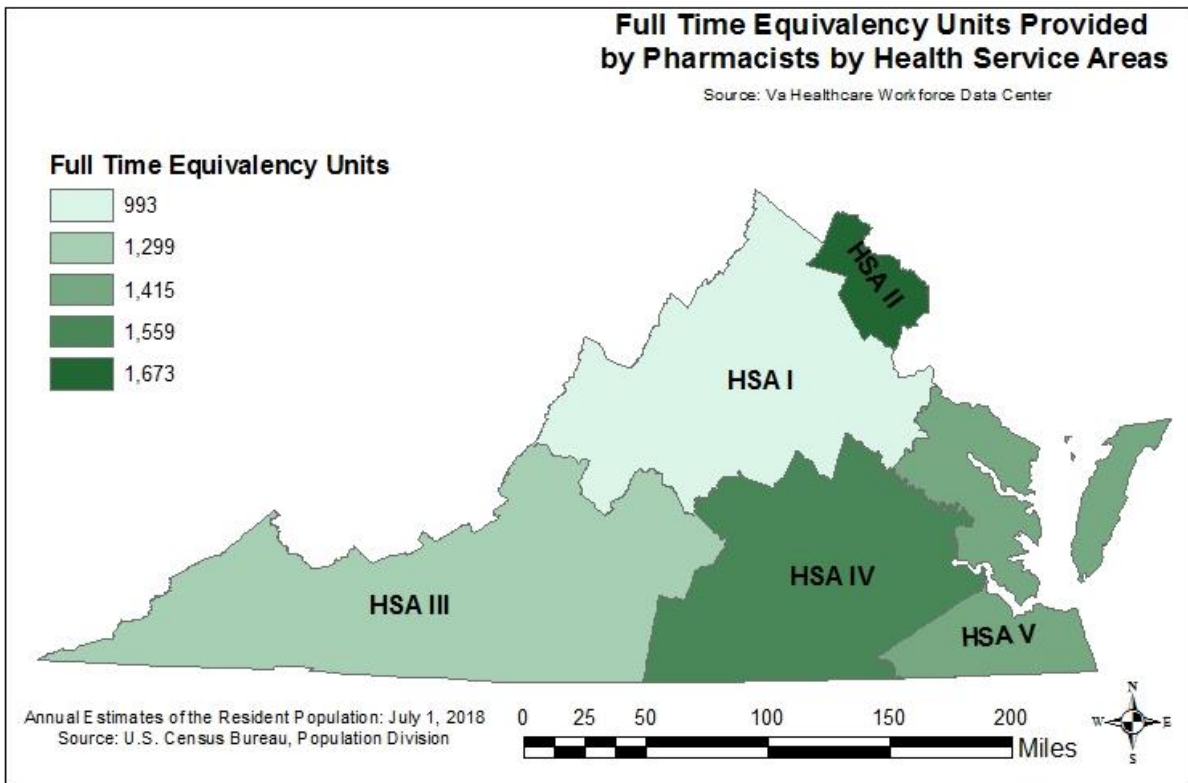


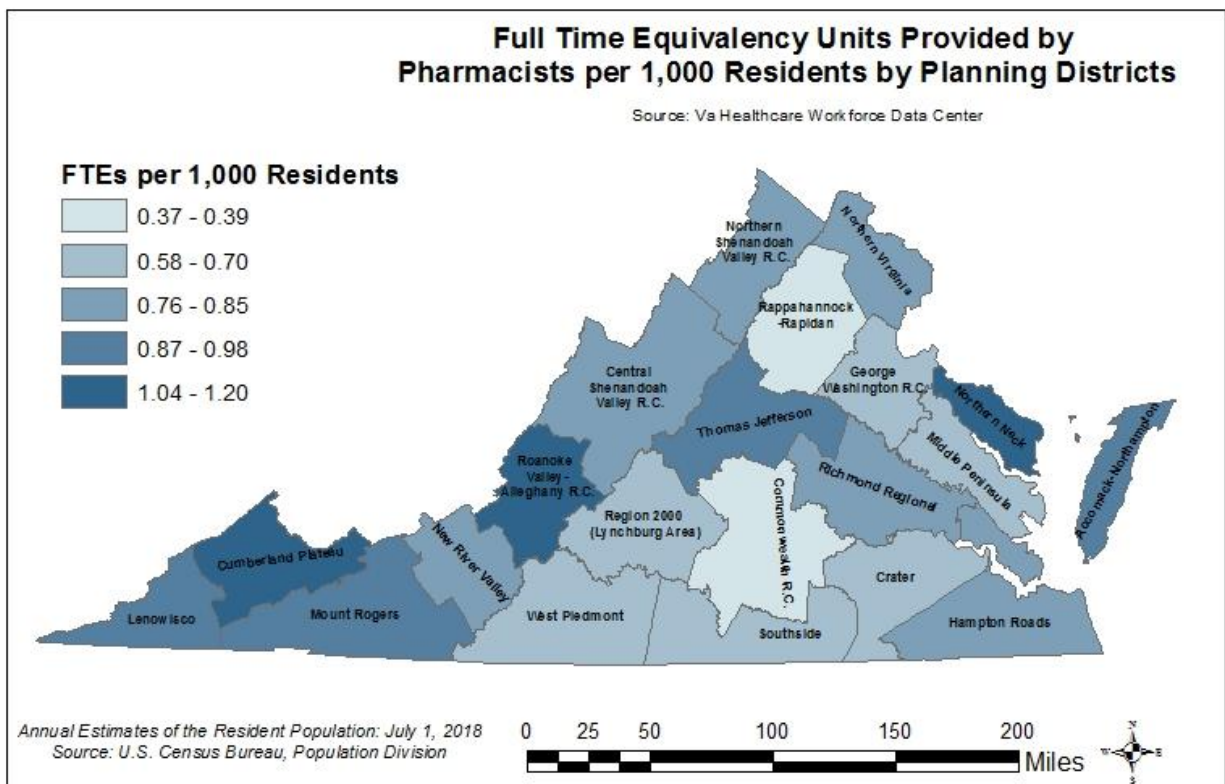
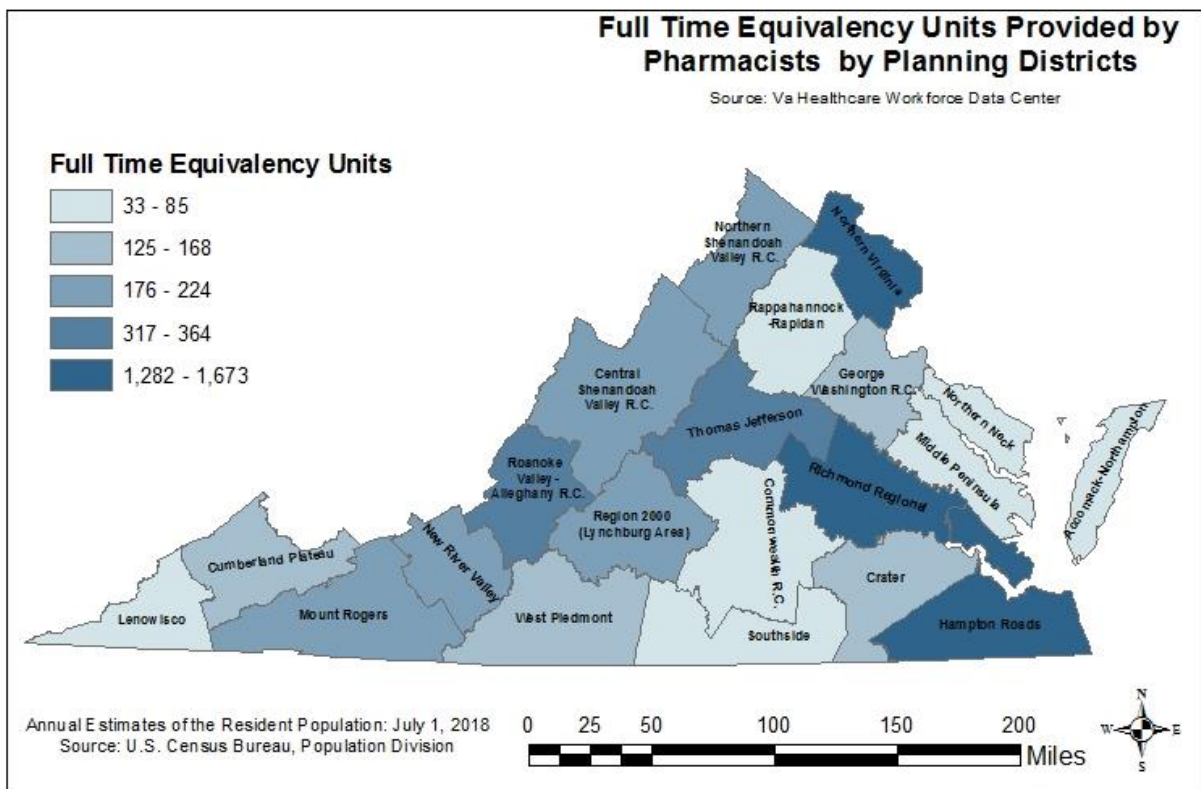












## Appendix

### Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 million+	6,549	92.96%	1.0757	1.0503	1.1394
Metro, 250,000 to 1 million	921	93.05%	1.0747	1.0493	1.1383
Metro, 250,000 or less	1,044	93.87%	1.0653	1.0401	1.1284
Urban pop 20,000+, Metro adj	122	90.98%	1.0991	1.0731	1.1642
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	365	88.77%	1.1265	1.0999	1.1932
Urban pop, 2,500-19,999, nonadj	292	94.18%	1.0618	1.0367	1.1247
Rural, Metro adj	232	89.22%	1.1208	1.0943	1.1871
Rural, nonadj	132	93.18%	1.0732	1.0478	1.1367
Virginia border state/DC	2,772	88.46%	1.1305	1.1038	1.1974
Other US State	3,444	87.02%	1.1491	1.1220	1.2172

Source: Va. Healthcare Workforce Data Center

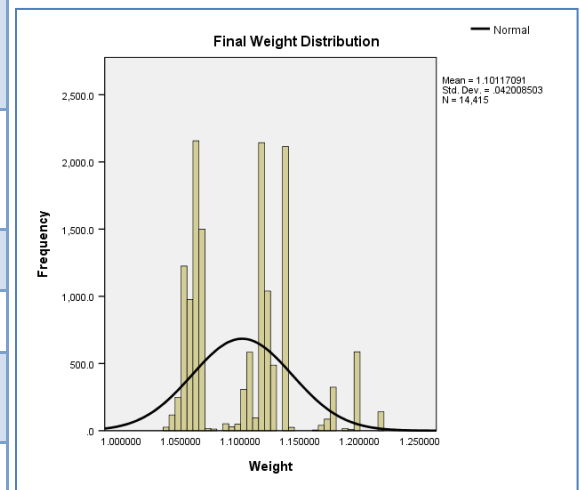
See the Methods section on the HWDC website for details on HWDC Methods:

[www.dhp.virginia.gov/hwdc/](http://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: 0.90803**



Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	1,044	85.73%	1.1665	1.1247	1.2172
30 to 34	2,532	91.90%	1.0881	1.0491	1.1354
35 to 39	2,465	91.64%	1.0912	1.0521	1.1386
40 to 44	1,996	91.73%	1.0901	1.0511	1.1375
45 to 49	1,910	92.57%	1.0803	1.0416	1.1273
50 to 54	1,758	93.00%	1.0752	1.0367	1.1220
55 to 59	1,405	91.60%	1.0917	1.0526	1.1391
60 and Over	2,765	87.27%	1.1459	1.1048	1.1957

Source: Va. Healthcare Workforce Data Center

# Attachment 2

**DRAFT**

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## *Virginia's Pharmacy Technician Workforce: 2019*

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Healthcare Workforce Data Center

January 2020

Virginia Department of Health Professions  
Healthcare Workforce Data Center  
Perimeter Center  
9960 Mayland Drive, Suite 300  
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Follow us on Tumblr: [www.vahwdc.tumblr.com](http://www.vahwdc.tumblr.com)

Get a copy of this report from:

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

*Nearly 11,000 Pharmacy Technicians voluntarily participated in this survey. Without their efforts, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for your ongoing cooperation.*

***Thank You!***

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Caroline D. Juran  
*Richmond*

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# The Pharmacy Technician Workforce: At a Glance:

## The Workforce

Licensees:	14,419
Virginia's Workforce:	13,366
FTEs:	10,277

## Background

Rural Childhood:	40%
HS Degree in VA:	73%
% Work Non-Metro:	14%

## Current Employment

Employed in Prof.:	81%
Hold 1 Full-Time Job:	67%
Satisfied?:	90%

## Survey Response Rate

All Licensees:	76%
Renewing Practitioners:	98%

## Education

High School/GED:	57%
Associate Degree:	21%

## Job Turnover

Switched Jobs:	4%
Employed over 2 Yrs.:	55%

## Demographics

Female:	85%
Diversity Index:	59%
Median Age:	35

## Finances

Median Inc.:	\$25k-\$30k
Health Insurance:	63%
Under 40 w/ Ed. Debt:	50%

## Primary Roles

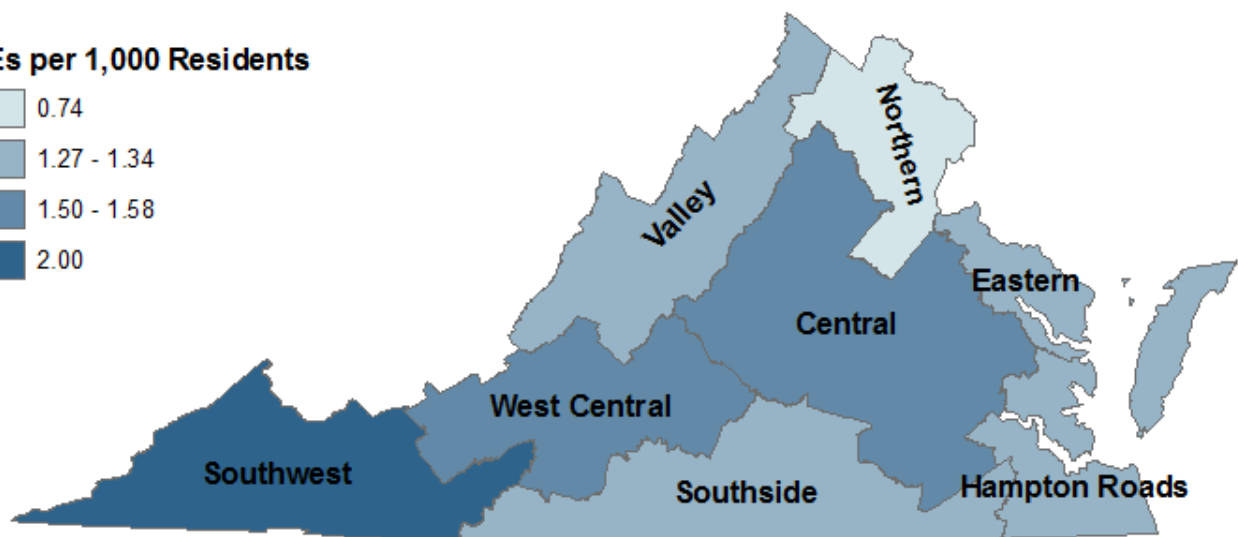
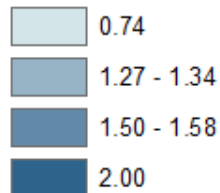
Medication Disp.:	57%
Administration:	5%
Supervision:	2%

Source: Va. Healthcare Workforce Data Center

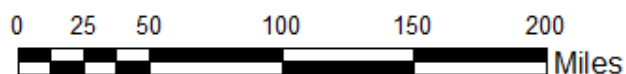
## Full-Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Virginia Performs Region

Source: Va Healthcare Work force Data Center

### FTEs per 1,000 Residents



Annual Estimates of the Resident Population: July 1, 2018  
Source: U.S. Census Bureau, Population Division



This report contains the results of the 2019 Pharmacy Technician Workforce Survey. Nearly 11,000 pharmacy technicians voluntarily took part in this survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacy technicians. These survey respondents represent 76% of the 14,419 pharmacy technicians who are licensed in the state and 98% of renewing practitioners.

The HWDC estimates that 13,366 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 10,277 "full-time equivalency units", which the HWDC defines simply as working 2,000 hours per year.

More than 80% of all pharmacy technicians are female, and the median age of this workforce is 35. In a random encounter between two pharmacy technicians, there is a 59% chance that they would be of different races or ethnicities, a measure known as the diversity index. This makes the pharmacy technician workforce slightly more diverse than the state's overall population, which has a diversity index of 57%. Two out of every five pharmacy technicians grew up in a rural area, and 28% of these professionals currently work in non-metro areas of Virginia. Overall, 14% of Virginia's pharmacy technicians work in non-metro areas of the state.

More than 80% of all pharmacy technicians are currently employed in the profession, two-thirds have one full-time job, and 46% work between 40 and 49 hours per week. As their primary work location, one-third of all pharmacy technicians work at large chain community pharmacies, while another 16% work at the inpatient department of hospitals. The median annual income of pharmacy technicians is between \$25,000 and \$30,000. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 63% who have access to health insurance. Nine out of every ten pharmacy technicians indicate that they are satisfied with their current work situation, including 47% who indicate that they are "very satisfied".

## Summary of Trends

---

In this section, all statistics for the current year are compared to the 2014 pharmacy technician workforce. Overall, the pharmacy technician workforce has not experienced significant changes. Compared to 2014, the number of licensed pharmacy technicians has fallen by 2% (14,419 vs. 14,686). In addition, the size of Virginia's pharmacy technician workforce has fallen by 3% (13,366 vs. 13,783), and the number of FTEs provided by this workforce has fallen by 2% (10,277 vs. 10,487). However, 2019 licensees are more likely to respond to the survey (76% vs. 71%).

Virginia's pharmacy technicians are slightly more likely to be female (85% vs. 84%). At the same time, the diversity index of the state's pharmacy technicians has increased (59% vs. 58%) as well as the median age of this workforce (35 vs. 34). Although pharmacy technicians are slightly less likely to have grown up in a rural area (40% vs. 41%), there has been no change in the percentage of all pharmacy technicians who work in non-metro areas of the state.

Pharmacy technicians are more likely to work in the profession (81% vs. 78%), hold one full-time job (67% vs. 62%), and work between 40 and 49 hours per week (46% vs. 40%). In addition, the rate of underemployment (4% vs. 5%) and involuntary unemployment (1% vs. 2%) have both fallen. Pharmacy technicians are relatively more likely to work in the non-profit sector (17% vs. 13%) relative to the for-profit sector (73% vs. 76%). With respect to establishment types, pharmacy technicians are relatively more likely to work at the inpatient department of hospitals (16% vs. 13%) relative to large chain community pharmacies (33% vs. 36%).

The median annual income of Virginia's pharmacy technician workforce has increased (\$25k-\$30k vs. \$20k-\$25k). In addition, pharmacy technicians are more likely to receive at least one employer-sponsored benefit (81% vs. 76%), including those who have access to health insurance (63% vs. 59%). Pharmacy technicians indicate that they are more satisfied with their current work situation (90% vs. 89%).

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	10,533	73%
New Licensees	1,665	12%
Non-Renewals	2,221	15%
<b>All Licensees</b>	<b>14,419</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

*HWDC surveys tend to achieve very high response rates. Nearly all renewing pharmacy technicians submitted a survey. These represent 76% of all pharmacy technicians who held a license at some point in 2019.*

Definitions

- 1. The Survey Period:** The survey was conducted in December 2019.
- 2. Target Population:** All professionals who held a Virginia license at some point in 2019.
- 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 2019.

Response Rates			
Statistic	Non Respondents	Respondents	Response Rate
<b>By Age</b>			
Under 30	1,565	3,049	66%
30 to 34	549	1,839	77%
35 to 39	399	1,458	79%
40 to 44	261	1,100	81%
45 to 49	199	1,009	84%
50 to 54	157	882	85%
55 to 59	129	749	85%
60 and Over	220	854	80%
<b>Total</b>	<b>3,479</b>	<b>10,940</b>	<b>76%</b>
<b>New Licenses</b>			
Issued in 2019	1,119	546	33%
<b>Metro Status</b>			
Non-Metro	385	1,649	81%
Metro	2,506	8,695	78%
Not in Virginia	588	596	50%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	10,940
Response Rate, All Licensees	76%
Response Rate, Renewals	98%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacy Tech.

Number:	14,419
New:	12%
Not Renewed:	15%

Survey Response Rates

All Licensees:	76%
Renewing Practitioners:	98%

Source: Va. Healthcare Workforce Data Center

## At a Glance:

### Workforce

Pharmacy Tech. Workforce: 13,366  
 FTEs: 10,277

### Utilization Ratios

Licensees in VA Workforce: 93%  
 Licensees per FTE: 1.40  
 Workers per FTE: 1.30

Source: Va. Healthcare Workforce Data Center

Pharmacy Tech. Workforce		
Status	#	%
Worked in Virginia in Past Year	13,144	98%
Looking for Work in Virginia	222	2%
Virginia's Workforce	13,366	100%
Total FTEs	10,277	
Licensees	14,419	

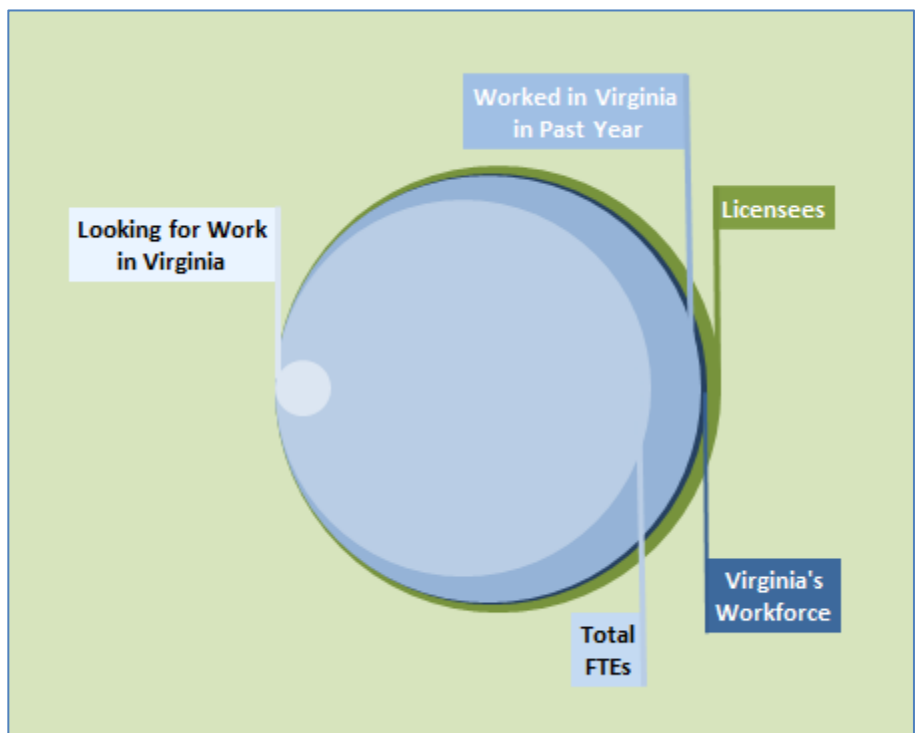
Source: Va. Healthcare Workforce Data Center

## 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.

*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:*

<https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/>



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	698	18%	3,134	82%	3,832	34%
30 to 34	274	15%	1,601	85%	1,876	17%
35 to 39	200	14%	1,208	86%	1,407	12%
40 to 44	155	15%	897	85%	1,052	9%
45 to 49	106	11%	828	89%	934	8%
50 to 54	112	14%	686	86%	798	7%
55 to 59	90	13%	596	87%	686	6%
60 and Over	95	12%	686	88%	781	7%
<b>Total</b>	<b>1,730</b>	<b>15%</b>	<b>9,637</b>	<b>85%</b>	<b>11,366</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacy Techs.		Pharmacy Techs. Under 40	
	%	#	%	#	%
White	61%	6,737	59%	3,961	55%
Black	19%	2,585	23%	1,720	24%
Asian	7%	982	9%	612	9%
Other Race	0%	155	1%	100	1%
Two or More Races	3%	364	3%	288	4%
Hispanic	10%	593	5%	459	6%
<b>Total</b>	<b>100%</b>	<b>11,416</b>	<b>100%</b>	<b>7,140</b>	<b>100%</b>

\*Population data in this chart is from the U.S. Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2018.

Source: Va. Healthcare Workforce Data Center

Among the 63% of pharmacy technicians who are under the age of 40, 84% are female. In addition, the diversity index among these professionals is 62%.

At a Glance:

**Gender**

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

**Age**

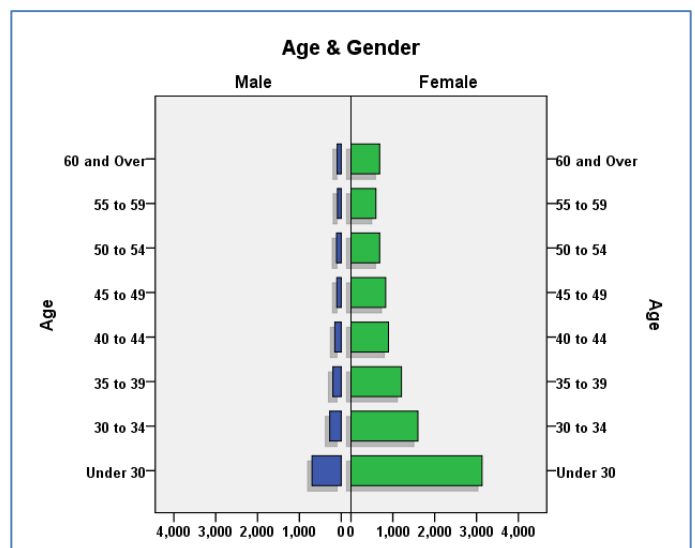
Median Age: 35  
% Under 40: 63%  
% 55 and Over: 13%

**Diversity**

Diversity Index: 59%  
Under 40 Div. Index: 62%

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 or ethnicity (a measure known as the diversity index). For Virginia's population as a whole, the diversity index is 57%.



Source: Va. Healthcare Workforce Data Center

## At a Glance:

### Childhood

Urban Childhood: 20%  
Rural Childhood: 40%

### Virginia Background

HS in Virginia: 73%  
HS in Va., Past 5 Years: 71%

### Location Choice

% Work Non-Metro: 14%  
% Rural to Non-Metro: 28%  
% Urban/Suburban to Non-Metro: 5%

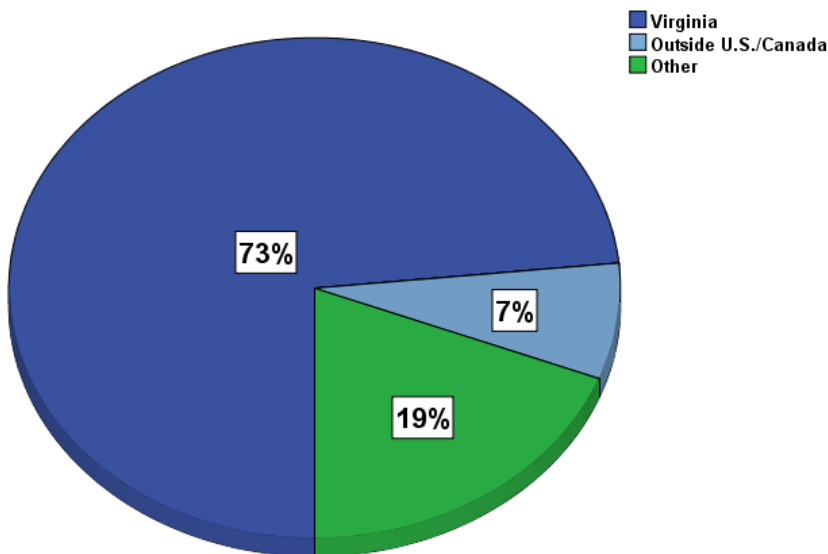
Source: Va. Healthcare Workforce Data Center

## A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
<b>Metro Counties</b>				
1	Metro, 1 Million+	24%	50%	26%
2	Metro, 250,000 to 1 Million	59%	30%	11%
3	Metro, 250,000 or Less	62%	28%	10%
<b>Non-Metro Counties</b>				
4	Urban Pop., 20,000+, Metro Adjacent	64%	27%	9%
6	Urban Pop., 2,500-19,999, Metro Adjacent	81%	11%	8%
7	Urban Pop., 2,500-19,999, Non-Adjacent	92%	5%	3%
8	Rural, Metro Adjacent	84%	13%	3%
9	Rural, Non-Adjacent	75%	19%	7%
<b>Overall</b>		<b>40%</b>	<b>40%</b>	<b>20%</b>

Source: Va. Healthcare Workforce Data Center

## High School Location



Source: Va. Healthcare Workforce Data Center

Two out of every five pharmacy technicians grew up in self-described rural areas, and 28% of these professionals currently work in non-metro counties. Overall, 14% of pharmacy technicians are 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	#
1	Virginia	8,264	Virginia	3,228
2	Outside U.S./Canada	844	Outside U.S./Canada	315
3	New York	196	North Carolina	98
4	North Carolina	191	Maryland	84
5	Maryland	171	New York	82
6	West Virginia	149	Florida	70
7	Florida	148	New Jersey	64
8	Pennsylvania	142	Pennsylvania	59
9	New Jersey	125	West Virginia	58
10	California	109	California	50

Source: Va. Healthcare Workforce Data Center

Nearly 75% of pharmacy technicians received their high school diploma in Virginia. Among those pharmacy technicians who received their initial license in the past five years, 71% also received their high school degree in the state.

Among all Virginia's licensed pharmacy technicians, 7% did not participate in the state's workforce in 2019. However, 84% of these professionals worked at some point in the past year, including 65% who currently work as pharmacy technicians.

### At a Glance:

#### Not in VA Workforce

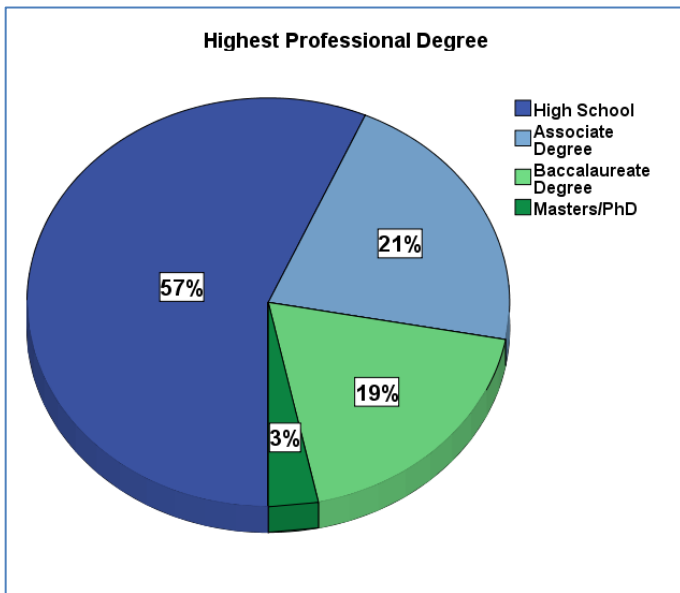
Total:	1,045
% of Licensees:	7%
Federal/Military:	5%
Va. Border State/D.C.:	37%

Source: Va. Healthcare Workforce Data Center

**A Closer Look:**

Highest Professional Degree		
Degree	#	%
High School/GED	6,287	57%
Associate	2,370	21%
Baccalaureate	2,083	19%
Masters	342	3%
PhD	28	0%
<b>Total</b>	<b>11,111</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Nearly 40% of all pharmacy technicians currently carry education debt, including 50% of those under the age of 40. For those with education debt, the median amount is between \$16,000 and \$18,000.

## At a Glance:

**Education**

High School/GED: 57%

Associate Degree: 21%

**Education Debt**

Carry Debt: 39%

Under Age 40 w/ Debt: 50%

Median Debt: \$16k-\$18k

Source: Va. Healthcare Workforce Data Center

Nearly 60% of pharmacy technicians hold either a high school degree or a GED as their highest professional degree.

Amount Carried	Education Debt			
	All Pharm. Tech.		Pharm. Tech. Under 40	
	#	%	#	%
<b>None</b>	5,474	61%	2,801	50%
<b>Less than \$10,000</b>	1,142	13%	915	16%
<b>\$10,000-\$19,999</b>	742	8%	596	11%
<b>\$20,000-\$29,999</b>	560	6%	461	8%
<b>\$30,000 or More</b>	1,104	12%	843	15%
<b>Total</b>	<b>9,022</b>	<b>100%</b>	<b>5,616</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center



## At a Glance:

### Top Certifications

PTCB:	65%
ExCPT:	10%
Total w/ Cert.:	74%

### National Certifications

Required:	53%
Pay Raise w/ Cert.:	44%

Source: Va. Healthcare Workforce Data Center

## Professional Certifications

Certification	#	% of Workforce
<b>Pharmacy Technician Certification (PTCB)</b>	8,664	65%
<b>Exam for Certification of Pharmacy Technicians (ExCPT)</b>	1,290	10%
<b>Total with Certification</b>	<b>9,954</b>	<b>74%</b>

Source: Va. Healthcare Workforce Data Center

Nearly three-quarters of Virginia's pharmacy technician workforce hold a professional certification, including 65% who have a Pharmacy Technician Certification (PTCB).

More than half of all pharmacy technicians work for an employer that requires a national certification as a condition of employment. Meanwhile, 44% of pharmacy technicians work for an employer that offers a pay raise for those who have earned a national certification.

## National Certifications

Required for Employment?	#	%
<b>Yes</b>	5,839	53%
<b>No</b>	5,128	47%
Pay Raise with Certification?	#	%
<b>Yes</b>	4,245	44%
<b>No</b>	4,668	48%
<b>No Certification Held</b>	818	8%

Source: Va. Healthcare Workforce Data Center

## At a Glance:

### Employment

Employed in Profession: 81%  
 Involuntarily Unemployed: 1%

### Positions Held

1 Full-Time: 67%  
 2 or More Positions: 9%

### Weekly Hours:

40 to 49: 46%  
 60 or More: 3%  
 Less than 30: 17%

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

Current Work Status		
Status	#	%
Employed, Capacity Unknown	9	< 1%
Employed in a Pharmacy Technician-Related Capacity	8,991	81%
Employed, NOT in a Pharmacy Technician-Related Capacity	1,689	15%
Not Working, Reason Unknown	0	0%
Involuntarily Unemployed	79	1%
Voluntarily Unemployed	286	3%
Retired	47	< 1%
<b>Total</b>	<b>11,100</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

*More than 80% of all pharmacy technicians are currently employed in the profession, while only 1% are involuntarily unemployed. In addition, 67% of all pharmacy technicians currently hold one full-time job, and 46% work between 40 and 49 hours per week.*

Current Positions		
Positions	#	%
No Positions	412	4%
One Part-Time Position	2,206	20%
Two Part-Time Positions	166	2%
One Full-Time Position	7,336	67%
One Full-Time Position & One Part-Time Position	757	7%
Two Full-Time Positions	30	0%
More than Two Positions	37	0%
<b>Total</b>	<b>10,944</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 Hours	412	4%
1 to 9 Hours	396	4%
10 to 19 Hours	542	5%
20 to 29 Hours	883	8%
30 to 39 Hours	2,830	26%
40 to 49 Hours	4,873	46%
50 to 59 Hours	425	4%
60 to 69 Hours	137	1%
70 to 79 Hours	63	1%
80 or More Hours	125	1%
<b>Total</b>	<b>10,686</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	141	3%
Less than \$10,000	512	10%
\$10,000-\$14,999	351	7%
\$15,000-\$19,999	369	7%
\$20,000-\$24,999	682	14%
\$25,000-\$29,999	663	13%
\$30,000-\$34,999	794	16%
\$35,000-\$39,999	544	11%
\$40,000-\$44,999	444	9%
\$45,000-\$49,999	219	4%
\$50,000 or More	313	6%
<b>Total</b>	<b>5,032</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Annual Income**  
Median Income: \$25k-30k

**Benefits**  
Health Insurance: 63%  
Retirement: 57%

**Satisfaction**  
Satisfied: 90%  
Very Satisfied: 47%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	5,140	47%
Somewhat Satisfied	4,632	43%
Somewhat Dissatisfied	785	7%
Very Dissatisfied	343	3%
<b>Total</b>	<b>10,899</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician earns between \$25,000 and \$30,000 per year. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 63% who have access to health insurance.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Leave	5,797	64%	58%
Health Insurance	5,647	63%	57%
Dental Insurance	5,447	61%	55%
Retirement	5,132	57%	52%
Group Life Insurance	3,163	35%	32%
Signing/Retention Bonus	345	4%	3%
<b>At Least One Benefit</b>	<b>7,257</b>	<b>81%</b>	<b>73%</b>

\*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 . . . ?	#	%
Work Two or More Positions at the Same Time?	1,394	10%
Switch Employers or Practices?	589	4%
Work Part-Time or Temporary Positions, but Would Have Preferred a Full-Time/Permanent Position?	471	4%
Experience Voluntary Unemployment?	403	3%
Experience Involuntary Unemployment?	119	1%
<b>Experienced At Least One</b>	<b>2,461</b>	<b>18%</b>

Source: Va. Healthcare Workforce Data Center

*Only 1% of pharmacy technicians were involuntarily unemployed at some point in the past year. For comparison, Virginia's average monthly unemployment rate was 2.8%.<sup>1</sup>*

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at This Location	273	3%	216	11%
Less than 6 Months	927	9%	237	12%
6 Months to 1 Year	1,000	10%	246	13%
1 to 2 Years	2,380	23%	406	21%
3 to 5 Years	2,614	25%	385	20%
6 to 10 Years	1,288	13%	217	11%
More than 10 Years	1,798	17%	249	13%
<b>Subtotal</b>	<b>10,280</b>	<b>100%</b>	<b>1,956</b>	<b>100%</b>
Did Not Have Location	585		11,187	
Item Missing	2,502		224	
<b>Total</b>	<b>13,366</b>		<b>13,366</b>	

Source: Va. Healthcare Workforce Data Center

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

**At a Glance:**

**Unemployment Experience**

Involuntarily Unemployed: 1%  
Underemployed: 4%

**Turnover & Tenure**

Switched: 4%  
New Location: 23%  
Over 2 Years: 55%  
Over 2 Yrs., 2<sup>nd</sup> Location: 44%

**Employment Type**

Hourly Wage: 91%

Source: Va. Healthcare Workforce Data Center

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

Employment Type		
Primary Work Site	#	%
Hourly Wage	8,852	91%
Salary/Commission	719	7%
By Contract/Per Diem	43	0%
Unpaid	43	0%
Business/Practice Income	20	0%
<b>Subtotal</b>	<b>9,678</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

<sup>1</sup> As reported by the U.S. Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fluctuated between a low of 2.4% and a high of 3.2%. The unemployment rate from December 2019 was still preliminary at the time of publication.

## At a Glance:

### Concentration

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

### Locations

2 or More (Past Year):	21%
2 or More (Now*):	17%

Source: Va. Healthcare Workforce Data Center

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

## A Closer Look:

Regional Distribution of Work Locations				
Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	2,462	24%	485	23%
Hampton Roads	2,229	22%	468	23%
Northern	2,214	22%	473	23%
West Central	1,139	11%	208	10%
Southwest	763	7%	135	7%
Valley	679	7%	113	5%
Southside	448	4%	67	3%
Eastern	203	2%	34	2%
Virginia Border State/D.C.	20	0%	29	1%
Other U.S. State	23	0%	45	2%
Outside of the U.S.	1	0%	10	0%
<b>Total</b>	<b>10,181</b>	<b>100%</b>	<b>2,067</b>	<b>100%</b>
Item Missing	2,601		113	

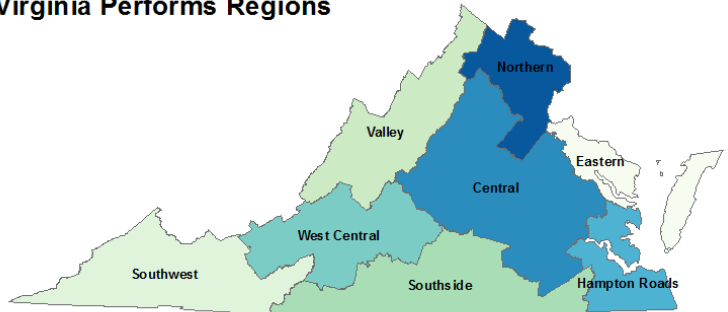
Source: Va. Healthcare Workforce Data Center

Number of Work Locations				
Locations	Work Locations in Past Year		Work Locations Now*	
	#	%	#	%
0	222	2%	404	4%
1	8,065	77%	8,250	79%
2	1,353	13%	1,148	11%
3	673	6%	576	6%
4	49	1%	28	0%
5	20	0%	10	0%
6 or More	59	1%	26	0%
<b>Total</b>	<b>10,441</b>	<b>100%</b>	<b>10,441</b>	<b>100%</b>

\*At the time of survey completion, December 2019.

Source: Va. Healthcare Workforce Data Center

### Virginia Performs Regions



*Nearly one in five pharmacy technicians currently have multiple work locations, while 21% have had multiple work locations at some point in the past year.*

**A Closer Look:**

Sector	Location Sector			
	Primary Location		Secondary Location	
	#	%	#	%
<b>For-Profit</b>	6,991	73%	1,280	72%
<b>Non-Profit</b>	1,625	17%	276	16%
<b>State/Local Government</b>	631	7%	129	7%
<b>Veterans Administration</b>	51	1%	5	0%
<b>U.S. Military</b>	201	2%	43	2%
<b>Other Federal Gov't</b>	134	1%	33	2%
<b>Total</b>	<b>9,633</b>	<b>100%</b>	<b>1,766</b>	<b>100%</b>
<b>Did Not Have Location</b>	585		11,187	
<b>Item Missing</b>	3,148		413	

Source: Va. Healthcare Workforce Data Center

## At a Glance: (Primary Locations)

**Sector**

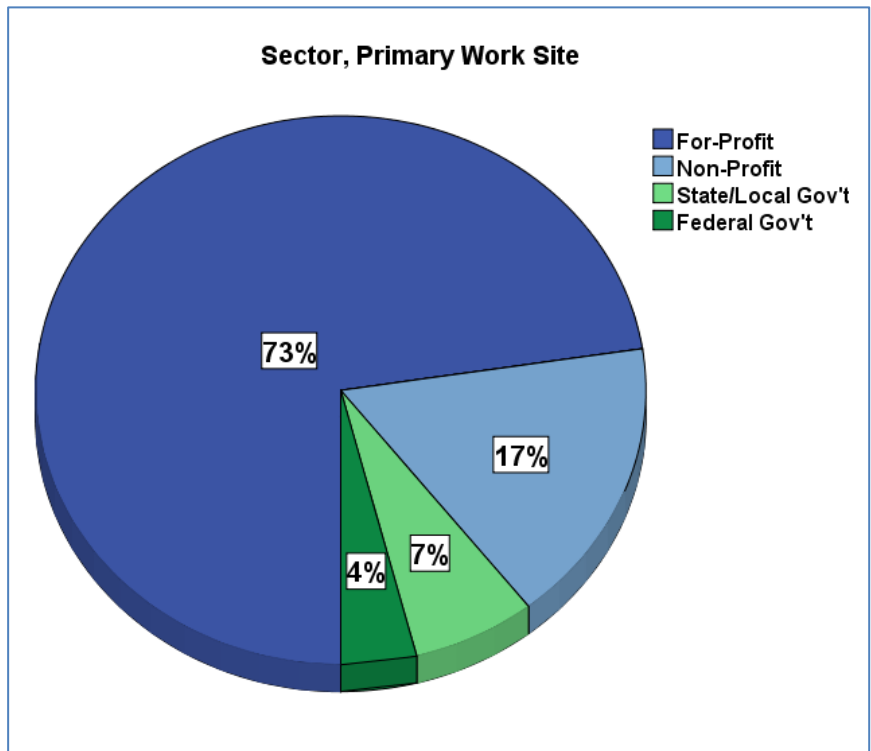
For Profit:	73%
Federal:	4%

**Top Establishments**

Large Chain Pharmacy: (11+ Stores)	33%
Hospital/Health System: (Inpatient)	16%
Independent Pharmacy: (1-4 Stores)	10%

Source: Va. Healthcare Workforce Data Center

Nine out of every ten pharmacy technicians work in the private sector, including 73% who work in a for-profit establishment. Another 7% of pharmacy technicians work for a state or local government.



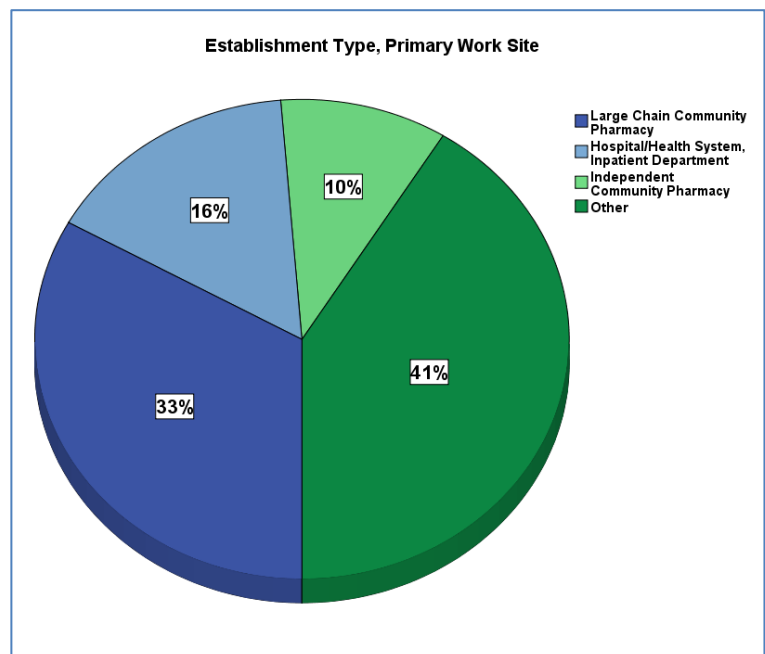
Source: Va. Healthcare Workforce Data Center

Location Type				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy (11+ Stores)	3,148	33%	606	35%
Hospital/Health System, Inpatient Department	1,487	16%	218	13%
Independent Community Pharmacy (1-4 Stores)	963	10%	150	9%
Supermarket Pharmacy	775	8%	119	7%
Hospital/Health System, Outpatient Department	607	6%	73	4%
Mass Merchandiser (i.e. Big Box Store)	365	4%	53	3%
Nursing Home/Long-Term Care	411	4%	48	3%
Clinic-Based Pharmacy	299	3%	55	3%
Pharmacy Benefit Administration (e.g. PBM, Managed Care)	217	2%	15	1%
Home Health/Infusion	122	1%	30	2%
Small Chain Community Pharmacy (5-10 Stores)	103	1%	30	2%
Mail Service Pharmacy	103	1%	13	1%
Academic Institution	64	1%	33	2%
Manufacturer	44	0%	7	0%
Wholesale Distributor	35	0%	2	0%
Other	769	8%	279	16%
<b>Total</b>	<b>9,512</b>	<b>100%</b>	<b>1,731</b>	<b>100%</b>
<b>Did Not Have Location</b>	<b>585</b>		<b>11,187</b>	

*One-third of all pharmacy technicians in Virginia work in large chain community pharmacies, while another 16% work in the inpatient department of hospitals.*

Source: Va. Healthcare Workforce Data Center

*For pharmacy technicians who also have a secondary work location, 35% are employed by large chain community pharmacies, while 13% are employed at the inpatient department of hospitals.*



Source: Va. Healthcare Workforce Data Center

## At a Glance: (Primary Locations)

### Typical Time Allocation

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

### Roles

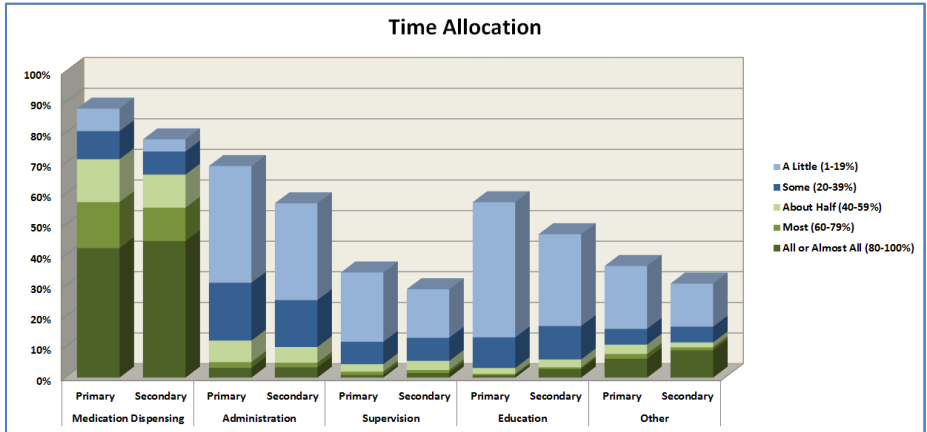
Medication Disp.: 57%  
Administration: 5%  
Supervision: 2%  
Education: 1%

### Patient Care Pharm. 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

Nearly 60% of all 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	
<b>All or Almost All (80-100%)</b>	42%	45%	3%	3%	1%	2%	1%	3%	6%	9%	
<b>Most (60-79%)</b>	15%	11%	2%	2%	1%	1%	0%	1%	2%	1%	
<b>About Half (40-59%)</b>	14%	11%	7%	5%	2%	3%	2%	3%	3%	2%	
<b>Some (20-39%)</b>	9%	8%	19%	15%	7%	8%	10%	11%	5%	5%	
<b>A Little (1-19%)</b>	7%	4%	38%	32%	23%	16%	44%	30%	21%	14%	
<b>None (0%)</b>	12%	22%	31%	43%	66%	71%	43%	53%	64%	69%	

Source: Va. Healthcare Workforce Data Center



**A Closer Look:**

Retirement Expectations				
Expected Retirement Age	All		50 and Over	
	#	%	#	%
<b>Under Age 50</b>	2,107	24%	-	-
<b>50 to 54</b>	417	5%	24	1%
<b>55 to 59</b>	508	6%	100	6%
<b>60 to 64</b>	1,411	16%	428	24%
<b>65 to 69</b>	2,205	25%	766	43%
<b>70 to 74</b>	554	6%	210	12%
<b>75 to 79</b>	142	2%	56	3%
<b>80 and Over</b>	115	1%	22	1%
<b>I Do Not Intend to Retire</b>	1,271	15%	178	10%
<b>Total</b>	<b>8,730</b>	<b>100%</b>	<b>1,784</b>	<b>100%</b>

Source: Va. Healthcare Workforce Data Center

**At a Glance:**

**Retirement Expectations**

**All Pharmacy Technicians**

Under 65: 51%

Under 60: 35%

**Pharm. Tech. 50 and Over**

Under 65: 31%

Under 60: 7%

**Time Until Retirement**

Within 2 Years: 4%

Within 10 Years: 14%

Half the Workforce: By 2049

Source: Va. Healthcare Workforce Data Center

*More than half of all pharmacy technicians expect to retire by the age of 65. Among pharmacy technicians who are age 50 and over, 31% expect to retire by the age of 65.*

*Within the next two years, 20% of all pharmacy technicians expect to pursue additional educational opportunities, and 7% expect to increase their patient care hours.*

**Future Plans**

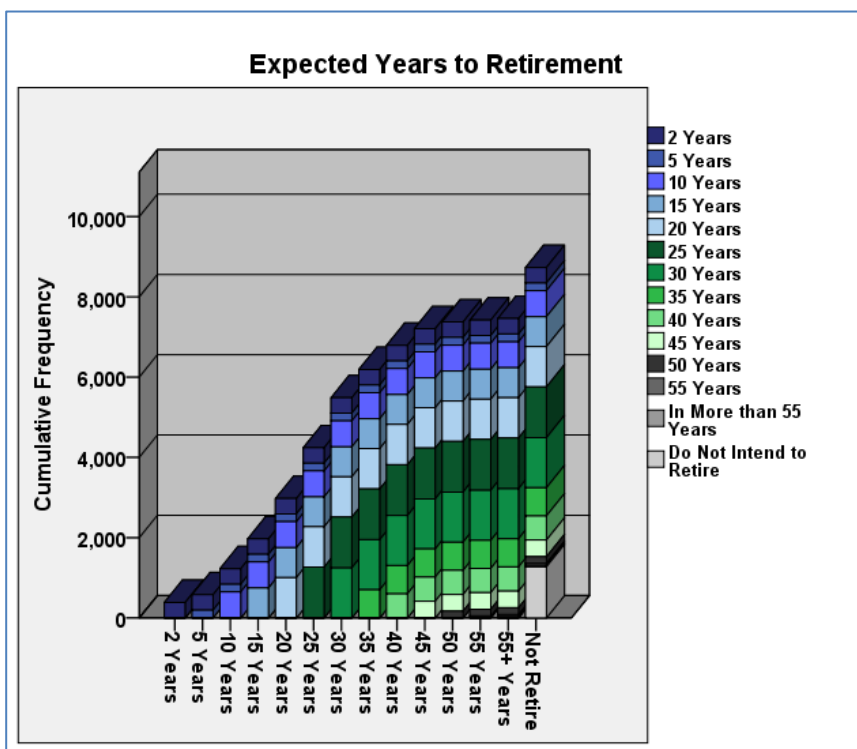
Two-Year Plans:	#	%
<b>Decrease Participation</b>		
<b>Leave Profession</b>	1,226	9%
<b>Leave Virginia</b>	516	4%
<b>Decrease Patient Care Hours</b>	203	2%
<b>Decrease Teaching Hours</b>	108	1%
<b>Increase Participation</b>		
<b>Pursue Additional Education</b>	2,608	20%
<b>Increase Patient Care Hours</b>	912	7%
<b>Increase Teaching Hours</b>	698	5%
<b>Return to the Workforce</b>	121	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 expect to retire in the next two years, while 14% expect to retire within the next ten years. Half of the current workforce expect to retire by 2049.

Time to Retirement			
Expect to Retire Within . . .	#	%	Cumulative %
2 Years	385	4%	4%
5 Years	193	2%	7%
10 Years	648	7%	14%
15 Years	745	9%	23%
20 Years	1,005	12%	34%
25 Years	1,265	14%	49%
30 Years	1,247	14%	63%
35 Years	702	8%	71%
40 Years	602	7%	78%
45 Years	415	5%	83%
50 Years	168	2%	84%
55 Years	47	1%	85%
In More than 55 Years	37	0%	85%
Do Not Intend to Retire	1,271	15%	100%
<b>Total</b>	<b>8,730</b>	<b>100%</b>	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2039. Retirement will peak at 14% of the current workforce around 2044 before declining to below 10% of the current workforce again around 2054.

## At a Glance:

### FTEs

Total: 10,277  
 FTEs/1,000 Residents<sup>2</sup>: 1.207  
 Average: 0.80

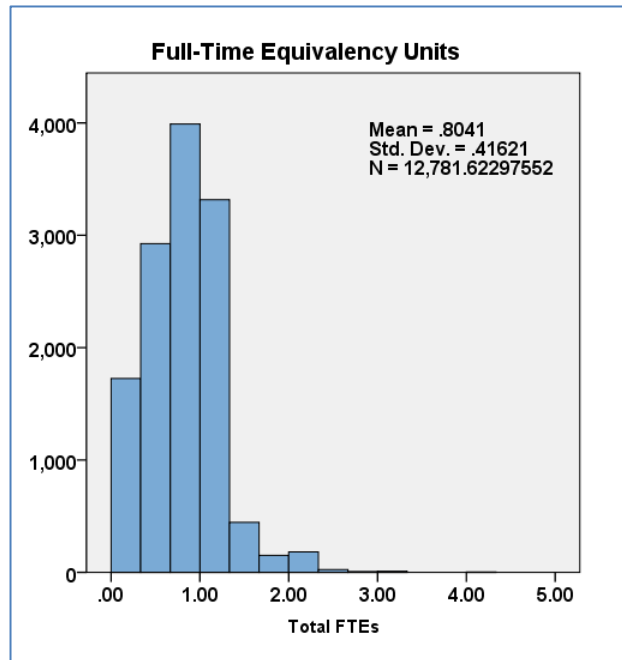
### Age & Gender Effect

Age, Partial Eta<sup>3</sup>: Small  
 Gender, Partial Eta<sup>3</sup>: Negligible

*Partial Eta<sup>3</sup> Explained:*  
 Partial Eta<sup>3</sup> is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

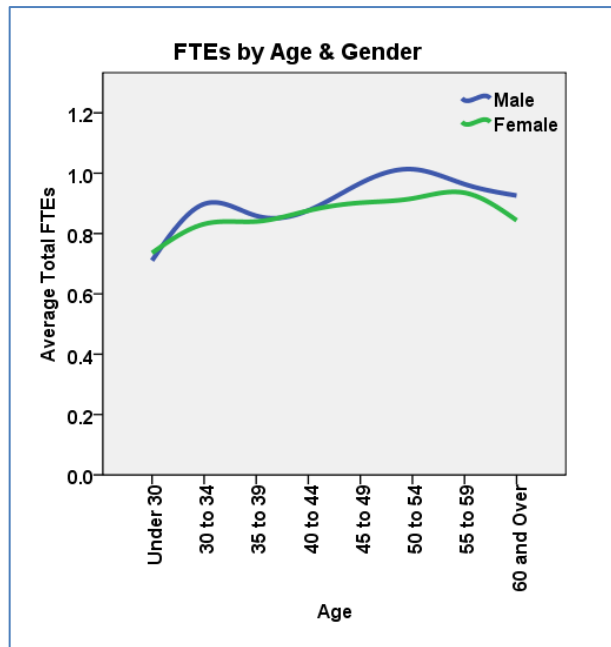


Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.81 FTEs in 2019, or approximately 32 hours per week for 50 weeks. Although FTEs appear to vary by age and gender, statistical tests did not verify that a difference exists.<sup>3</sup>

Full-Time Equivalency Units		
	Average	Median
<b>Age</b>		
Under 30	0.71	0.67
30 to 34	0.83	0.82
35 to 39	0.80	0.80
40 to 44	0.84	0.88
45 to 49	0.88	0.86
50 to 54	0.88	0.92
55 to 59	0.96	1.05
60 and Over	0.83	0.80
<b>Gender</b>		
Male	0.83	0.91
Female	0.82	0.89

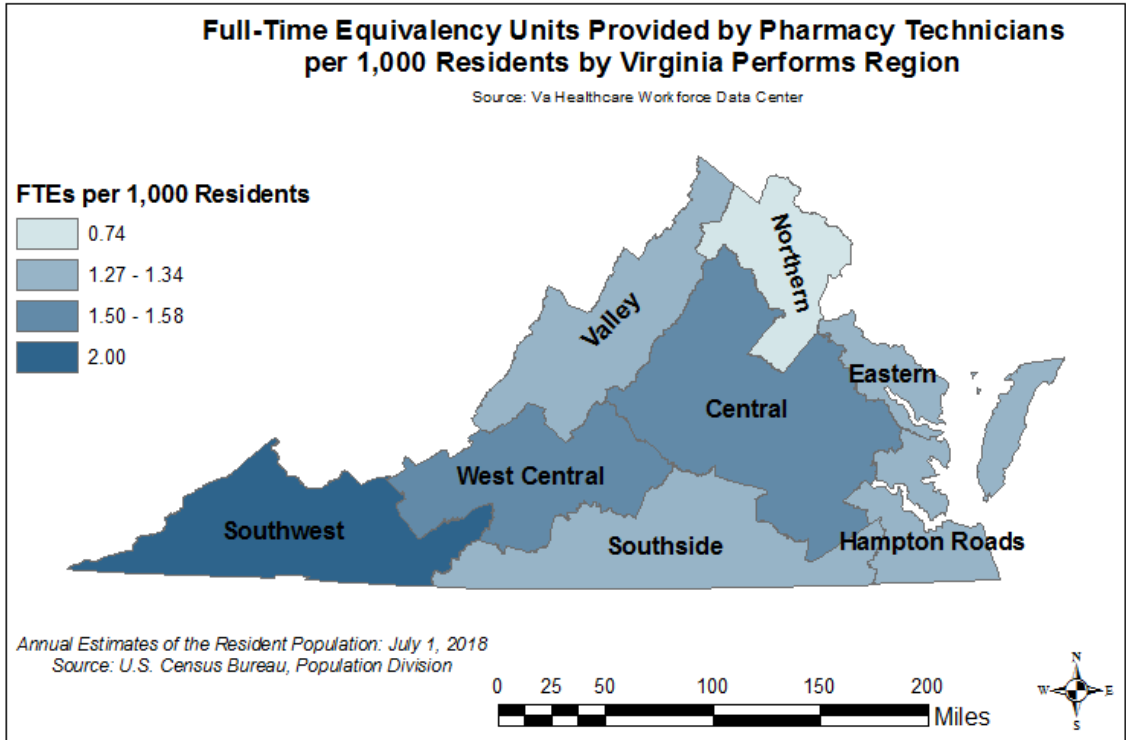
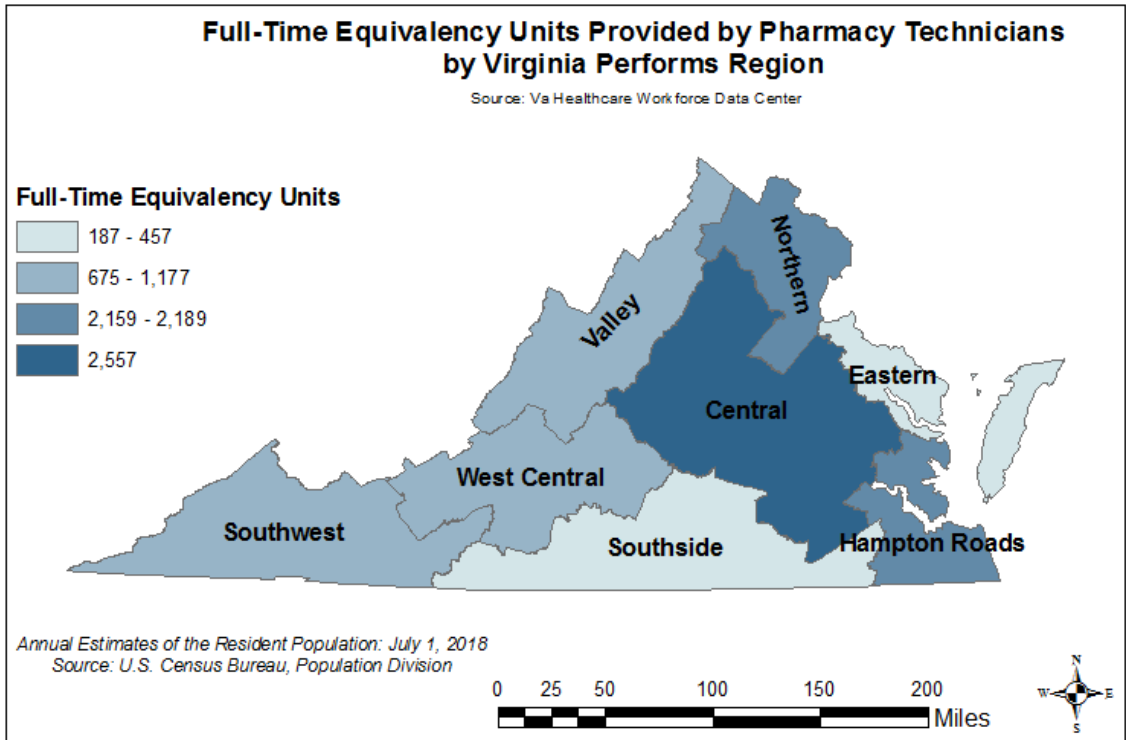
Source: Va. Healthcare Workforce Data Center

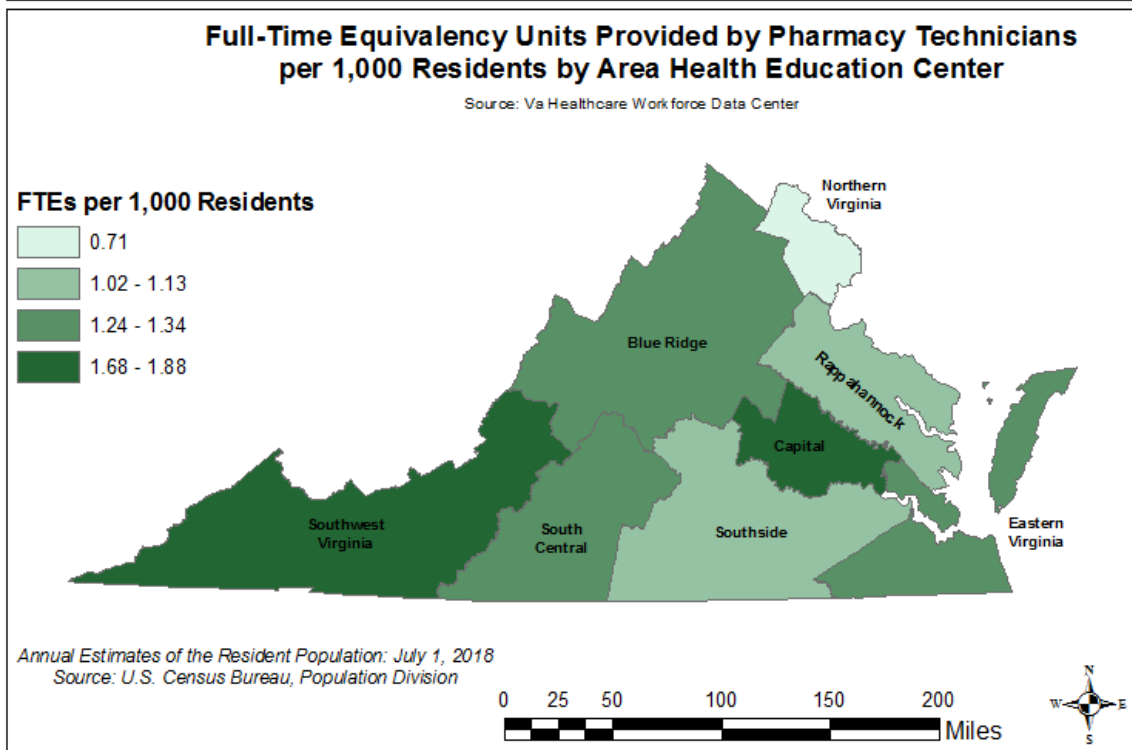
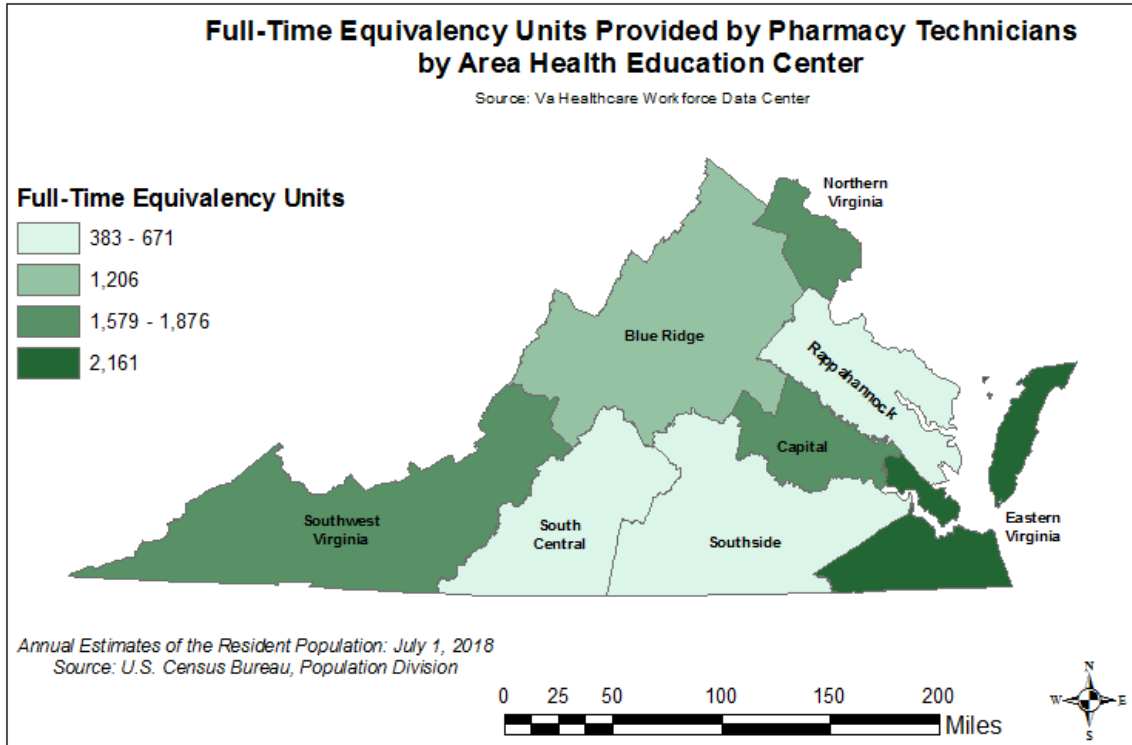


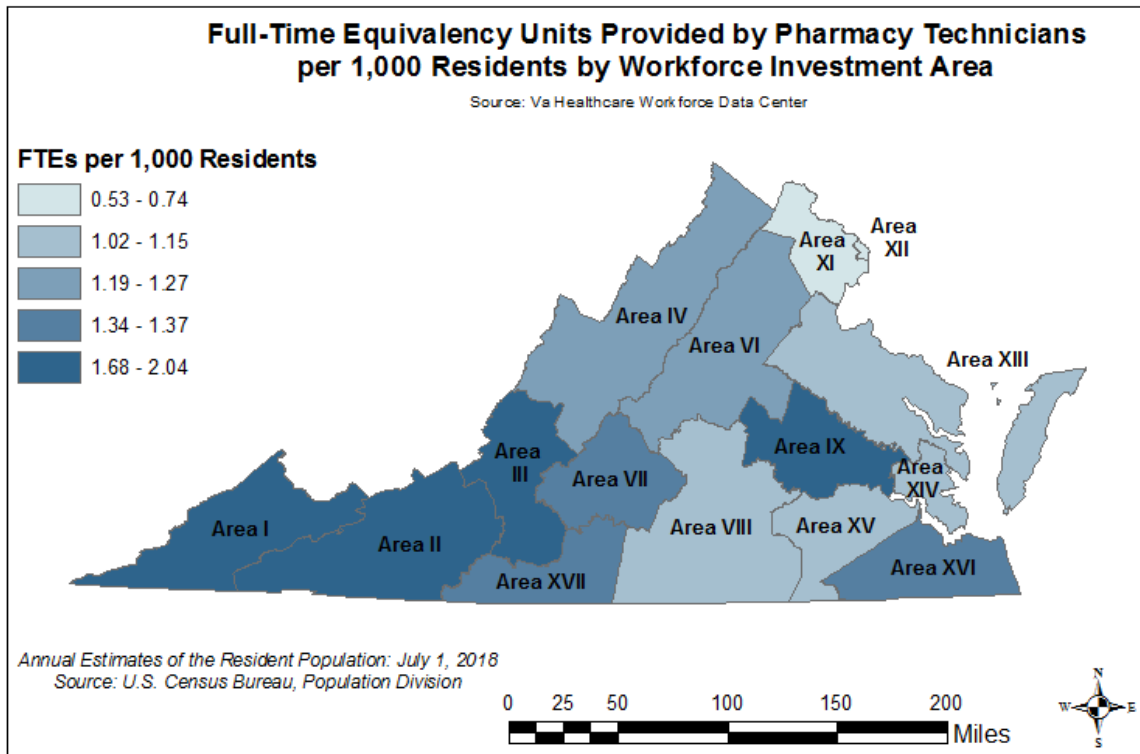
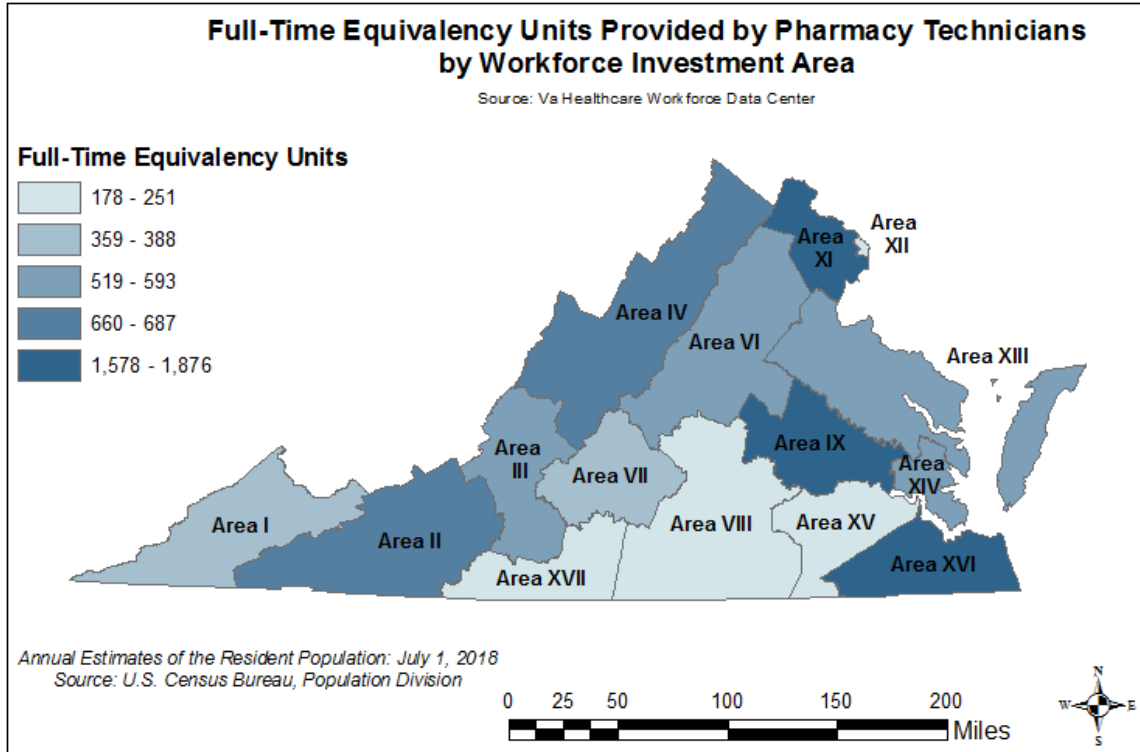
Source: Va. Healthcare Workforce Data Center

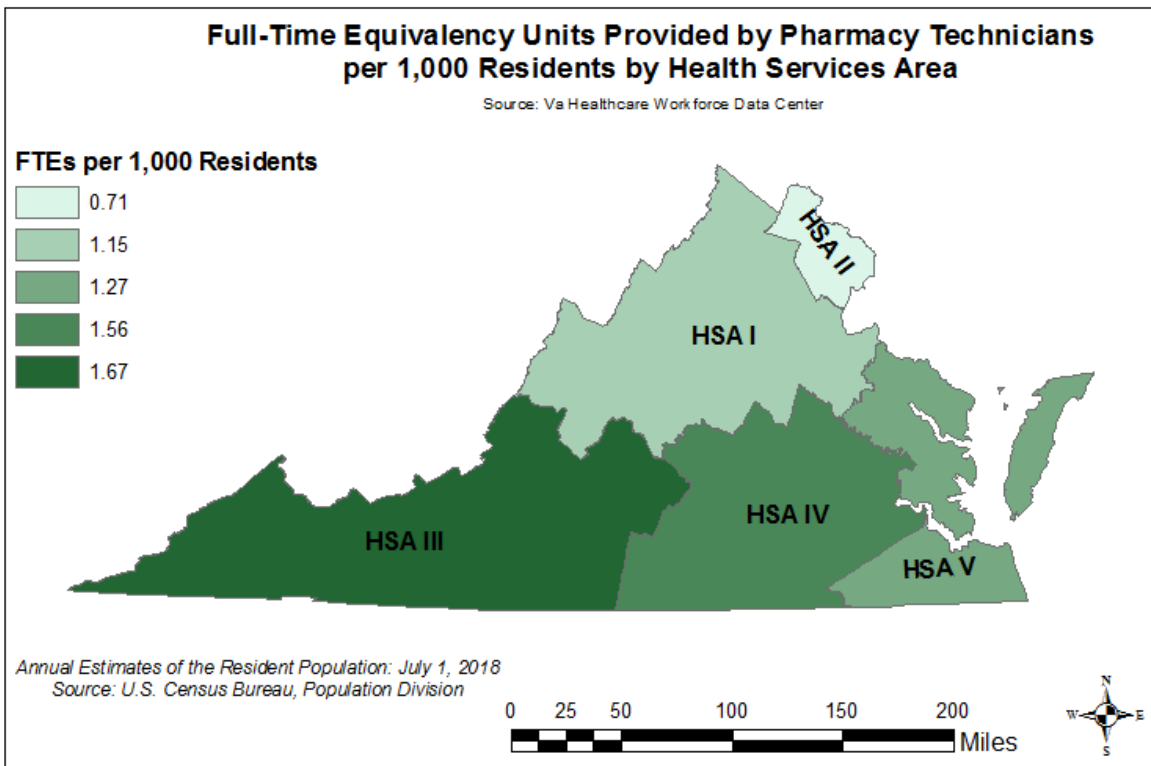
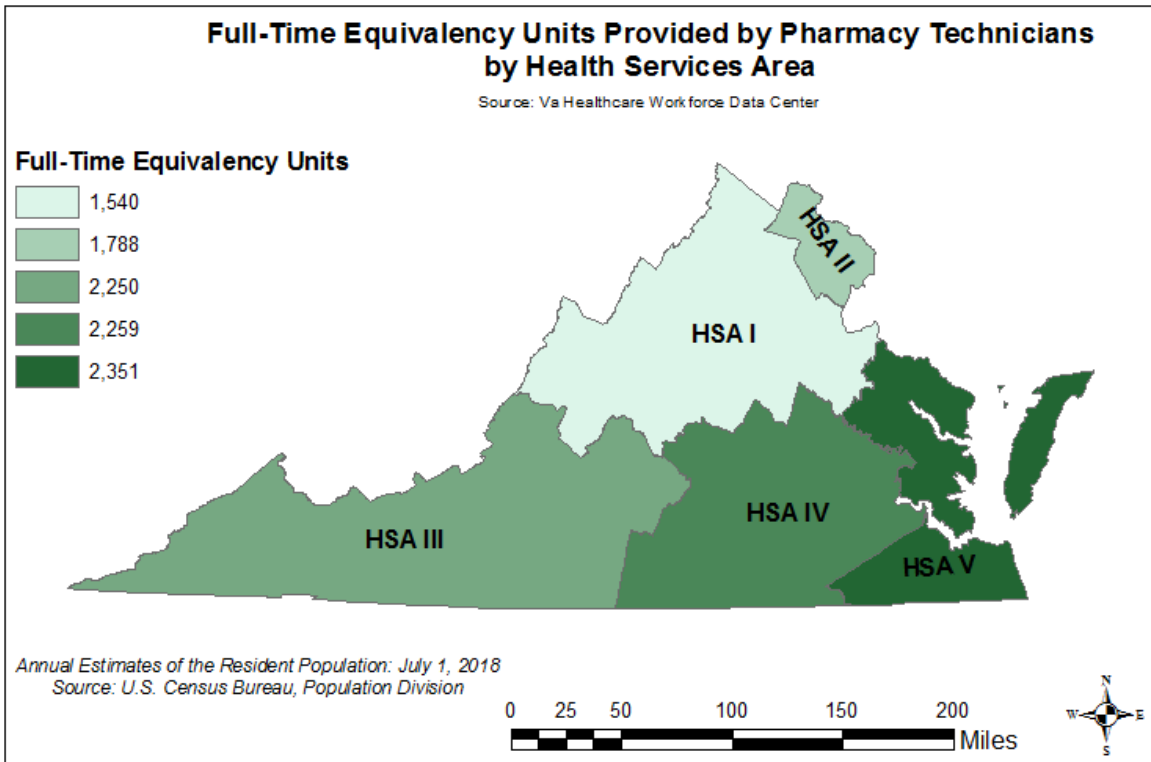
<sup>2</sup> Number of residents in 2018 was used as the denominator.

<sup>3</sup> Due to assumption violations in Mixed between-within ANOVA (Levene's Test was significant).













## Appendix

### Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
<b>Metro, 1 Million+</b>	8,613	77.17%	1.295773	1.152454	1.487754
<b>Metro, 250,000 to 1 Million</b>	1,292	81.04%	1.234002	1.097516	1.416831
<b>Metro, 250,000 or Less</b>	1,296	77.24%	1.294705	1.151505	1.486529
<b>Urban Pop., 20,000+, Metro Adj.</b>	307	81.76%	1.223108	1.087826	1.404323
<b>Urban Pop., 20,000+, Non-Adj.</b>	0	NA	NA	NA	NA
<b>Urban Pop., 2,500-19,999, Metro Adj.</b>	711	81.29%	1.230104	1.094049	1.412356
<b>Urban Pop., 2,500-19,999, Non-Adj.</b>	512	80.08%	1.24878	1.11066	1.4338
<b>Rural, Metro Adj.</b>	288	78.82%	1.268722	1.128396	1.456696
<b>Rural, Non-Adj.</b>	216	84.72%	1.180328	1.049778	1.355205
<b>Virginia Border State/D.C.</b>	755	57.35%	1.743649	1.550793	2.001988
<b>Other U.S. State</b>	429	38.00%	2.631902	2.340801	3.021844

Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
<b>Under 30</b>	4,614	66.08%	1.513283	1.355205	3.021844
<b>30 to 34</b>	2,388	77.01%	1.298532	1.162887	2.593012
<b>35 to 39</b>	1,857	78.51%	1.273663	1.140615	2.543351
<b>40 to 44</b>	1,361	80.82%	1.237273	1.108027	2.470685
<b>45 to 49</b>	1,208	83.53%	1.197225	1.072162	2.390714
<b>50 to 54</b>	1,039	84.89%	1.178005	1.05495	2.352333
<b>55 to 59</b>	878	85.31%	1.17223	1.049778	2.340801
<b>60 and Over</b>	1,074	79.52%	1.257611	1.126241	2.511298

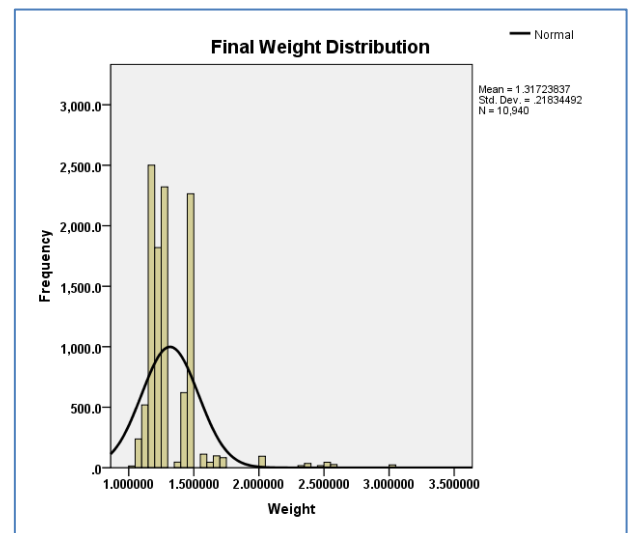
Source: Va. Healthcare Workforce Data Center

See the Methods section on the HWDC website for details on HWDC Methods:  
<https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/>

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

$$\text{Age Weight} \times \text{Rural Weight} \times \text{Response Rate} = \text{Final Weight.}$$

**Overall Response Rate: 0.758721**



Source: Va. Healthcare Workforce Data Center