



# 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

*June 16, 2020 Virtual 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> Cindy Warriner, Chairman	
• Welcome & Roll Call	
• Reading of Emergency Evacuation Script	
<b>Public Hearing:</b>	
• Delivery of Dispensed Prescriptions; Labeling	10-22
<b>Adjournment of Public Hearing</b>	
<b>Call to Order of Full Board Meeting:</b> Cindy Warriner, Chairman	
• Approval of Agenda	
<b>Approval of Previous Board Meeting Minutes:</b>	
o May 18, 2020, Virtual Full Board Meeting and Public Hearings on Scheduling Actions	1-9
<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	
• Update on Regulatory/Policy Actions Resulting from 2020 General Assembly	23-24
• Report of Regulatory Actions	25-26
• Adopt Exempt Regulations for Pharmaceutical Processors	27-69
• Consider Petition for Rulemaking to Amend 18VAC110-20-276 to Allow Remote Order Processing by Pharmacy Technicians Outside of a Pharmacy	70-80
• Consider Adoption of Fast-track Regulation to Allow Volunteer CE to Satisfy Live CE Requirement	81-83
• Adoption of Emergency Regulations for Limited-Use License and Permit for Non-Profit Facilities	84-89
• Adopt Guidance Document 110-49 <i>Credentials for Nonresident Pharmacies Dispensing Only for Animals</i>	90-92
• Adopt Guidance Document 110-48 <i>Verification Sources for a Pharmaceutical Processor</i>	93-96

- Amend Guidance Documents 110-4, 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, 110-35 97-151
- Repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40 152-158
- Request to Amend Guidance Document 110-39 *Guidance for Continuous Hours Worked by Pharmacists and Breaks* 159-160
- Request for Guidance for Granting Exception to Minimum Two Years' Experience for PIC Eligibility 161-163
- Request to Amend Regulation to Extend Change of PIC Timeframe from 14 to 30 Days 164-166

**Old Business:**

- Consideration for Requiring CE on a Specific Topic in 2021 167-168
- Verbal Update on Action Item from December 2019 Board Meeting regarding Virginia Immunization Information System

**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 169  
Confidential  
Handout
- ADA examination accommodation request Confidential  
Handout
- Elections for Chairman and Vice Chairman

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- Report on Board of Health Professions – Ryan Logan 171-181
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- Report on Pharmaceutical Processors – Annette Kelley 210
- 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 and will honor former board member Rafael Saenz.\*\***

## Virginia Board of Pharmacy

### **Instructions for Accessing June 16, 2020 Virtual Public Hearing/Full Board Meeting and Providing Public Comment**

- **Access:** Perimeter Center building access remains restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Disregard any reference to the Board of Dentistry as a shared subscription to WebEx is being utilized. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov) **no later than 8am on June 16, 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.
- Public participation connections will be muted following the public comment periods.
- Should the Board enter into a closed session, public participants will be blocked from seeing and hearing the discussion. When the Board re-enters into open session, public participation connections to see and hear the discussions will be restored.
- Please call 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 BY AUDIO ONLY**

+1-408-418-9388

Meeting number (access code): 132 086 1167

Meeting password: Pharmacy123! (74276229 from phones and video systems)

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

**Click or copy one of the links below:**

[Join Meeting](#)

<https://virginia-dhp.my.webex.com/virginia-dhp.my/j.php?MTID=mcf7ecc78508b3bc0ec70919f92b2fa01>

DRAFT/UNAPPROVED

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

May 18, 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 9:15 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  
PARTICIPATING  
VIRTUALLY:**

Kristopher S. Ratliff, Vice Chairman  
Glen Bolyard  
Melvin L. Boone, Sr.  
James L. Jenkins, Jr.  
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**

Ellen B. Shinaberry, Deputy Executive Director  
James Johnson, Deputy Executive Director  
Annette Kelley, Deputy Executive Director  
Beth O' Halloran, Deputy Executive Director  
Elaine Yeatts, Senior Policy Analyst, DHP  
David E. Brown, D.C., Director, DHP

**QUORUM:**

With ten members present, a quorum was established.

**APPROVAL OF AGENDA:**

**MOTION:**

**The agenda was unanimously approved as presented. (motion by Jenkins, second by Ratliff)**

**APPROVAL OF PREVIOUS  
BOARD MEETING  
MINUTES**

**MOTION:**

**The Board voted unanimously to adopt the minutes as presented and amended for the following meetings:**

- **December 4, 2019, Special Conference Committee**
- **December 9, 2019, Full Board Meeting**
- **December 9, 2019, Public Hearing for Delivery of Schedule VI Devices and White Bagging/Brown Bagging**
- **December 9, 2019, Formal Hearing**
- **December 9, 2019, Formal Hearing**
- **December 10, 2019, Formal Hearing**
- **February 14, 2020, Telephone Conference Call**
- **February 18, 2020, Special Conference Committee**
- **March 10, 2020, Special Conference Committee (motion by Nelson, second by Richards-Spruill)**

**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 May 18, 2020 indicating that they wish to offer comment. Ms. Juran received an email from the following individuals and the chairman invited them to offer comment.

Christina Barrille, Executive Director of the Virginia Pharmacists Association thanked the Board for acting quickly and being proactive during pandemic. She also thanked the State Health Commissioner and VDH. Ms. Barrille commented that members are prepared to offer COVID-19 testing and vaccinations. She referenced HB1506 and SB1026 as means to increase access to patient care, clinical preventative services, and development of statewide protocols. Ms. Barrille congratulated Ms. Juran on her election as NABP President-Elect.

Phil Abraham, Director & General Counsel for Vectre Corp, offered comment on behalf of Covetrus Maine, an online nonresident pharmacy servicing animals. Mr. Abraham commented that Atlas Pharmaceuticals, an affiliated entity of Covetrus Maine, received an FDA warning letter which precluded Covetrus Maine from obtaining a required NABP certification, but that FDA has not had an opportunity to close out the issues with Atlas due to the pandemic. He noted that Virginia had recently renewed the Atlas nonresident outsourcing facility registration. Mr. Abraham asked the board to adopt one of the following: 1) find as the state of Indiana that certification from LegitScript is substantially similar to the NABP certification required in Code; 2) acknowledge that Covetrus Maine only does

business within the Commonwealth in limited transactions and waive the requirement to obtain certification from NABP or a substantially similar program pursuant to 54.1-3434.1(A)(4).

Jennifer O'Grady, Vice President of Pharmacy Operations Global Tech Solutions for Covetrus, requested the board recognize certification from LegitScripts. She shared her experience working with LegitScript and found it to provide a thorough review. She stated it is nationally recognized.

Charlton McGinley emailed Ms. Juran indicating a desire to offer public comment. It was unclear if she would be participating in the meeting virtually. Ms. Juran asked during the meeting if she was present. After no response, Ms. Juran read the email to the board which requested information regarding expedited licenses issued to military spouses. Ms. Juran informed the board that staff would respond to her email.

Greg O'Grady, PIC with Covetrus Maine thanked the board for the opportunity to provide comment and offered support of the comments offered by Mr. Abraham and Ms. O'Grady.

DHP DIRECTOR'S  
REPORT:

Dr. Brown thanked the Board for coordinating the use of Webex for this meeting. He offered that the Board of Pharmacy has issued many waivers to assist in the COVID-19 pandemic. Dr. Brown shared that DHP closed the building, and has had no meetings or hearings to date. DHP is currently in the process of developing a policy for meetings after the state of emergency expires to follow a method for high risk individuals to participate remotely, but will require an in-person quorum. He said that >75% of staff is teleworking with some physical presence in building, and that he anticipates long-term use of some of these accommodations will continue in order to increase efficiencies. Dr. Brown congratulated Ms. Juran for being elected NABP President-Elect.

LEGISLATIVE/  
REGULATORY/  
GUIDANCE UPDATE

Update on Legislative/Policy  
Actions

Information relevant to the 2020 General Assembly Session was included in the agenda package and Ms. Yeatts offered to answer any questions. Ms. Juran reported on the Governor's amendments to SB 976 that were not captured in the agenda package. Mr. Lee asked if USP defines "cannabis oil". Ms. Juran indicated that she was not familiar with USP having such a definition. Mr. Ratliff suggested that a front line pharmacist currently practicing be included on the workgroup required by HB 1506 and with any discussions regarding costs of drugs. Ms. Nelson noted the deadlines for reports are rapidly approaching and commented about the impact of the pandemic. Ms. Yeatts stated it's possible the deadlines may be extended. Ms. Juran also stated that it's possible that discussions

regarding the Joint Commission on Health Care request for consideration of statewide orders may overlap with board discussions regarding HB 1506.

**ACTION ITEM:**

**The Board requested staff to share with them at the September meeting the naloxone language required to appear on the upcoming pharmacist license renewal per the request from the Joint Commission on Health Care.**

Update on Regulatory Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet, and noted a change in that the proposed regulations for an increase in fees has been approved by the Secretary's office and is now in the Governor's office.

Adoption of Exempt  
Regulation to Schedule  
Certain Chemicals into  
Schedule I

Ms. Yeatts commented that the proposed final regulations included in the agenda packet do not show the deletion of chemicals that were scheduled by the 2020 General Assembly and placed into Code.

**MOTION:**

**The board voted unanimously to adopt the exempt regulation of 18VAC110-20-322 as presented and amended to remove the drugs scheduled into Code by the 2020 General Assembly and to place the following drugs identified by the Department of Forensic Science into a new subsection D:**

**1. Synthetic opioids**

- a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-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-piperazinyl]-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, a-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)-1 H-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)-1 H-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)-1 H-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)-1 H-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 (18 months after the effective date of the regulation), unless enacted into law in the Drug Control Act. (motion by Jenkins, second by Richards-Spruill)

Adoption of Exempt  
Regulation to Conform Drug  
Schedules to Actions Taken  
by DEA

**MOTION:**

The board voted unanimously to adopt the exempt regulation as presented to amend 18VAC110-20-323 by adding the following drugs to conform drug schedules to actions taken by DEA:

5. Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I.
6. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers,



and salts of isomers is possible, to Schedule IV.

7. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II.

8. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl)-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V.

9. Adds brexanolone (3 $\alpha$ -hydroxy-5 $\alpha$ -pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV.

10. Deletes naloxegol and 6 $\beta$ -naltrexol from Schedule II.

11. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP).

12. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I.

13. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I. (motion by Thornbury, second by Nelson)

Adoption of Final Regulations  
for Delivery of Prescription  
Devices

**MOTION:**

The board voted 9-0 to adopt the final regulation of 18VAC110-50-55 as presented regarding delivery of prescription devices. (motion by Ratliff, second by Nelson; Mr. Bolyard temporarily lost connection and did not vote)

Adoption of Final Regulations  
for Delivery of Dispensed  
Prescriptions, Labeling

**MOTION:**

Ms. Warriner expressed concerns for the regulatory amendment and requested the recent comment period be extended since the pandemic may have precluded persons from offering comment. Ms. Juran stated that she received an email on 5-17-20 asking if the public comment period could be extended due to the COVID health crisis. Counsel noted that a public hearing on the subject was noticed for the March board meeting which was subsequently cancelled due to the pandemic.

The board voted unanimously to extend the public comment period to the June 16<sup>th</sup> board meeting and conduct a public hearing on this topic at that meeting. (motion by Ratliff, second by Nelson)

Adoption of Proposed  
Regulations for  
Pharmaceutical Processors

**MOTION:**

The board voted unanimously to adopt proposed amendments to 18VAC110-60 et. seq. as presented to replace emergency regulations for registered agents

**and wholesale distribution by pharmaceutical processors. (motion by Nelson, second by Boone)**

Adoption of Final Regulations  
for White Bagging and Brown  
Bagging

**MOTION:**

**The board voted unanimously to adopt the final regulation of 18VAC110-20-275 as presented regarding white bagging and brown bagging. (motion by Thornbury, second by Jenkins)**

Adoption of Regulatory  
Amendments for Handling  
Fee for Returned Check

Ms. Yeatts commented that the Office of the Comptroller advised DHP that it should be charging \$50 for a return check, rather than the current \$35.

**MOTION:**

**The board voted unanimously to amend 18VAC110-20-20, 18VAC110-50-20, and 18VAC110-60-20 as presented to increase the handling fee for returned check or dishonored credit card or debit card from \$35 to \$50. (motion by Nelson, second by Bolyard)**

**NEW BUSINESS:**

Consideration of  
certification from a  
substantially similar program  
approved by the Board for  
nonresident pharmacies (§  
54.1-3434.1(A)(4))

Ms. Juran provided background information indicating that § 54.1-3434.1(A)(4) was amended in 2008 to require a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, to hold certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site (VIPSS), or certification from a substantially similar program approved by the Board. Shortly after the law passed, NABP created Vet-VIPPS for veterinary online pharmacies, but this certification was discontinued in 2016. Additionally, the VIPPS certification is no longer available as it was incorporated into the Digital Pharmacy accreditation. Ms. Juran indicated that board has been accepting the Digital Pharmacy accreditation from nonresident pharmacies as satisfying compliance with § 54.1-3434.1(A)(4) since VIPPS was incorporated into it. However, Digital Pharmacy accreditation does not extend to prescription drugs/devices, human or veterinary, that are dispensed to animals. Digital Pharmacy accreditation requires the pharmacy to obtain .Pharmacy and .Pharmacy is available for veterinary pharmacies. .Pharmacy is a secure and trustworthy Top-Level Domain indicating to users that it is a legitimate online pharmacy.

There was discussion that Covetrus Maine is ineligible, per NABP's policy, for the Digital Pharmacy accreditation because an affiliated outsourcing facility was issued an FDA warning letter. The nonresident outsourcing facility registration is current active in Virginia.

**MOTION:**

**The Board voted unanimously that online pharmacies dispensing only to animals are doing business within the Commonwealth in limited transactions**

and therefore, the Board waives pursuant to § 54.1-3434.1(A)(4) the requirement to obtain Verified Internet Pharmacy Practice Site (VIPSS) certification or certification from a substantially similar program approved by the Board, if the pharmacy is credentialed with .Pharmacy from NABP or certification from LegitScript. (motion by Thornbury, second by Richards-Spruill)

**ACTION ITEM:**

**The Board requested staff to prepare guidance for adoption at the June board meeting related to credentialing requirements from .Pharmacy or LegitScript for nonresident online pharmacies dispensing only to animals.**

Ms. Warriner asked if there was any other business to consider. Mr. Jenkins commented that he remains concerned for the Board's proposed increased in licensure fees particularly in light of the pandemic's impact on the economy.

**REPORTS**

**Chairman's Report**

Ms. Warriner reminded the Board that the regulatory requirement for a PIC to have a minimum of two years of experience as a licensed pharmacist became effective 12/11/19, and that there is an allowance to grant an exception. She stated staff will seek guidance from the board at the June board meeting. Thus far, she has worked with Ms. Juran in reviewing exemption requests. If the PIC does not have 2 years of experience but assumed the role prior to the regulation becoming effective, he or she may continue to serve in this capacity. However, if the person relocates to another pharmacy, the two year minimum requirement must be taken into account at the time that application is submitted and the person may be denied eligibility to serve as the PIC. Ms. Warriner discussed her participation with the Virtual NABP meeting. There were five resolutions that were passed. One included a task force and she encouraged board members interested in participating to contact staff. Information for volunteering is also noted on the NABP webpage.

Ms. Warriner served as the Resolution Committee member for District 2.

**Report on Board of Health Professions**

Mr. Logan provided updates from the most recent Board of Health Professions meeting.

**Report on Inspection and Licensure Program**

Report was included in the agenda packet. No questions were asked of staff.

**Report on Pharmaceutical Processors**

Report can be found on page 169 of the agenda packet. No questions were asked of staff.

**Report on Disciplinary Program**

Report can be found on page 170-175 of the agenda packet. No questions were asked of staff.

Executive Director's Report

Report can be found on page 176 of the agenda packet. No questions were asked of staff.

**ADJOURNMENT:**

With all business concluded, the meeting adjourned at 11:48 AM.

\_\_\_\_\_  
Cynthia Warriner, Chairman

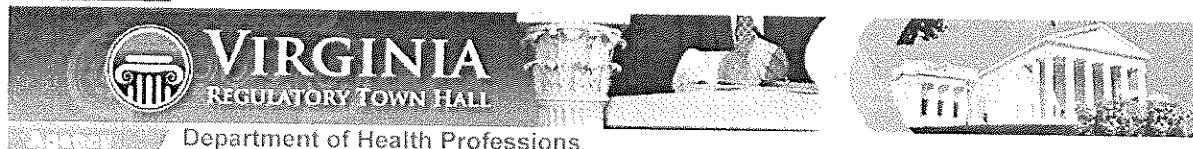
\_\_\_\_\_  
Caroline D. Juran, Executive Director

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

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

DRAFT

Virginia.gov Agencies | Governor



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

## General Information

<b>Action Summary</b>	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.
<b>Chapters Affected</b>	Only affects this chapter.
<b>Exempt from APA</b>	No, this action is not exempt from Article II of the APA and executive branch review.
<b>RIS Project</b>	Yes [005715]
<b>Associated Petitions for Rulemaking</b>	<u>Unique identifier on prescription labels</u>
<b>New Periodic Review</b>	This action will not be used to conduct a new periodic review.

## Stages

Stages associated with this regulatory action.

Stage ID	Stage Type	Status
<u>8346</u>	NOIRA	Stage complete. Comment period ended 11/28/2018.
<u>8779</u>	Proposed	Comment period is underway and will end on 06/16/2020.

## Contact Information

**Name / Title:** Caroline Juran, RPh / *Executive Director*

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Suite 300  
Richmond, VA 23233-1463

**Email Address:** [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov)

**Phone:** (804)367-4456 FAX: (804)527-4472 TDD: (-)

*This person is the primary contact for this chapter.*

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VIRGINIA  
REGULATORY TOWN HALL

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

## Documents

<a href="#">Proposed Text</a>	1/29/2020 8:05 am
<a href="#">Agency Background Document</a>	10/2/2019 (modified 11/20/2019)
<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="#">Governor's Review Memo</a>	1/7/2020

## Status

<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 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 <b><u>The Virginia Register of Regulations</u></b> Publication Date: 2/3/2020 <b><u>Volume: 36 Issue: 12</u></b>
<b>Public Hearings</b>	<b><u>03/24/2020 9:00 AM</u></b> canceled <b><u>06/16/2020 9:00 AM</u></b>
<b>Comment Period</b>	<b><u>In Progress!</u></b> <b><u>Ends 6/16/2020</u></b> <b><u>Currently 4 comments</u></b>

## Contact Information

**Name / Title:** Caroline Juran, RPh / *Executive Director*

**Address:** 9960 Mayland Drive  
Suite 300  
Richmond, VA 23233-1463

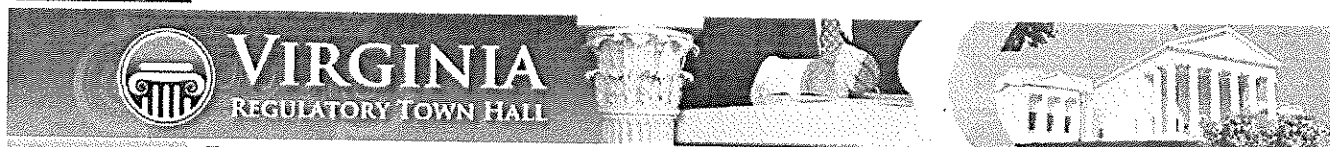
**Email Address:** [caroline.juran@dhp.virginia.gov](mailto:caroline.juran@dhp.virginia.gov)

**Telephone:** (804)367-4456 FAX: (804)527-4472 TDD: (-)

*This person is the primary contact for this chapter.*

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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

Stage Proposed

Comment Period Ends 6/16/2020

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Commenter: Jennifer Helmke, Brema 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



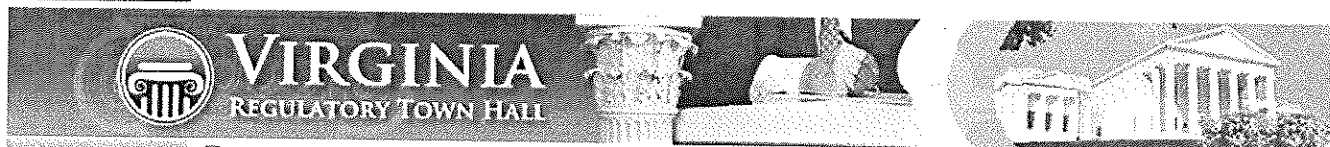
BLOOD PRESSURE).

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

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Department of Health Professions

Board Board of Pharmacy

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

Action Delivery of dispensed prescriptions; labelingStage Proposed

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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

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Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

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

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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 let us substitute medications like generic albuterols when there is a shortage in the market

Steven C Hylton, PharmD  
CommentID: 80176

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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; labelingStage Proposed

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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

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



## 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.

**Department of Health Professions – Board of Pharmacy  
Regulatory/Policy Actions – 2020 General Assembly**

**EMERGENCY REGULATIONS:**

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB1304/SB830	Training requirements for pharmacy technicians	Pharmacy	9/9/20	<b>12/16/20</b>
HB1654/SB1074	Issuance of limited-use permit for dispensing of certain CVI drugs and devices	Pharmacy	6/16/20	<b>1/7/21</b>
SB976	Permitting of dispensing facilities, etc	Pharmacy	9/9/20	<b>1/27/21</b>
HB1506	Pharmacists initiating treatment with specified drugs, to include provisions for ensuring that physical settings in compliance with the HIPPA.	Pharmacy	9/9/20	<b>1/11/21</b>

**EXEMPT REGULATORY ACTIONS**

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1460 and SB976	Conforming pharmaceutical processor regulations	Pharmacy	6/16/20	8/19/20
HB1263/SB538	Deletion of chemicals in Schedule I by regulation	Pharmacy	5/18/20	8/19/20

**NON-REGULATORY ACTIONS**

Legislative source	Action needed	Participants/Responsible party	Due date
HB1506	Protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 as amended and regulations to implement the provisions	Collaboration with staff of Board of Medicine and VDH  Two or three board members to review and provide input for draft to present to the Board	Adoption by Board at September meeting  November 1, 2020
Letter from JCHC  HB1506	Workgroup on expansion of statewide standing orders for drugs that may be dispensed without prescription  Work group consisting of specified stakeholders to provide recommendations regarding the development of protocols for the initiating of	Workgroup to include representation from Boards of Pharmacy and Medicine, Department of Health, Schools of Medicine and Pharmacy and other stakeholder groups such as MSV and VPhA	October 1, 2020 (JCHC)  November 1, 2020 (HB1506)

	treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of certain drugs and devices		
Letter from JCHC	Information with renewal on availability of naloxone	Pharmacy staff responsibility	October 1, 2020
HB1531	Stakeholder group to develop strategies to increase drug disposal sites; report to Committee Chairs	Pharmacy staff with 2 or 3 board members and other stakeholders	November 15, 2020
SB270	Annual report to House and Senate on outsourcing facilities that have a contract with Corrections to compound drugs for lethal injections and the name of any such outsourcing facilities that received disciplinary action for a violation of law or regulation related to compounding.	Pharmacy staff report	December 1, 2020
Code Commission	Re-write of 54.1-3408 –	Review by Executive Directors of all boards with prescribers or dispensers  Legal staff of Legislative Services responsibility	November 1, 2020
HB908/SB836	Revision of protocols for administration of naloxone by employees of public places – guidance document	Pharmacy and BDHDS staff in collaboration with VDH staff	September 2020
HB967/SB981	1) Collection of data on applicant who is spouse of a veteran; 2) Decision on waiver of experience requirements	Staff responsibility	July 1, 2020

### Future Policy Actions:

**HB1304/SB830 (2020)** – 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**.

**HB2559 (2019)** - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by **November 1, 2022**.

## Report of Regulatory Actions - 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 - At Governor's Office for 3 days</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 Public hearing on 6/16/20</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Handling fee</u> [Action 5519]</p> <p>Fast-Track - AT Attorney General's Office for 14 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 742 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Increase in fees</u> [Action 4938]</p> <p>Final - At Governor's Office for 23 days</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 DPB for 14 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><sup>(E)</sup> <u>Placement of chemicals in Schedule I</u> [Action 5517]</p> <p>Final - AT Attorney General's Office for 14 days</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><sup>(E)</sup> <u>Scheduling for conformity to DEA scheduling</u> [Action 5518]</p> <p>Final - AT Attorney General's Office for 14 days</p>
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehouse	<p><u>Delivery of Schedule VI prescription devices</u> [Action 5084]</p> <p>Final - At DPB for 14 days</p>
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	<p><u>Prohibition of products for vaping or inhalation with vitamin E acetate</u> [Action 5452]</p> <p>Emergency/NOIRA - At Governor's Office for 5 days</p>

[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	<u>Registered agents and wholesale distribution</u> [Action 5398] Proposed - <i>DPB Review in progress for 5 days</i>
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**Agenda Item: Adopt exempt regulations for pharmaceutical processors**

**Included in agenda package:**

Copy of HB 1460

Copy of SB 976

Draft exempt regulatory amendments of 18VAC110-60 et seq.

**Board action:**

Adopt exempt regulatory amendments of 18VAC110-60 et seq. as presented or amended.

# VIRGINIA ACTS OF ASSEMBLY -- 2020 SESSION

## CHAPTER 730

*An Act to amend and reenact §§ 54.1-3408.3 and 54.1-3442.7 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; telemedicine; non-Virginia residents.*

[H 1460]

Approved April 6, 2020

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 54.1-3408.3 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 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.

"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. *The practitioner shall use his professional judgment 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 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.

**§ 54.1-3442.7. 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~~, *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~~ *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 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. 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.



# VIRGINIA ACTS OF ASSEMBLY -- 2020 RECONVENED SESSION

## 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 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 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 of 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 or THC~~ 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.**

## Exempt Regulatory Amendments to 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 ~~cannabidiol oil or THC-A~~ cannabis oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

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

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

"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 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 ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ 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°	50% - 60%
Nursery phase	71 - 85° F	65% - 75%
Vegetation phase	71 - 85° F	55% - 65%
Flower/harvest phase	71 - 85° F	55% - 60%
Drying/extraction rooms	< 75° F	55% - 60%

**18VAC110-60-20. Fees.**

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

B. Registration of practitioner.

- 1. Initial registration. \$50
- 2. Annual renewal of registration. \$50
- 3. Replacement of registration for a qualifying practitioner whose information has changed or 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. \$25
- 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 <del>eannabidiol oil or THC-A</del> <u>cannabis</u> oil product.	\$25

## Part II Requirements for Practitioners and Patients

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

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

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition, ~~including an in-person physical examination;~~
2. Diagnose the patient;
3. Be of the opinion that the potential benefits of ~~eannabidiol oil or THC-A~~ cannabis oil would likely outweigh the health risks of such use to the qualifying patient;
4. Explain proper administration and the potential risks and benefits of the ~~eannabidiol oil or THC-A~~ cannabis oil to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;
5. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient,



including physical examinations, to determine the efficacy of ~~eannabidiol oil or THC-A~~ cannabis oil for treating the diagnosed condition or disease;

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

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

8. Access or direct the practitioner's delegate to access the Virginia Prescription Monitoring Program of the Department of Health Professions for the purpose of determining which, if any, covered substances have been dispensed to the patient.

~~C. Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the~~ The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation which may include the use of telemedicine. Such telemedicine use shall be consistent with federal requirements for the prescribing of Schedule II through V controlled substances.

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

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

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

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

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

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis oil product;
3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where ~~eannabidiol oil or THC-A~~ 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 or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ 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;
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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 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 ~~cannabidiol oil or THC-A~~ 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.

**18VAC110-60-70. Reporting requirements for practitioners, patients, parents, legal guardian, or registered agent.**

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

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

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

D. If a patient, parent, or legal guardian, or registered agent notifies the board of any change that results in information on the registration of the patient, parent, legal guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, legal guardian, or registered agent shall destroy in a nonrecoverable manner the registration that was replaced.

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

**18VAC110-60-80. Proper storage and disposal of ~~eannabidiol oil or THC-A~~ cannabis oil by patients, parents, legal guardians, or registered agents.**

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

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

1. By removing the oil from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.
2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

**18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, 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;
4. The registrant obtained more than a 90-day supply of ~~eannabidiol oil or THC-A~~ cannabis oil in a 90-day period;
5. The registrant provided or sold ~~eannabidiol oil or THC-A~~ 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.

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

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

B. Submission of initial application.

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

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

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

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

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

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

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

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

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

- i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of ~~eannabidiol oil~~ or ~~THC-A~~ cannabis oil;
  - j. Text and graphic materials showing the exterior appearance of the proposed pharmaceutical processor;
  - k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and oils; (iii) the location of all areas that may contain Cannabis plants; ~~eannabidiol oil~~, or ~~THC-A~~ cannabis oil; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;
  - l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;
  - m. Information about the applicant's expertise in agriculture and other production techniques required to produce ~~eannabidiol oil~~ or ~~THC-A~~ cannabis oil and to safely dispense such products; and
  - n. Such other documents and information required by the board to determine the applicant's suitability for permitting or to protect public health and safety.
2. In the event any information contained in the application or accompanying documents changes after being submitted to the board, the applicant shall immediately notify the board in writing and provide corrected information in a timely manner so as not to disrupt the permit selection process.
  3. The board shall conduct criminal background checks on applicants and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

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

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

#### **18VAC110-60-120. Conditional approval.**

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

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

1. The results of the criminal background checks required in 18VAC110-60-110 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;
2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;
3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, ~~the cannabidiol oil,~~ or the ~~THC-A~~ cannabis oil;
4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of ~~cannabidiol oil or THC-A~~ cannabis oil;
5. The extent to which the applicant or any of the applicant's pharmaceutical processor owners have a financial interest in another license, permit, registrant, or applicant; and
6. Any other reason provided by state or federal statute or regulation that is not inconsistent with the law and regulations regarding pharmaceutical processors.

C. The board may disqualify any applicant who:

1. Submits an incomplete, false, inaccurate, or misleading application;
2. Fails to submit an application by the published deadline;
3. Fails to pay all applicable fees; or
4. Fails to comply with all requirements for a pharmaceutical processor.

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

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

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

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



1. Designation of a PIC;
2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;
3. Evidence of utilization of an electronic tracking system; and
4. A satisfactory inspection of the facility conducted by the board or the board's agents.

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

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

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

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

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

G. Once the permit is issued, a processor may begin cultivation of Cannabis. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. 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 pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

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

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

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

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of ~~cannabidiol oil or THC-A~~ 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, ~~cannabidiol oil or THC-A~~ 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. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

#### **Part IV**

### **Requirements for Pharmaceutical Processor Personnel**

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

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

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

C. 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 ~~eannabidiol oil and THC~~ 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, ~~eannabidiol oil, and THC-A oil~~ cannabis 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 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.

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

A. All employees of a pharmaceutical processor shall complete training prior to the employee commencing work at the pharmaceutical processor. At a minimum, 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; ~~eannabidiol oil, and THC-A~~ 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 ~~eannabidiol oil or THC-A~~ 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 PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

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

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

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed ~~four~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~routine cannabidiol oil or THC-A~~ 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) ~~cannabidiol oil, THC-A~~ cannabis oil; or other drugs either before or after ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ cannabis oil should be substituted for the ~~cannabidiol oil or THC-A~~ 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. No person shall be PIC for more than one pharmaceutical processor or 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. The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

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

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

2. All record retention requirements are met;

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

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

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

a. Pharmaceutical processor permit;

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

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

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

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

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, ~~cannabidiol oil~~, or ~~THC-A~~ 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. 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. 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 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**

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

A. A pharmaceutical processor shall only sell ~~cannabidiol oil~~ or ~~THC-A~~ 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 ~~cannabidiol oil~~ or ~~THC-A~~ 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 ~~cannabidiol oil~~ or ~~THC-A~~ cannabis oil.

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

1. A person whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or
2. 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, ~~cannabidiol oil~~, or ~~THC-A~~ cannabis oil are stored.

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

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

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

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

H. A pharmacist shall counsel registered patients, parents, and legal guardians, and registered agents if applicable, regarding the use of ~~eannabidiol oil or THC-A~~ cannabis oil. Such counseling shall include information related to safe techniques for proper use and storage of ~~eannabidiol oil or THC-A~~ cannabis oil and for disposal of the oils in a manner that renders them nonrecoverable.

I. The pharmaceutical processor 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 prohibitions.**

A. No pharmaceutical processor shall:

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



B. 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, No 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.

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

DC. A pharmaceutical processor shall not advertise ~~cannabidiol oil or THC-A~~ cannabis 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~~ cannabis oil products;
4. Laboratory results;
5. Product information and pricing; and
6. Directions to the processor facility.

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

FE. 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~~ 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.

GF. 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.

~~HG.~~ No ~~cannabidiol oil or THC-A~~ cannabis 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~~ cannabis oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors

~~HI.~~ 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~~ 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 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~~ 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, ~~cannabidiol oil,~~ and ~~THC-A~~ 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 ~~cannabidiol oil and THC-A~~ 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 ~~cannabidiol oil or THC-A~~ cannabis oil was sold; the address of such person; and the kind and quantity of ~~cannabidiol oil or THC-A~~ cannabis oil sold.

C. The record of all ~~eannabidiol oil or THC-A~~ cannabis 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 ~~eannabidiol oil or THC-A~~ cannabis oil was sold; the kind and quantity of ~~eannabidiol oil or THC-A~~ cannabis 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; ~~eannabidiol oil, and THC-A~~ 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. 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.

#### **18VAC110-60-240. Security requirements.**

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis oil in excess of the quantity required for normal, efficient operation;
3. Maintain all Cannabis plants, seeds, parts of plants, extracts; ~~eannabidiol oil, and THC-A~~ cannabis oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;
4. Store all cut parts of Cannabis plants, extracts; ~~eannabidiol oil, or THC-A~~ cannabis oil in an approved safe or approved vault within the pharmaceutical processor and not sell ~~eannabidiol oil or THC-A~~ cannabis oil products when the pharmaceutical processor is closed;
5. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of ~~eannabidiol oil or THC-A~~ 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; ~~eannabidiol oil, or THC-A~~ cannabis oil;

6. Keep all locks and security equipment in good working order;
7. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor; and
8. Not allow keys to be left in the locks or accessible to non-pharmacists.

B. The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, ~~cannabidiol oil~~, or THC-A 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. 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 processor facility and shall be capable of detecting breaking by any means when activated;
4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and
5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor, and the system shall be activated whenever the pharmaceutical processor is closed for business.

C. A pharmaceutical processor shall keep the outside perimeter of the premises well-lit. A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, ~~cannabidiol oil~~, or THC-A 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 shall direct cameras at all approved safes, approved vaults, dispensing areas, ~~cannabidiol oil~~ or THC-A cannabis oil sales areas, and any other area where Cannabis plants, seeds, extracts, ~~cannabidiol oil~~, or THC-A cannabis oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility;
2. The video system shall have:

- a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message;
  - b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image, live or recorded;
  - c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and
  - d. The ability to remain operational during a power outage;
3. All video 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 shall erase all recordings prior to disposal or sale of the facility; and
4. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.
- D. The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.
- E. A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor. The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.
- F. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, ~~cannabidiol oil,~~ or THC-A cannabis oil has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

**18VAC110-60-250. Requirements for the storage and handling of Cannabis, ~~eannabidiol oil~~, or ~~THC-A~~ cannabis oil.**

A. A pharmaceutical processor shall:

1. Have storage areas that provide adequate lighting, ventilation, sanitation, temperature, and humidity as defined in 18VAC110-60-10 and space, equipment, and security conditions for the cultivation of Cannabis and the production and dispensing of ~~eannabidiol oil~~ or ~~THC-A~~ cannabis oil;
2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including ~~eannabidiol oil~~ or ~~THC-A~~ 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, ~~eannabidiol oil~~, or ~~THC-A~~ 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 ~~eannabidiol oil~~ or ~~THC-A~~ 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 ~~eannabidiol oil~~ or ~~THC-A~~ cannabis oil; and
4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, ~~eannabidiol oil~~, and ~~THC-A~~ cannabis oil products.

C. The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, ~~eannabidiol oil~~, and ~~THC-A~~ cannabis oil. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors shall include in their written policies and procedures a process for the following:

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

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

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

**18VAC110-60-251. Wholesale distribution of ~~eannabidiol oil and THC-A~~ cannabis oil products.**

A. ~~Cannabidiol oil and THC-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.

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 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 receiving the product in its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years in compliance with 18VAC110-60-260.

C. A pharmaceutical processor wholesale distributing ~~eannabidiol oil or THC-A~~ 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.

D. If a pharmaceutical processor wholesale distributing ~~eannabidiol oil or THC-A~~ cannabis oil products uses an electronic system for the storage and retrieval of records related to distributing ~~eannabidiol oil or THC-A~~ 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 uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing ~~eannabidiol oil or THC-A~~ cannabis oil, the pharmaceutical processor 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 ~~eannabidiol oil or THC-A~~ cannabis oil; or (iii) any loss or unauthorized alteration of records related to ~~eannabidiol oil or THC-A~~ cannabis oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law-enforcement authorities and the board.

B. A pharmacist or processor shall provide the notice required by subsection A of this section to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of ~~eannabidiol oil or THC-A~~ cannabis oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified. A pharmacist or processor shall make such notice no later than 24 hours after discovery of the event.



C. A pharmacist or pharmaceutical processor shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:

1. An alarm activation or other event that requires a response by public safety personnel;
2. A breach of security;
3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and
4. Corrective measures taken if any.

D. A pharmacist or pharmaceutical processor 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.

## **Part VI**

### **Cultivation, Production, and Dispensing of ~~Cannabidiol Oil or THC-A~~ Cannabis Oil**

#### **18VAC110-60-280. Cultivation and production of ~~eannabidiol oil or THC-A~~ cannabis oil.**

A. No ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil and THC-A~~ cannabis oil 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, ~~eannabidiol oil,~~ or ~~THC-A~~ cannabis oil not in compliance with this section shall be deemed adulterated.

#### **18VAC110-60-285. Registration of products.**

A. A pharmaceutical processor shall assign a brand name to each product of ~~eannabidiol oil or THC-A~~ cannabis oil. The pharmaceutical processor shall register each brand name with the board on a form prescribed by the board prior to any dispensing and shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);
2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD); and
4. Cannabidiolic acid (CBDA).

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 90% to 110%.

C. The board shall not register any brand name that:

1. Is identical to or confusingly similar to the name of an existing commercially available product;
2. Is identical to or confusingly similar to the name of an unlawful product or substance;
3. Is confusingly similar to the name of a previously approved ~~cannabidiol oil or THC-A~~ cannabis oil product brand name;
4. Is obscene or indecent;
5. May encourage the use of marijuana, ~~cannabidiol oil~~, or ~~THC-A~~ cannabis oil for recreational purposes;
6. May encourage the use of ~~cannabidiol oil or THC-A~~ cannabis oil for a disease or condition other than the disease or condition the practitioner intended to treat;
7. Is customarily associated with persons younger than the age of 18; or
8. Is related to the benefits, safety, or efficacy of the ~~cannabidiol oil or THC-A~~ cannabis oil product unless supported by substantial evidence or substantial clinical data.

**18VAC110-60-290. Labeling of batch of ~~cannabidiol oil or THC-A~~ cannabis oil products.**

- A. ~~Cannabidiol oil or THC-A~~ Cannabis oil produced as a batch shall not be adulterated.
- B. ~~Cannabidiol oil or THC-A~~ Cannabis 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 ~~eannabidiol oil or THC-A~~ cannabis 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 ~~eannabidiol oil or THC-A~~ cannabis 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 ~~eannabidiol oil or THC-A~~ cannabis oil unless such laboratory:

- 1. Is independent from all other persons involved in the ~~eannabidiol oil or THC-A~~ 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, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of ~~eannabidiol oil or THC-A~~ 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.

B. After processing and before dispensing the ~~eannabidiol oil or THC-A~~ 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. The sample size shall be a statistically valid sample as determined by the board. 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 ~~eannabidiol oil or THC-A~~ 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 sell a ~~eannabidiol oil or THC-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 ~~eannabidiol oil or THC-A~~ cannabis oil products and materials upon the completion of any testing, use, or research.

F. If a sample of ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-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 ~~eannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 ~~cannabidiol oil or THC-A~~ 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 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 ~~eannabidiol oil or THC-A~~ cannabis oil.**

A. A pharmacist in good faith may dispense ~~eannabidiol oil or THC-A~~ 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 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 ~~eannabidiol oil or THC-A~~ 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.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of ~~eannabidiol oil or THC-A~~ cannabis oil. The pharmacist may dispense the remaining portion of the 90-day supply of ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis 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 ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis oil;
5. The quantity of ~~eannabidiol oil or THC-A~~ 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;
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 ~~eannabidiol oil or THC-A~~ cannabis oil products as "organic" unless the Cannabis plants have been organically grown and the ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis 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 ~~eannabidiol oil or THC-A~~ cannabis oil to a registered patient, parent, or legal guardian or registered agent if the pharmacist suspects that dispensing ~~eannabidiol oil or THC-A~~ 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.

**18VAC110-60-330. Disposal of ~~eannabidiol oil or THC-A~~ cannabis oil.**

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, ~~eannabidiol oil,~~ or ~~THC-A~~ cannabis oil by disposal in accordance with a plan approved by the board and in a manner as to render the ~~eannabidiol oil or THC-A~~ cannabis oil nonrecoverable.

B. The destruction shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmaceutical processor. The persons disposing of the ~~eannabidiol oil or THC-A~~ 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 ~~eannabidiol oil or THC-A~~ cannabis oil disposed of; and
4. The signatures of the persons disposing of the ~~eannabidiol oil or THC-A~~ cannabis oil.

C. The record of disposal shall be maintained at the pharmaceutical processor for three years from the date of disposal.



**Agenda Item: Petition for rulemaking:**

**Included in your package are:**

Copy of petition from Bioscrip Infusion Services

Copy of Notice on Townhall

Copy of Comments on the petition

**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 section 276 to the Regulation Committee.**



# 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,) HomeChoice Partners, Inc. dba Bioscrip Infusion Services		
Street Address 5365 Robin Hood Road, Suite 200	Area Code and Telephone Number 757-855-4255 (Pharmacy) 312-715-5139 (Counsel)	
City Norfolk	State Virginia	Zip Code 23513-2416
Email Address (optional) <a href="mailto:James.vermaak@bioscrip.com">James.vermaak@bioscrip.com</a> (James Vermaak, PIC) <a href="mailto:Edward.rickett@quarles.com">Edward.rickett@quarles.com</a> (counsel for Bioscrip Infusion Services)	Fax (optional)	

<b>Respond to the following questions:</b>
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.  18 VAC 110-20-276. Central or Remote Processing.
2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.  See attached.
3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.  The legal authority is found in VA Code § 54.1-2400.

**Signature:**   
Counsel for Petitioner

**Date:** 4-01-2020

## Substance of Proposed Change to 18 VAC 110-20-276

Petitioner is seeking an amendment to 18 VAC 110-20-276 to allow remote order entry by technicians to occur from outside the licensed pharmacy space. Petitioner operates a sterile compounding pharmacy in Norfolk, VA. There is no need from a patient safety or security standpoint for pharmacy personnel that perform order entry activities to be physically located in the licensed space. Virginia's Central or Remote Processing regulation presently allows pharmacists to access the pharmacy's database from a remote location for the purpose of performing certain prescription processing functions. Petitioner is seeking to expand this regulation to allow a technician under the supervision of a pharmacist to perform those functions from outside the licensed pharmacy, in a space that is located on the same premises as the licensed pharmacy.

The following is a proposed amendment to address this issue. The proposed language is identified by double underscoring.

### **18 VAC 110-20-276. Central or Remote Processing.**

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

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

B. A pharmacy may outsource certain prescription processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

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

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

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

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
3. ~~Procedures for protecting the confidentiality and integrity of patient information;~~

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

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

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

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

1. The remote location must be a location that is on the same premises as the licensed pharmacy;
2. The technician is performing only prescription processing functions, patient care documentation, patient and prescriber communications, activities falling within the scope of VA ST § 54.1-3321 that do not require the handling of or access to prescription drug inventory; and activities that do not fall within the scope of the practice of pharmacy;
3. The prescription processing functions performed by the pharmacy technician shall be limited to the entry of prescription information and drug history into the database; and
4. A policy and procedure manual that relates to remote processing functions performed by a pharmacy technician shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:
  - a. Procedures for protecting the confidentiality and integrity of patient information;
  - b. Procedures for ensuring that original prescriptions received by the pharmacy as an original hard copy or verbally and reduced to writing do not leave the licensed space, and that technicians performing processing functions have access to an exact, unalterable image of such prescriptions to perform prescription order entry;
  - c. Procedures for ensuring adequate pharmacist supervision of pharmacy technicians that perform prescription processing functions;
  - d. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
  - e. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

### **Rationale or Purpose for the Amended Rule**

Petitioner believes that it is important that a licensed pharmacy have sufficient space to allow for drug storage and fulfillment activities. Pharmacies that perform compounding, including sterile compounding, require even more space. Pharmacy personnel that are not directly performing activities related to the physical preparation of drug products should be allowed to perform those functions from outside the licensed space.

The proposed amendment will ensure adequate supervision and security in connection with the performance of prescription processing functions. Amending the existing regulation will not have a negative impact on patient safety, and could potentially result in improved patient safety. Allowing processing functions to be moved outside the licensed space will

decrease noise and other distractions that are present in a busy pharmacy, and could improve accuracy associated with this important pharmacy activity.

Petitioner believes that a rule amendment is preferable to a pilot project, because the technology required to perform processing from outside of a licensed space is already in common use throughout the state, and there is no need to validate that technology. Petitioner further believes that other licensed pharmacies in the state would benefit from a rule amendment.

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VIRGINIA  
REGULATORY TOWN HALL

Secretariat Health and Human Resources

Agency Department of Health Professions

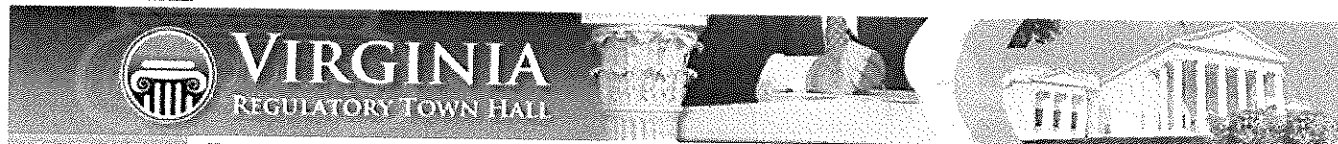
Board Board of Pharmacy

Petition 320

## Petition Information

<b>Petition Title</b>	Remote order processing by technicians
<b>Date Filed</b>	4/2/2020 <a href="#">[Transmittal Sheet]</a>
<b>Petitioner</b>	Bioscript Infusion Services
<b>Petitioner's Request</b>	To amend section 276 to allow remote order processing by technicians outside the physical location of a licensed pharmacy. Currently, pharmacists are allowed to perform prescription processing functions from remote location. Petitioner's request is to allow pharmacy technicians to also process orders under the supervision of a pharmacist under certain conditions as specified in regulation.
<b>Agency's Plan</b>	Following a 30-day comment period, the Board will consider the petition and any comment received at its next meeting, which is currently scheduled for June 16.
<b>Comment Period</b>	Ended 5/27/2020  <a href="#">2 comments</a>
<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>
<b>Telephone:</b>	(804)367-4456 FAX: (804)527-4472 TDD: (-)

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Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

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

[Back to List of Comments](#)

Commenter: Lauren Paul

5/5/20 10:28 am

**CVS Health's comments on petition for rule-making of 18VAC110-20-276. Central or Remote Processing**

Dear Executive Director Juran:

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 petition for rule-making of 18 VAC 110-20-276 to allow technicians to practice remote order entry from outside the licensed pharmacy space. 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.

While CVS Health appreciates the petitioners sentiment to amend 18 VAC 110-20-276 allowing technicians to perform remote order entry from outside the licensed pharmacy space, we feel the petitioner places undue restrictions on the allowance by proposing additional requirements outlined in subsection (F)(1-4), which are mostly duplicative of requirements already in regulation through policy and procedure. We support the allowance for technicians to perform prescription processing functions without specific additional restrictions. The NABP Model Rules address individual practice of not only a pharmacist, but also a pharmacy intern and pharmacy technician in the Practice of Pharmacy, within Section 8, Shared Pharmacy Services. The model rules provide an avenue for these individuals to access the pharmacy's electronic database from inside or outside the pharmacy to perform prescription drug order processing functions if there are established controls to protect confidentiality and integrity of protected health information and if no part of the database is duplicated, downloaded or removed. This is similar to language in Virginia regulations allowing pharmacists to perform certain prescription processing functions. Currently 11 states allow technicians to work remotely performing prescription processing functions, with 4 of those states using language from the model act to permit the practice. In light of the COVID-19 pandemic, an additional 34 states, including Virginia, either through guidance, waivers, emergency regulations or suspension of laws and/or regulations have allowed technicians to practice remotely. Therefore, we support the allowance of technicians to perform remote order entry and prescription processing functions remotely. Please see below our recommended language based on the petitioner's proposal along with NABP Model Rules for your reference.

**Suggested Language:**

18VAC 110-20-276 Central or Remote Processing

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist, pharmacy intern or pharmacy technician in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records. No part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database. A pharmacy technician is permitted to access the pharmacy's database only under the following conditions:

1. The remote location must be a location that is on the same premises as the licensed pharmacy;
2. The technician is performing only prescription processing functions, patient care documentation, patient and

prescriber communications, activities falling within the scope of VA ST § 54.1-3321 that do not require the handling of or access to prescription drug inventory; and activities that do not fall within the scope of the practice of pharmacy;

3. The prescription processing functions performed by the pharmacy technician shall be limited to the entry of prescription information and drug history into the database; and

4. A policy and procedure manual that relates to remote processing functions performed by a pharmacy technician shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

- a. Procedures for protecting the confidentiality and integrity of patient information;
- b. Procedures for ensuring that original prescriptions received by the pharmacy as an original hard copy or verbally and reduced to writing do not leave the licensed space, and that technicians performing processing functions have access to an exact, unalterable image of such prescriptions to perform prescription order entry;
- c. Procedures for ensuring adequate pharmacist supervision of pharmacy technicians that perform prescription processing functions;
- d. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
- e. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

#### NABP Model Rules Section 8. Shared Pharmacy Services

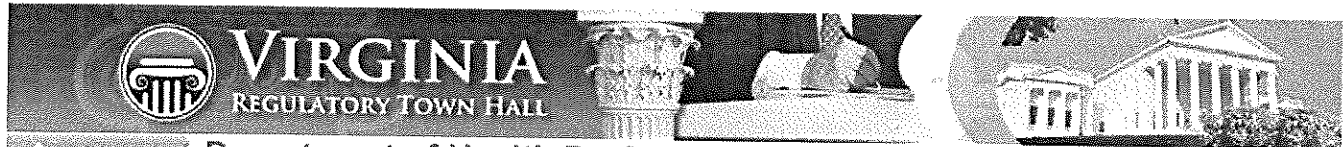
##### (e) Individual Practice

- (1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern, working under the supervision of the Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:
  - (i) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and
  - (ii) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

CVS Health appreciates the opportunity to submit comments on this petition for rule-making.

CommentID: 80133



[Virginia.gov](#) Agencies | Governor**Agency** Department of Health Professions**Board** Board of Pharmacy**Chapter** Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20][Previous Comment](#) [Back to List of Comments](#)

**Commenter:** Natalie Nguyen, Virginia Society of Health-System Pharmacists (VSHP) 5/27/20 2:05 pm

### **VSHP's Comments on Remote Order Processing By Technicians**

We ask the Board to consider amending Section 276 at the conclusion of the emergency provisions within the context of a Board of Pharmacy workgroup, that can carefully distinguish tasks more administrative in nature (appropriate for well-educated, well-trained pharmacy technicians) versus those more clinical in nature (reserved for pharmacists). As well, to include discussion of the specifics and practicality of pharmacist oversight of such.

Thank you for your time and consideration.

CommentID: 80169



Mid-Atlantic Permanente Medical Group, P.C.  
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc

Caroline Juran, RPh  
Executive Director  
Virginia Board of Pharmacy  
9960 Mayland Drive, Suite 300  
Richmond, VA 23233-1463

May 27, 2020

Re: 18VAC110-20-276. Central or Remote Processing

Dear Ms. Juran,

Thank you for the opportunity to provide comment on proposed new regulations 18VAC110-20-276. Established in 1980, Kaiser Permanente is the trade name for the total health organization comprised of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group that features approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our myriad patients. We provide and coordinate comprehensive health care services for approximately 780,000 members throughout the metropolitan area. Our organization operates thirteen pharmacies across ten medical facilities in the Commonwealth of Virginia, with several more planned in the near future.

We commend the Board for acknowledging the significant role pharmacy technicians play to support the profession and considering their contributions to operational efficiencies that extend the reach of pharmacy care. Kaiser Permanente is very interested in exploring opportunities that enhance value by allowing pharmacy technicians to process orders remotely beyond the physical location of a licensed pharmacy. Additionally, we encourage the Board to consider the inclusion of registered pharmacy interns in the proposed rule to enhance the ability of organizations to take full advantage of its capabilities.

Kaiser Permanente pharmacies use a shared common database. Our electronic pharmacy software encompasses HIPAA-compliant databases that integrate with patients' virtual medical records. Aided by multiple levels of quality assurance, patient safety and security – including the use of Virtual Private Network (VPN) technology when feasible – we have in place secure connectivity for remote order processing accessible from countless locations.

Under the proposed regulation, our pharmacy technicians would continue to be supervised by licensed pharmacists to review actions taken as well as manage all appropriate prescription evaluation, accuracy verification and patient counseling responsibilities. Over many years, evidence demonstrates that remote processing adds value by increasing the capacity to offer

expanded pharmacy coverage and allows organizations to redeploy pharmacists into direct patient care functions.<sup>1</sup> Remote processing, with proper checks and balances, provides the opportunity to augment creative and safe ways to provide care to our patients as the profession continues to evolve.

With a growing population in the Commonwealth of Virginia, an invigorated healthcare workforce practicing at the top of their profession is necessary to ensure adequate capacity and provision of health care services. Kaiser Permanente strongly supports the proposed petition for 18VAC110-20-276 – Central or Remote Processing.

Feel free to contact me at monet.stanford@kp.org or (301)552-5571, should any further inquiries arise. Thank you for your time and consideration.

Sincerely,

*Monet M. Stanford*

Monet Stanford, PharmD  
Pharmacy Government Relations and Regulatory Affairs  
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.  
4000 Garden City Drive  
New Carrollton, MD 20785

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<sup>1</sup> Alicia Thorne, Pharm.D., Sarah Williamson, Pharm.D., Tara Jellison, Pharm.D., Chris Jellison, Pharm.D., Implementation of home-based medication order entry at a community hospital, American Journal of Health-System Pharmacy, Volume 66, Issue 21, 1 November 2009, Pages 1939–1942. <https://doi.org/10.2146/ajhp080545>

**Agenda Item: Consider Adoption of Fast-track Regulation to Allow Volunteer CE to Satisfy Live CE Requirement**

**Included in agenda package:**

Copy of 18VAC110-21-120

Excerpt of §54.1-2400 from *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019

**Possible Board action:**

Adopt fast-track regulatory amendment of 18VAC110-21-120 to allow volunteer CE referenced in subsection D to satisfy the live or real-time interactive CE requirement referenced in subsection C.

**18VAC110-21-120. Requirements for continuing education.**

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the ACPE;
2. One that is approved as a Category I continuing medical education course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or
3. One that is approved by the board in accordance with the provisions of 18VAC110-21-130.

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

1. A maximum of one hour for attendance at a board meeting or formal hearing; or
2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

F. Pharmacists are required to attest to compliance with the CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years CE documents to verify compliance with the requirements. Pharmacists are required to maintain for two years following renewal the original certificates documenting successful completion of CE, showing the date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

Excerpt of §54.1-2400 from *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019

**§ 54.1-2400. General powers and duties of health regulatory boards.**

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.
2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.
3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.
4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.
5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions, and the health regulatory boards.
6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, 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 health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

**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

**Board action:**

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

## Summary of HB1654/SB1074

### **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 **HB 1654**.

### **Amendments to Code**

§ 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.**



## **Amendments to Regulations for Practitioners of the Healing Arts to Sell Controlled Substances**

18VAC110-30-10. Definitions.

Part I

Definitions and Fees

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 and who is authorized to prescribe drugs.

"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.

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.

~~BC. 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 facility permit may be issued to a nonprofit facility for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances.

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

**18VAC110-30-40. 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 § 54.1-3321 of the Code of Virginia, provided such person is not licensed to sell controlled substances and is 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.

**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: Adopt Guidance Document for Credentials for Nonresident Pharmacies Dispensing Only for Animals**

**Included in agenda package:**

Draft copy of Guidance Document 110-49

**Board action:**

Adopt Guidance Document 110-49 regarding credentials for nonresident pharmacies dispensing only for animals as presented or as amended.

## VIRGINIA BOARD OF PHARMACY

### Credentials for Nonresident Pharmacy Dispensing only for Animals

For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, and that performs limited transactions in the Commonwealth by only dispensing drugs for animals, the Board waives the requirement in § 54.1-3434.1(A)(4) to receive certification from the National Association of Boards of Pharmacy as a Verified Internet Pharmacy Practice Site, or certification from a substantially similar program approved by the Board if it is credentialed as a Pharmacy Verified Website by the National Association of Boards of Pharmacy or maintains LegitScript certification.

#### **§ 54.1-3434.1. Nonresident pharmacies to register with Board.**

*A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:*

- 1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.*
- 2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.*
- 3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.*
- 4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received*

*certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.*

*5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.*

*6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.*

*7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.*

*The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.*

*B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.*

*C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.*

*D. The registration fee shall be the fee specified for pharmacies within Virginia.*

*E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.*

*F. Pharmacies subject to this section shall comply with the requirements set forth in § 54.1-3408.04 relating to dispensing of an interchangeable biosimilar in the place of a prescribed biological product.*

*G. Every nonresident pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.*

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

**Included in agenda package:**

Draft copy of Guidance Document 110-48

**Board action:**

Adopt Guidance Document 110-48 *Verification Sources for a Pharmaceutical Processor* as presented or as amended.



## Virginia Board of Pharmacy

### Verification Sources for a Pharmaceutical Processor

To assist pharmacists and pharmacy technicians practicing at a pharmaceutical processor in complying with §54.1-3442.7 and 18VAC110-60-310 to verify current board registration of the patient, registered agent, parent, or legal guardian obtaining cannabidiol oil or THC-A oil, the Board of Pharmacy will provide the pharmacist-in-charge (PIC) of each pharmaceutical processor with access to the Virginia Cannabis Patient Registration Lookup (VCPRL).

The registration information contained in the VCPRL is confidential and includes the following information: name of patient; name of registered agent, parent, or legal guardian, as applicable; registration number; and expiration date of registration. The PIC is responsible for granting, monitoring, maintaining, and denying access to the VCPRL for all pharmacist and pharmacy technician staff that have, as part of their job, the responsibility to verify that a patient, parent, legal guardian or registered agent is currently registered with the Board of Pharmacy.

As instructed in the VCPRL, the PIC must provide information to the pharmacist or pharmacy technician to complete his own request for access to the Lookup system. Once the request has been submitted, an email will be sent to the PIC for granting access to the pharmacist or pharmacy technician. The PIC should verify the necessity of the employee to have access to the VCPRL prior to approving the request. The approved pharmacist or pharmacy technician will receive an email alerting them that their access request has been granted. The PIC should regularly audit the list of employees with access to the VCPRL to ensure it remains accurate. Upon termination of employment of a pharmacist or pharmacy technician, or a change in employment responsibilities that does not warrant access to the VCPRL, the PIC should immediately terminate the employee's access to the VCPRL.

Verification of a practitioner's registration or a pharmaceutical processor permit may be completed through the Department of Health Professions' online License Lookup feature at [www.dhp.virginia.gov](http://www.dhp.virginia.gov) as this registration and permit information is considered public information.

To assist in ensuring no pharmaceutical processor dispenses more than a 90-day supply for any patient during any 90-day period, the pharmacist or pharmacy technician, who is an authorized delegate of the pharmacist, should verify the quantity and last dates of dispensing of cannabidiol oil or THC-A oil by accessing the Prescription Monitoring Program.

#### ***§ 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. 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.*

*Excerpt from 18VAC110-60-310:*

**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.*

*Excerpt from 18VAC110-60-10:*

***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 cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.*

**Agenda Item: Amend Guidance Documents 110-4, 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, and 110-35**

**Included in agenda package:**

Copy of Guidance Documents 110-4, 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, and 110-35 with draft amendments.

**Staff Note:**

Amendments are necessary based on periodic regulatory review changes that became effective December 11, 2020 or statutory changes from the 2020 General Assembly Session.

**Board action:**

Motion to amend Guidance Documents 110-4, 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, and 110-35 as presented or amended.

# Virginia Board of Pharmacy

## Guide to Continuing Pharmacy Education Requirements

~~Since 1993, To maintain an active license in Virginia, pharmacists who are licensed in Virginia have been~~ required to obtain a minimum of 15 contact hours of continuing pharmacy education (CE) per calendar year, ~~at least three of which must be from courses or programs that are live or real-time interactive in order to maintain an active license.~~ Pharmacy technicians are required to obtain a minimum of 5 contact hours of CE per calendar year. ~~The requirement for obtaining CE from a live or real-time interactive program does not apply to pharmacy technicians.~~ This brochure is intended to help pharmacists and pharmacy technicians better understand the CE requirements. The Board of Pharmacy prepared this document as a guide in order to promote compliance with the statutes and regulations concerning CE.

### **Q. What is the minimum number of CE hours required? When do I have to take them?**

A. The law requires a minimum of 15 contact hours for pharmacists and 5 contact hours for pharmacy technicians per calendar year. ~~For pharmacists, at least three of the required 15 hours must be from courses or programs that are live or real-time interactive. Pharmacists and pharmacy technicians~~ ~~You should receive all your certificates~~ obtain all required CE prior to ~~sending in the license renewal~~ renewing their license or registration in order to properly attest that ~~you they~~ they have met the CE requirements. The certificates or transcript of awarded CE should be dated between January 1 and December 31, inclusive, of the calendar year they are used.

### **Q: What types of courses or programs may a pharmacist successfully complete to meet the requirement for obtaining at least 3 hours annually of “live or real-time interactive” CE?**

A. The following options will satisfy the requirement for live or real-time interactive CE:

- Programs accredited by the Accreditation Council for Pharmacy Education (ACPE) designated with the letter “L” in the second to last section of the program number;
- Category 1 continuing medical education courses accredited by the American Medical Association (AMA), the primary focus of which is pharmacy, pharmacology, or drug therapy designated with the term “live” in the statement of credit provided to the attendee;
- Board-approved CE designated in the certificate of completion as having been approved by the board as “live or real-time interactive” CE; and
- Credit obtained from the board for:
  - A maximum of one hour for attendance at a board meeting or formal hearing; or
  - A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

**Note:** Counsel has advised that volunteering at a free clinic or local health department does not legally satisfy the annual requirement for 3 hours of “live or real-time interactive” CE.

### **Q. May I use hours worked as a volunteer at a free clinic or local health department toward the continuing education requirement?**

A. Yes. Up to two contact hours of the 15 contact hours required for pharmacist annual renewal and one contact hour of the 5 contact hours required for pharmacy technician annual renewal may be satisfied through delivery of pharmacy services, 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 contact hour of continuing education may be credited for three hours of providing such volunteer

services, as documented by the health department or free clinic on the “Continuing Education (CE) Credit Form for Volunteer Practice” found at [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy) under “Forms and Applications”.  
**Credit Note: Counsel has advised that volunteering at a free clinic or local health department does not legally satisfy the annual requirement for 3 hours of “live or real-time interactive” CE.**

**Q. May I carry over my extra hours to next year? What if I’m licensed in another state?**

A. No. The law does not allow carryover. Although some states permit courses to be taken over a two-year period, Virginia does not. This means a pharmacist licensed in Virginia must obtain at least 15 CE hours each and every calendar year and technicians 5. However, if a pharmacist resides in another state whose requirements allow the pharmacist to spread out the required number of hours for more than one year, for example 30 hours every two years, and the pharmacist meets the CE requirements of that other state, Virginia will accept this provided the resident state board of pharmacy attests that the pharmacist has met its requirements and provided the CE requirement of the other state equates to an average of 15 hours a year over the time period allowed.

**Q. May I obtain an extension?**

A. Yes. A one-time extension may be possible if the request is made in writing to the Board prior to renewal. Any further extension requests will only be granted for good cause shown.

**Q. What is the NABP CPE Monitor and must I sign up for this?**

A. NABP CPE Monitor is a collaborative service from NABP and ACPE that provides an electronic system for pharmacists and pharmacy technicians to track their completed CE credits. All ACPE-approved continuing education credits are now required to report to CPE Monitor within 60 days of completion of a course. In order to receive credit for an ACPE-approved continuing education course, you must have an e-profile ID number obtained from CPE Monitor through [www.nabp.pharmacy](http://www.nabp.pharmacy) and provide this number to receive credit for these ACPE-approved CE courses.

**Q. I recently graduated from an ACPE-approved school of pharmacy in Virginia and obtained my initial pharmacist license. Do I need to obtain CE to renew my license for the first time?**

A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination are not required to attest to having obtained CE during their first licensure renewal.

**Q. I recently graduated from an ACPE-approved school of pharmacy in another state and obtained my initial pharmacist license in Virginia via score transfer. Do I need to obtain CE to renew my license for the first time?**

A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination, to include via score transfer, are not required to attest to having obtained CE during their first licensure renewal.

**Q. I am a pharmacist who has held licensure in another state for more than one year and recently endorsed/reciprocated my license to Virginia. Do I need to obtain CE to renew my license for the first time?**

A. Yes, the Board interprets the exemption from CE in §54.1-3314.1 C to apply only to pharmacists who are truly in their first year of licensure as a pharmacist by examination.

**Q. I am a graduate of a foreign school of pharmacy and have obtained my initial license as a pharmacist in the United States from Virginia. Do I need to obtain CE to renew my license for the first time?**

A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination, to include foreign graduates, are not required to attest to having obtained CE during their first licensure renewal.

**Q. I am a graduate of a foreign school of pharmacy who has held licensure as a pharmacist in another state and recently endorsed/reciprocated my license to Virginia. Do I need to obtain CE to renew my license for the first time?**

A. Yes, the Board interprets the exemption from CE in §54.1-3314.1 C to apply only to pharmacists who are truly in their first year of licensure as a pharmacist by examination.

**Q. I received my pharmacist license from Virginia in October. When will I need to renew my license for the first time and how do I comply with the CE requirement?**

A. Regulation 18VAC110-21-~~1100-80~~ states that a pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year. Regulation 18VAC110-21-~~1300-90~~ states a pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure, at least three of which must be from courses or programs that are live or real-time interactive. Therefore, unless exempted from obtaining CE as indicated in §54.1-3314.1 C and discussed above, the pharmacist must obtain 1.5 CEUs or 15 contact hours of CE between the date of issuance of the Virginia pharmacist license and December 31 of the following year.

**Q. I received my pharmacy technician registration from Virginia in July. When will I need to renew my registration for the first time and how do I comply with the CE requirement?**

A. Regulation 18VAC110-20-~~105 21-170~~ states that 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. Regulation 18VAC110-20-~~106 21-180~~ states a pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved CE for each annual renewal of registration. Therefore, the pharmacy technician must obtain 0.5 CEUs or 5 contact hours of CE between the date of issuance of the Virginia pharmacy technician registration and December 31 of the following year.

**Q: Are pharmacy technicians required to obtain continuing education during the first year that they are registered?**

A: Yes, pharmacy technicians are required to obtain 5 hours of continuing education annually. The exemption in §54.1-3314.1 C from obtaining CE during the first licensure renewal applies only to pharmacists.

**Q. Do I have to obtain credits from any particular providers?**

A. Yes. In order to meet the CE requirements, courses must be ACPE-approved, Board-approved, or certain Category 1 CME, the primary focus of which is pharmacy, pharmacology, or drug therapy. Any credits taken that do not meet these requirements cannot be used to satisfy CE hours. For pharmacists, at least three of the required 15 hours must be from courses or programs that are live or real-time interactive.

**Q. I am a pharmacist or pharmacy technician actively taking courses in an ACPE accredited college of pharmacy. Do I have to obtain CE as well, or will my college of pharmacy coursework count as CE?**

A. College of pharmacy coursework may possibly be counted, but must be approved by the Board. There is a form on the Board's website under "Forms and Applications", "Miscellaneous" to submit in order to obtain approval of a college of pharmacy course/courses. Only didactic and laboratory coursework will be considered, and the course must be completed prior to the end of the calendar year in which it is to be counted. Experiential hours, i.e. clerkships, will not be approved. Courses taken as prerequisite coursework for a college of pharmacy program are not approved.

**Q. I've lost my certificates. What should I do?**

A. You should obtain a replacement from the course provider. Some providers make it possible to print duplicates from their web sites. If the CE program awards credit through the NABP CPE Monitor, you may alternatively obtain a copy of your CE transcript online from the NABP CPE Monitor at [www.nabp.net](http://www.nabp.net).

**Q. Do I have to keep my certificates or CE transcript at work?**

A. No. However, the original certificates or printout of the CE transcript must be made available for audit.

**Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied?**

A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course.

**Q. What should I do if the Board audits me?**

A. Whenever the Board contacts you, you should respond promptly. Failure to respond may cause the Board to pursue disciplinary action. If the Board audits your continuing pharmacy education credits, find your original certificates and make a copy for yourself or download a copy of your transcript from NABP CPE Monitor and provide the Board with this transcript. Send the original certificates or printed transcript to the Board office by the deadline in the letter. Although not required, you may want to send your response by certified mail so that you have proof of mailing. If you have lost some or all of your certificates, you should immediately contact the respective providers for a replacement certificate and inform the Board of your actions. The Board has approved standard sanctions for CE non-compliance which can be found in guidance document 110-42.

**Q. What can I do to keep my records better organized?**

A. Here are some suggestions that may help you to keep your CE records organized and avoid disciplinary action:

1. Store your original certificates in a safe place where they are unlikely to be thrown out by mistake.
2. Keep a copy of your certificates, or at least a record of the course number, provider and date, in a secondary safe location (not with the originals). These are a back-up if you lose the originals.
3. BEFORE YOU RENEW YOUR LICENSE, look at your original certificates and/or the NABP CPE Monitor to verify compliance with the CE requirements:
  - 15 contact hours for pharmacists, at least 3 hours of which must be from live or real-time interactive courses or programs, or 5 contact hours for pharmacy technicians (some courses may carry a different number of credits for other professions)
  - ACPE approved for either pharmacists, pharmacy technicians, or both (look for the ACPE logo), or Category 1 CME courses focused on pharmacy, pharmacology or drug therapy
  - each of your CE certificates or the CE transcript shows a "date issued" on or prior to December 31 for the year in question.

**Note: Pharmacists and pharmacy technicians are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. For programs that no longer issue CE certificates, but award credit through the NABP CPE Monitor, it is recommended that pharmacists and pharmacy technicians maintain a copy of their CE transcript from NABP for two years following renewal.**



## Virginia Board of Pharmacy Prescriptive Authority in Virginia

Reference: § 54.1-3400 *et seq.* of the Code of Virginia commonly known as the Drug Control Act and § 54.1-3303 of the Code of Virginia, and respective Board regulations.

In Virginia all prescription drugs are categorized into schedules. Schedules I through V, for the most part, mirror the federal schedules. All prescription or legend drugs not included in Schedules II through V are placed in Schedule VI in Virginia and are also referred to as "controlled" drugs or substances within the Drug Control Act. This is sometimes confusing as the term "controlled" is usually applied only to drugs in Schedules II through V.

Before prescribing any drug in Schedules II-V, a practitioner must obtain a registration from the U.S Drug Enforcement Administration (DEA). The DEA registration must also be on any prescription written for a Schedule II-V drug.

Nurse practitioners who meet certain criteria may be ~~issued a license authorized~~ to prescribe Schedule II-VI drugs by the Boards of Nursing and Medicine. Unless a nurse practitioner has been authorized for autonomous practice, the authorization to prescribe schedules or categories of drugs will be set out in a practice agreement with a collaborating physician. Nurse practitioners with prescriptive authority may dispense samples of those drugs they are authorized to prescribe and may also sign for the receipt of those samples.

Physician assistants (PA's) who meet criteria and have been approved by the Board of Medicine for prescriptive authority may prescribe Schedule II-VI drugs that have been approved by the ~~supervising collaborating medical practitioner~~ physician or podiatrist. A prescription written by a physician assistant for a Schedule II-V drug must include the name of the ~~supervising collaborating~~ physician or podiatrist. Physician assistants may dispense samples of those drugs they are authorized to prescribe and may sign for receipt of samples.

Nurse practitioners or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For nurse practitioners, there is a 10-digit license number beginning with 00470024, which should be on the prescription. To verify the license and click on "License Lookup" at ~~can be verified through the web site~~ [www.dhp.virginia.gov](http://www.dhp.virginia.gov) under "License Lookup" and using "Licensed Nurse Practitioner" for checking the occupation. On the screen displaying the results of the individual's licensure information, the phrase "Rx Authority" will appear under "Specialization" if the nurse practitioner is authorized to prescribe drugs. ~~"Authorization to Prescribe"~~ For physician assistants, there is a 10-digit license number beginning with 011, which can be verified through the web site [www.dhp.virginia.gov](http://www.dhp.virginia.gov) under "License Lookup" and checking the occupation "Physician Assistant."

Practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine have independent prescriptive authority and may prescribe drugs in Schedules II through VI.

Optometrists who have been certified to use therapeutic pharmaceutical agents have independent authority to prescribe and administer certain controlled substances and devices to treat diseases and abnormal conditions of the human eye and its adnexa in these categories:

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV and VI narcotic and non-narcotic agents. They may also prescribe gabapentin in Schedule V.
2. Topically administered Schedule VI agents:
  - a. Alpha-adrenergic blocking agents;
  - b. Anesthetic (including esters and amides);
  - c. Anti-allergy (including antihistamines and mast cell stabilizers);
  - d. Anti-fungal;
  - e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
  - f. Anti-infective (including antibiotics and antivirals);
  - g. Anti-inflammatory;
  - h. Cycloplegics and mydriatics;
  - i. Decongestants; and
  - j. Immunosuppressive agents.
3. Orally administered Schedule VI agents:
  - a. Aminocaproic acids (including antifibrinolytic agents);
  - b. Anti-allergy (including antihistamines and leukotriene inhibitors);
  - c. Anti-fungal;
  - d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
  - e. Anti-infective (including antibiotics and antivirals);
  - f. Anti-inflammatory (including steroidal and non-steroidal);
  - g. Decongestants; and
  - h. Immunosuppressive agents.

Inquiries as to the certification of an optometrist to prescribe therapeutic pharmaceutical agents or requests for regulations may be made by checking the web site [www.dhp.virginia.gov](http://www.dhp.virginia.gov) under "on-line license lookup" and checking for the occupation "TPA certified optometrist." After June 30, 2004, every person who is initially licensed to practice optometry in Virginia must meet the qualifications for a TPA-certified optometrist.

In order to be valid, prescriptions must meet the criteria set forth in § 54.1-3303 of the Code of Virginia (attached). A prescription must be written in the context of a bona fide practitioner-patient relationship, for a medicinal or therapeutic purpose, and within the course of the professional practice of the prescriber. The elements that constitute a bona fide practitioner patient relationship are set forth in this statute.

***from the Code of Virginia:***

***§ 54.1-3303. (Effective July 1, 2020) Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.***

*A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship.*

*For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. A practitioner who performs or has performed an appropriate examination of the patient required pursuant to clause (iii), either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, for the purpose of establishing a bona fide practitioner-patient relationship, may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.*

*For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.*

*For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural*

animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona-fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.

D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, a nurse practitioner, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

*G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.*

*H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.*

*I. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.*

**§ 54.1-3303. (Effective until July 1, 2020) Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.**

*A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32.*

*B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship.*

*A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health*

department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient, provided that, in cases in which the practitioner has performed the examination required pursuant to clause (iii) by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

*C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription. A practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than for medicinal or therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.*

*D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists. A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal or therapeutic purpose within the course of his professional practice.*

*In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed.*

*Any person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.*

*E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, for the close contact except for the physical examination required in clause (iii) of subsection B; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona-fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.*

*F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, a nurse practitioner, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).*

*G. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*H. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers'*

*professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.*

*J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.*

*K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.*



## Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and <u>18VAC110-20-110</u>	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and <u>18VAC110-20-110</u>		1000
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	54.1-3321 and <u>18VAC110-20-111</u> <del>18VAC110-20-80,</del> <del>18VAC110-20-40, and</del> <del>18VAC110-20-105</del>	per individual	250  First documented occurrence = no penalty Repeat = \$ penalty
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	<u>18VAC110-21-60,</u> <u>18VAC110-21-110, and</u> <u>18VAC110-21-170</u>	per individual	100  First documented occurrence = no penalty Repeat = \$ penalty
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320 <u>18VAC110-20-112</u>	per individual	500

Guidance Document: 110-9

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320 <u>18VAC110-20-112</u>	per each technician over the ratio	First documented occurrence = no penalty Repeat = \$ penalty  100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	First documented occurrence = no penalty; drugs may be embargoed Repeat = \$ penalty  100  Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000
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. <u>The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.</u>	18VAC110-20-180		First documented occurrence and no drug loss = no penalty  Drug loss or repeat = \$ penalty  250

**Guidance Document: 110-9**

<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Monetary Penalty</b>
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
<p>12a. Schedule II drugs are not dispersed with other schedules of drugs, or maintained in a securely locked cabinet, drawer, or safe, <u>or maintained in a manner that combines the two methods.</u></p>		<p>Do not cite if stored in a combination method as allowed in Guidance Document 110-40.</p>	<p>First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = \$ penalty</p>
<p>13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.</p>	<p>18VAC110-20-200</p>	<p>Cite Deficiency 113 if only expired drugs not included in inventory.</p>	<p>Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = \$ penalty</p>
<p>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</p>	<p>54.1-3404 and 18VAC110-20-240</p> <p>54.1-3434 and 18VAC110-20-240</p>	<p>Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory.</p>	<p>500</p> <p>500</p>

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
<p>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</p> <p><u>Perpetual inventory not being maintained as required as it does not:</u></p> <ul style="list-style-type: none"> <li><u>Include all Schedule II drugs received and dispensed;</u></li> <li><u>Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory;</u></li> <li><u>Include a reconciliation of each Schedule II drug at least monthly; or</u></li> <li><u>Include a written explanation for any difference between the physical count and the theoretical count;</u></li> </ul> <p><u>Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.</u></p>	<p>18VAC110-20-240</p> <p>54.1-3404 and 18VAC110-20-240</p>	<p>Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.</p> <p>per report/theft-loss</p>	<p>250</p> <p>250</p>
<p>16. Theft/unusual loss of drugs not reported to the Board as required</p>	<p>18VAC110-20-240</p>	<p>per report/theft-loss</p>	<p>250</p>

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<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Monetary Penalty</b>
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)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
<p>21a. Performing sterile compounding outside of a clean room.</p> <p>21b. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.</p>	<p>54.1-3410.2</p>	<p>Compliant clean room present but not utilized for preparation of compounded sterile drug products.</p>	<p>3000</p>
<p>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.</p>	<p>54.1-3410.2</p>	<p>Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification</p>	<p>3000</p>
<p>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.</p>	<p>54.1-3410.2</p>	<p>Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification</p>	<p>1000</p>
<p>24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas</p>	<p>54.1-3410.2</p>		<p>2000</p>

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



Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
<p>26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.</p>	<p>54.1-3410.2</p>	<p>Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated.</p>	<p>500</p>
<p>26a. Documentation that a person who failed a media-fill test or gloved fingertip 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 and gloved fingertip test</p>	<p>54.1-3410.2</p>		<p>500</p>
<p>27. Compounding using ingredients in violation of 54.1-3410.2.</p>	<p>54.1-3410.2</p>		<p>1000</p>
<p>28. Compounding copies of commercially available products</p>	<p>54.1-3410.2</p>	<p>per Rx dispensed up to maximum of 100 RX or \$5000</p>	<p>50</p>
<p>29. Unlawful compounding for further distribution by other entities</p>	<p>54.1-3410.2</p>		<p>500</p>

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<b>Deficiency</b>	<b>Law/Reg Cite</b>	<b>Conditions</b>	<b>\$ Monetary Penalty</b>
30. Security of after-hours stock not in compliance	18VAC110-20-450		First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty 500
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.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First documented occurrence and no known patient harm = no penalty Repeat = \$ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

**Other Deficiencies**

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

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
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	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
stock container)		
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
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.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 <u>18VAC110-20-270</u>	10% threshold
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20- 255, 18VAC110-20-310, and 18VAC110-20-320	

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Deficiency	Law/Regulation Cite	Conditions
120. Offer to counsel not made as required	54.1-3319	
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a. Compounded products not properly labeled	54.1-3410.2	

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold

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<b>Deficiency</b>	<b>Law/Regulation Cite</b>	<b>Conditions</b>
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. Repealed 6/21/2018		
144. Repealed 6/21/2018		
145. Repealed 6/21/2018		
146. Repealed 6/21/2018		
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

**Guidance Document: 110-9**

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

**Examples:**

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

Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

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

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

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

Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.



## Virginia Board of Pharmacy

### Performing Inventories

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

- ~~• Those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and he is unable to determine the exact kind and quantity of the drug loss;~~
- Dispensers, researchers, and reverse distributors may otherwise perform the inventory in a manner consistent with federal allowances, as listed in 21 CFR 1304.11 (attached to this document), which require a physical count of drugs in Schedules I and II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; and
- Nothing shall prohibit a person from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

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

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

*from 21 CFR 1304.11*

### **Section 1304.11 Inventory Requirements**

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

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

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

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

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

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

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

~~(A) The name of the substance and~~

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

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

~~(A) The name of the substance;~~

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

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

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

~~(A) The name of the substance;~~

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

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

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

~~(iv) For each controlled substance not included in paragraphs (e)(1)~~

~~(i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:~~

~~(A) The name of the substance;~~

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

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

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

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

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

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

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

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

### **§1304.11 Inventory requirements**

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

substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

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

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

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

(e) *Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors.* Each person registered or authorized (by §§1301.13, 1307.11, 1307.13, or part 1317 of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.

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

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

(A) The name of the substance and

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

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

(A) The name of the substance;

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

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate

identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

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

(A) The name of the substance;

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

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

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

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

(A) The name of the substance;

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

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

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance;

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II, make an exact count or measure of the contents;

or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: The number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

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

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

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

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

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

(7) Inventories of collectors. Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);

(C) The unique identification number of each inner liner.





## Virginia Board of Pharmacy

### Practice by a Pharmacy Technician Trainee

Regulations of the Board of Pharmacy allow a person enrolled in a Board-approved pharmacy technician training program to perform duties restricted to pharmacy technicians, for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia, for no more than nine months without that person becoming registered as a pharmacy technician. (See Regulations ~~18VAC110-20-101-140~~, 18VAC110-20-111, and definition of "pharmacy technician trainee" in 18VAC110-201-10)

The Board interprets the restriction of nine months of practice for a pharmacy technician trainee to mean **nine consecutive months** from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of a Board-approved pharmacy technician training program. For example, a pharmacy technician trainee completes the didactic or classroom portion of a training program and begins performing tasks restricted to a pharmacy technician on January 1<sup>st</sup>. The technician may conduct tasks restricted to a pharmacy technician until October 1<sup>st</sup> of that year. If she/he ceases enrollment in the pharmacy technician training program in March and enrolls in a second pharmacy technician training program in July, she/he may still only perform tasks restricted to a pharmacy technician until October 1<sup>st</sup> of that year. By that date, the trainee must either be registered with the Board as a pharmacy technician or cease performing any tasks restricted to pharmacy technicians.

~~18VAC110-20-101. Application for registration as a pharmacy technician.~~

~~D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.~~

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

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.

18VAC110-20-111. Pharmacy technicians.

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

*inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.*

### **18VAC110-201-10 Definitions.**

*"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.*

### **§ 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 that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.*

*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 of continued competency as a condition of renewal of a registration as a pharmacy technician.*

*F. 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.*

## Virginia Board of Pharmacy

### Use of Dispensing Records to Identify Pharmacist Responsible for Dispensing Error

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

#### Dispensing Scenario #1

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

#### Dispensing Scenario #2

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

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

~~Adopted: June 12, 2012~~

~~Revised: December 12, 2013-March 24, 2020~~

~~Re-adopted: June 21, 2018-Effective:~~

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

### **Dispensing Scenario #3**

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

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

#### ***Relevant sections of law and regulation:***

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

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

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

~~Adopted: June 12, 2012~~

~~Revised: December 12, 2013-March 24, 2020~~

~~Re-adopted: June 21, 2018 Effective:~~

- A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:
1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:
    - a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.
    - b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.
    - c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.
  2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.
  3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.
  4. Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).

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

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

#### **18VAC110-20-255. Other dispensing records.**

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

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

~~C. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If~~

Adopted: June 12, 2012

Revised: December 12, 2013 March 24, 2020

Re-adopted: June 21, 2018 Effective:

~~the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.~~

**18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions.**

**B. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects and place his initials on the record of dispensing as a certification of the accuracy of and the responsibility for the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which each pharmacist is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.**

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

- A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:
1. Receiving, interpreting, analyzing, or clarifying prescriptions;
  2. Entering prescription and patient data into a data processing system;
  3. Transferring prescription information;
  4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
  5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
  6. Interpreting clinical data for prior authorization for dispensing;
  7. Performing therapeutic interventions; or
  8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.
- B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:
1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
  2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
  3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
  4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.
- C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing

Adopted: June 12, 2012

Revised: December 12, 2013 March 24, 2020

Re-adopted: June 21, 2018 Effective:

central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

- D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:
1. The responsibilities of each pharmacy;
  2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
  3. Procedures for protecting the confidentiality and integrity of patient information;
  4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
  5. Procedures for maintaining required records;
  6. Procedures for complying with all applicable laws and regulations to include counseling;
  7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
  8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.
- E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.
1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
  2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.
- F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

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

- A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:
1. Receiving, interpreting, analyzing, or clarifying prescriptions;
  2. Entering prescription and patient data into a data processing system;
  3. Transferring prescription information;
  4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;
  5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;
  6. Interpreting or acting on clinical data;
  7. Performing therapeutic interventions;
  8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or

~~Adopted: June 12, 2012~~

~~Revised: December 12, 2013 March 24, 2020~~

~~Re-adopted: June 21, 2018 Effective: \_\_\_\_\_~~

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.
- B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:
  1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
  2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
  3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and
  4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.
- C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:
  1. The responsibilities of each pharmacy;
  2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;
  3. Procedures for protecting the confidentiality and integrity of patient information;
  4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
  5. Procedures for maintaining required records;
  6. Procedures for complying with all applicable laws and regulations;
  7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
  8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.
- D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.
  1. The record shall be available by prescription order or by patient name.
  2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.
  3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.
- E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.



## Virginia Board of Pharmacy

### PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

#### New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Additionally, the alarm must have at least one hard-wired communication method and a notification of any breach of the alarm must be communicated to the pharmacist-in-charge or a pharmacist working at the pharmacy. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.
- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a \$150 reinspection fee will be assessed in order to schedule and conduct the reinspection.
- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must

ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.
- Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, you must notify the board office, and a pharmacist shall continue to be on site on a daily basis.
- Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.

#### **Upon taking over responsibility as PIC:**

- A pharmacy permit application must be submitted to the Board indicating the effective date you intend to assume the role as PIC. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Assuming you are eligible to assume the role of PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on April 30<sup>th</sup> annually. Be sure that the permit is renewed each year. *Note: A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.*
- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."
- Take an incoming change of PIC inventory of all Schedule II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, prior to opening for business on the date you first assume the role as PIC, i.e., the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business, if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or

distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm).

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy).
- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board-approved training program for not more than nine months from the date the trainee began performing duties restricted to a pharmacy technician. When considering a person for employment as a pharmacy technician, verify through "License Lookup" at [www.dhp.virginia.gov/pharmacy](http://www.dhp.virginia.gov/pharmacy) that the person has not been a registered pharmacy technician within the past 5 years. If the person has a pharmacy technician registration that expired less than 5 years ago, he or she must first renew or reinstate this registration before being authorized to perform the duties of a pharmacy technician in the pharmacy.
- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from <http://www.dhp.virginia.gov>. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -13°F and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at [http://www.dhp.virginia.gov/Pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm). You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.
- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

**Safeguards against Diversion of All Controlled Substances:**

- The PIC “shall provide safeguards against diversion of all controlled substances”. This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.
- It is the policy of the Board to include the name of the PIC (s) in the findings of fact in any disciplinary proceeding involving diversion of drugs.
- The PIC shall:
  - Ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;
  - Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm)
  - Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at [http://www.dhp.virginia.gov/pharmacy/pharmacy\\_guidelines.htm](http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm)
  - Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.
  - Not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.
- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:
  - Perform state and federal criminal background checks on all personnel with access to controlled substances;

- Require periodic urine drug screening of all personnel with access to controlled substances;
- Prohibit personnel from bringing smocks or bags into the prescription department;
- Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;
- Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;
- In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconcile all discrepancies;
- Do not delegate the management of drug inventory to solely one individual;
- Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
- Install surveillance cameras to prevent and/or identify theft or loss of controlled substances; and
- Have full and timely access to all reports relating to inventories, invoices, and audits
- In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

**Upon leaving as PIC:**

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.
- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately.

For your protection, we would suggest that you return it by certified mail, return receipt requested.

DRAFT

# VIRGINIA BOARD OF PHARMACY

## GUIDANCE ON VIRGINIA PRESCRIPTION REQUIREMENTS

### Written Prescriptions:

- Written prescriptions shall include the patient's first and last name. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.
- The prescription shall contain the prescriber's name, address, and telephone number, and DEA number if for a Schedule II-V prescriptions. Prescriber information shall be either preprinted on the blank, electronically printed, typed, stamped, or printed by hand in a legible manner. Interns and residents in a residency program may use the hospital DEA number and an assigned suffix.
- Prescriptions issued by physician assistants for drugs in Schedule II-V shall also include the name of their supervising collaborating physician or podiatrist. Note: The physician is not required to *co-sign* a physician assistant's prescription for a Schedule II-VI drug.
- As of March 4, 2020, nurse practitioners are no longer issued a separate license for prescriptive authority. Nurse practitioners who have been granted prescriptive authority will have an additional designation of 'RX Authority' clearly displayed on their license to practice nursing which begins with the numbers 0024. Nurse practitioners who are authorized for autonomous practice or who are authorized by a practice agreement with a collaborating physician to prescribe Schedule II-VI drugs are not required to include the prescriptive authority number issued to them by the Boards of Nursing and Medicine, if their DEA registration number is included on the prescription. Nurse practitioners who are authorized by a practice agreement to only prescribe Schedule VI drugs and who do not have a DEA number must include the prescriptive authority number issued to them by the Boards of Nursing and Medicine.
- Written prescriptions shall be legibly written with ink or individually typed or printed.
- Written prescriptions may be prepared by an agent for the prescriber's signature, but shall be manually signed by the prescriber.
- Computer-generated prescriptions that are printed out shall be manually signed by the prescriber.
- Written prescriptions shall be dated with the date the prescription is written.
- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or

authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

- Prescriptions for Schedule VI drugs may be preprinted with the drug name, directions for use, quantity, but must still meet all other requirements of individually written prescriptions for patient name, signatures, issue date, and any other required information. Preprinted prescriptions may contain a list of drugs with a checkbox beside the drug name to be selected by the prescriber, but only one drug may be selected for each prescription.
- Schedule II prescriptions shall be written and may not be refilled.
- There is no longer a specific format required for written prescriptions. A pharmacist may substitute an Orange-Book rated "therapeutically equivalent drug product" for a brand name drug unless the prescriber prohibits substitution by indicating "brand medically necessary."
- A prescription blank may only contain one prescription. There are a few limited exceptions to this law such as multiple blanks for the Department of Corrections and chart orders for hospital, nursing home, home infusion, and hospice patients.
- A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:
  - The chart order was written for a patient while in a hospital or long term care facility.
  - The pharmacist has all information necessary to constitute a valid outpatient prescription.
  - The pharmacist in an outpatient setting must have direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.
  - The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

**Requirements of the Virginia Department of Medical Assistance Services for written prescriptions for Medicaid and FAMIS fee-for-service patients:**

- Tamper-resistant prescriptions are required for all prescriptions used for Medicaid and FAMIS fee-for-service recipients. Tamper resistant pads are defined as having at least one feature in all three of the following categories:
  - 1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form,
  - 2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, or
  - 3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.



**Oral Prescriptions:**

- Oral prescriptions shall contain all the same information as written prescriptions except for the prescriber's signature, and shall be reduced to writing by the pharmacist receiving the prescription.
- The prescriber or his authorized agent may transmit the prescription. If transmitted by an authorized agent, the pharmacist shall record the full name of the agent. According to Virginia law, an authorized agent may only be an employee of the prescriber under his immediate and personal supervision, or if not an employee may only be someone who holds a license to administer drugs, such as a nurse, physician assistant, or another pharmacist. For Schedule II-V oral prescriptions, DEA may interpret the authority of an agent differently, as well as who can be an authorized agent.

**Faxed Prescriptions:**

- A faxed prescription that starts out as a written prescription and is placed onto a fax machine in the physician's office and sent via phone to a pharmacy's fax machine where a facsimile image is printed for the pharmacy records must meet all requirements for a written prescription, to include the manual signature of the prescriber.
- Computer-generated prescriptions that are faxed must be manually signed by the prescriber.
- Schedule III-VI prescriptions may be faxed to a pharmacy.
- Schedule II prescriptions (or chart orders) may **only** be faxed to a pharmacy for long term care facility patients, home infusion patients, and hospice patients.
- Pharmacies may not begin the dispensing process when a prescription is faxed directly from the patient, even if the patient brings in the hard copy when they come to pick up the medication. Prescriptions may only be faxed from the prescriber's practice location

**Electronically transmitted prescriptions:**

- An electronically transmitted prescription is one that is generated from the prescriber's office electronically, sent out as an electronic transmission, is normally routed through a switch to the appropriate pharmacy, and is received by the pharmacy in the form of an electronic transmission or is converted by the switch to a fax, and is printed out on the pharmacy's fax machine. "Electronic prescription" means a written prescription that is generated on an electronic application and transmitted to a pharmacy as an electronic data file. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber that identifies him as the source of the message and indicates his approval of the information contained in the message. If the prescription is generated electronically, but then is printed out in the office and given to the patient, it is no

longer an electronic prescription and must follow the guidelines of a written prescription to include bearing the prescriber's manual signature.

- Schedule II - VI prescriptions may be transmitted electronically. Schedule II – V prescriptions must meet all federal requirements including required security and authenticity features, as well as required recordkeeping for the prescriber and pharmacy.
- The application provider used by a prescriber or a pharmacy for electronic prescriptions of Schedules II-V drugs must be reviewed and certified by an approved certification body for compliance with DEA's standards. The application provider must provide a copy of this report to the pharmacy or prescriber using its services. A pharmacy or prescriber shall not dispense or issue an electronic prescription for Schedules II-V drugs until a report is received from the application provider indicating full compliance with DEA's standards. A pharmacy or prescriber may continue dispensing or issuing electronic prescriptions for Schedule VI drugs in compliance with Board regulations prior to receiving a report from the application provider regarding its status of compliance with federal law.
- Individual prescribers authorized to prescribe Schedules II-V drugs who choose to issue electronic prescriptions for Schedules II-V drugs shall first apply to certain federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates.
- An electronic prescription for a Schedule VI drug may either directly populate the pharmacy's automated dispensing system or may be converted by the switch to a fax, and printed out on the pharmacy's fax machine. Federal law does not permit an electronic prescription for a Schedule II-V drug to be converted to the pharmacy's fax machine. It must directly populate the pharmacy's automated dispensing system in conformity with federal law.
- Please refer to the federal regulations for additional guidance.

**Agenda Item: Repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40**

**Included in agenda package:**

Copy of Guidance Documents 110-14, 110-19, 110-32, and 110-40

**Staff Note:**

Repeal is necessary based on periodic regulatory review changes that became effective December 11, 2020 or statutory changes from the 2020 General Assembly Session.

**Board action:**

Motion to repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40.

## VIRGINIA BOARD OF PHARMACY

### Statistically Valid Sample Size for Pharmaceutical Processors

The Board deems that a sample size consistent with the sampling requirements found in the United States Pharmacopeia Chapter < 561> *Articles of Botanical Origin* will satisfy the requirement in Regulation 18VAC110-60-300 for a “statistically valid sample.”

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

*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.*

## Virginia Board of Pharmacy

### Transferring Valid Orders between Medical Equipment Suppliers

A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer should be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, or by facsimile machine or by electronic transmission.

The transferring medical equipment supplier should:

- a. Record the word "VOID" on the face of the invalidated order;
- b. Record on the reverse of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information; and,

The receiving medical equipment supplier should:

- a. Write the word "TRANSFER" on the face of the transferred prescription.
- b. Provide all information required to be on a valid order to include:
  - (1) Date of issuance of original order;
  - (2) Original number of refills authorized on the original order;
  - (3) Date of original dispensing, if applicable;
  - (4) Number of valid refills remaining and date of last dispensing;
  - (5) Medical equipment supplier name and address from which the order information was transferred; and
  - (6) Name of transferring individual, if transferred orally.

Both the original and transferred order should be maintained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical equipment supplier may record all required information in an automated data processing system used for storage and retrieval of dispensing information.

*Related statute and regulation:*

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

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

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

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

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

**18VAC110-20-680. Medical equipment suppliers.**

*A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.*

*B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.*

*C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and*

*provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.*

*D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:*

- 1. Name and address of patient;*
- 2. Item dispensed and quantity, if applicable; and*
- 3. Date of dispensing.*

## **Virginia Board of Pharmacy**

### **The Use of a Drop Box for the Collection of Prescriptions**

A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box must be located in a visible area within the permitted facility and must be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. At no time shall a patient be allowed to leave containers to be refilled which contain drug.



## Virginia Board of Pharmacy

### Storage of Schedule II Drugs in a Pharmacy

Regulations governing the practice of pharmacy provide in subsection B of 18VAC110-20-200 that:

*Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.*

The Board interprets the regulation to mean that Schedule II drugs in a pharmacy may be dispersed with other schedules of drugs on the shelves, maintained within a securely locked cabinet, drawer, or safe, or maintained in a manner which combines the two methods for storage.

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

**Included in agenda package:**

Copy of Guidance Documents 110-39

**Staff Note:**

A pharmacist expressed concern to staff that the current guidance document indicating that the pharmacy is not required to close when a pharmacist is on break does not really afford a pharmacist an uninterrupted break. The pharmacist requested the board to amend its guidance document to require a pharmacy to close when the pharmacist is on break.

**Board action:**

Motion to amend Guidance Document 110-39, or

Take no action.

## Virginia Board of Pharmacy

### Guidance for Continuous Hours Worked by Pharmacists and Breaks

#### *Regulations Governing the Practice of Pharmacy*

#### *18VAC110-20-110. Pharmacy permits generally.*

*B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.*

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

**Agenda Item: Request for Guidance for Granting Exception to Minimum Two Years' Experience for PIC Eligibility**

**Included in agenda package:**

Copy of 18VAC110-20-110

**Board action:**

Discuss process for considering, granting, and denying requests for an exception to the minimum two years' experience for PIC eligibility.

*From Regulations Governing the Practice of Pharmacy, December 11, 2019*

**18VAC110-20-110. Pharmacy permits generally.**

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

\* D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

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

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day

deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

**Agenda Item: Request to Amend Regulation to Extend Change of PIC Timeframe from 14 to 30 Days**

**Included in agenda package:**

Copy of §54.1-3434

Excerpt from 18VAC110-20-110

**Staff Note:**

Request from board member to consider increasing timeframe from 14 days to 30 day for designating new PIC.

**Possible Board actions:**

Motion to adopt Notice of Intended Regulatory Action to amend 18VAC110-20-110;

Refer to Regulation Committee this fall;

Request additional information for September board meeting;

Take no action.

*From The Pharmacy Act and The Drug Control Act with Related Statutes, July 1, 2019*

**§ 54.1-3434. Permit to conduct pharmacy.**

No person shall conduct a pharmacy 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 pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within 15 days of receipt of this notice. At the conclusion of the 15-day period, the Director or his authorized agent, or any law-enforcement officer in coordination with the Director, shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and the Director shall notify the owner of such seizure. The Director, his authorized agent, or the law-enforcement officer may properly dispose of the seized drugs and devices after 60 days from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board or law-enforcement agency shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.



The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Every pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

Each day during which a person is in violation of this section shall constitute a separate offense.

**Excerpt from *Regulations Governing the Practice of Pharmacy*, December 11, 2019**

**18VAC110-20-110**

H. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

**Agenda Topic: Consideration for requiring CE on a specific topic in 2021**

**Background information:**

Action item from December 9, 2019 board meeting. Refer to draft minutes.

Statutory allowance:

**§ 54.1-3314.1. Continuing education requirements; exemptions; extensions; procedures; out-of-state licensees; nonpractice licenses.**

J. As part of the annual 15-hour requirement, the Board may require up to two hours of continuing education in a specific subject area. If the Board designates a subject area for continuing education, it shall publish such requirement no later than January 1 of the calendar year for which the specific continuing education is required.

Topics Required in the Past:

2015 – pharmacists - one hour on the topic of "opioid use or abuse"

2017 – pharmacists - one hour "in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration"

**THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate.**

Consideration of  
Amendments to Incorporate  
Changes Currently in  
Approved Innovation Pilots

Mr. Johnson provided an overview to the board of the Medication Carousel and Radio Frequency Identification (RFID) technologies currently in use in certain hospital pharmacies via innovative pilot programs. The Regulation Committee voted unanimously to recommend to the board to amend the language in 18VAC110-20-425(C)(2) to allow for these technologies.

**MOTION:**

**The board voted unanimously to accept the recommendation of the Regulation Committee to adopt a NOIRA to allow for the use of medication carousels and RFID technology in hospital pharmacies.**

Discussion of  
Immunization Records

Mr. Ratliff shared some background on his experience using the Virginia Immunization Information System (VIIS) database.

**ACTION ITEM:**

**The board requested staff to reach out to VDH to determine if an immunization coalition is being formed that would possibly be discussing immunization administration recordkeeping, how a hospital pharmacist would report to the database since the pharmacist may not know if the vaccine was truly administered or if a template exists for hospitals to report immunization administrations, and if the database could potentially support increased usage via mandatory reporting from pharmacists or all health care providers. The board also requested that staff educate pharmacists on the VIIS database in an upcoming board e-newsletter.**

**OLD BUSINESS:**

Review Pharmacy Closing  
Statistics

Ms. Juran provided a review of pages 104-115 of agenda packet regarding the number of pharmacy permits issued and closed during recent years. She also provide the board with a map indicating the location of current pharmacies in Virginia. She reminded the board that there is only one type of pharmacy permit and that staff could not easily distinguish the type of pharmacy services being provided at each pharmacy location.

**NEW BUSINESS:**

\* Discuss Request from  
VPhA to Require CE for  
Statewide Standing Order  
for Dispensing Naloxone

Ms. Juran shared that she is not aware of a current CE program specifically developed on the use of the Virginia Health Commissioner's standing order for naloxone. She also stated that the board is not currently in a position to develop such a program. She reminded the board that the board can require pharmacists to complete up to two hours of CE on a specific subject, but that they must notify licensees prior to January 1. There was some discussion regarding whether to require CE on the general subject of naloxone.

\* **ACTION ITEM:**

**The board decided to table the discussion of whether to require CE in a particular subject to the March board meeting.**



CAROLYN W. DULL, MAYOR



BIRTHPLACE OF THE  
COUNCIL-MANAGER  
FORM OF GOVERNMENT

April 24, 2020

BY ELECTRONIC MAIL  
Cynthia Warriner, Chair  
Virginia Board of Pharmacy  
Perimeter Center  
9960 Mayland Drive, Suite 300  
Henrico Virginia 23233-1463

Dear Chair Warriner:

It is my pleasure to support MedMen Enterprises Inc.'s efforts to be the pharmaceutical processor in Health District 1 here in the City of Stanton, through its affiliated entity, PharmaCann of Virginia, LLC. In 2018, the City's economic development department worked with PharmaCann, LLC (unrelated to PharmaCann of Virginia, LLC) to secure a site within the city's Green Hills Industry and Technology Center. As the new controlling interest in this venture, MedMen will also enjoy convenient access to two major interstates so that citizens living outside the City of Stanton have access to the facility as well.

Like many others, I hope this facility will help improve the lives of our citizens who are suffering from chronic illnesses. It will also support our local economy with a significant capital investment and new, good paying jobs for our citizens. I welcome this opportunity and hope that the Board of Pharmacy will approve MedMen's proposed corrective action plan to get this project completed.

MedMen is a leader in the medical cannabis industry and is well respected in the several other states in which it operates. I appreciate their continued interest in the City of Stanton, and I hope that they receive final approval. Our region would be very grateful.

Sincerely,

Carolyn W. Dull  
Mayor

cc: Members of Stanton City Council

Virginia Board of Pharmacy  
 Inspection Report  
 June 16, 2020

Licenses Issued

	12/1/18-2/28/19	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	License Count 5/1/2020
Business CSR	41	19	36	32	23	25	1,418
CE Courses	0	0	0	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	11
Medical Equipment Supplier	2	1	3	7	1	4	225
Nonresident Manufacturer	24	8	11	11	10	7	191
Nonresident Medical Equipment Supplier	10	5	30	12	14	9	338
Non-resident Outsourcing Facility	0	0	1	0	1	0	30
Non-resident Pharmacy	24	22	27	18	21	33	801
Non-resident Third Party Logistics Provider		8	58	42	17	14	139
Non-resident Warehouse		6	10	16	6	19	54
Non-resident Wholesale Distributor	13	3	22	13	8	8	612
Non-restricted Manufacturer	1	1	2	0	0	1	31
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor					1	1	2
Pharmacist	157	134	316	328	187	120	15,413
Pharmacist Volunteer Registration	0	0	2	1	0	0	0
Pharmacy	13	7	13	10	11	10	1,775
Pharmacy Intern	122	74	65	225	43	160	1,642
Pharmacy Technician	388	249	426	433	485	345	12,988
Pharmacy Technician Training Program	3	2	3	3	1	0	131
Physician Selling Controlled Substances	44	7	25	18	23	28	619
Physician Selling Drugs Location	8	3	7	4	3	6	171
Pilot Programs	0	2	1	0	1	0	23
Registered Practitioner For CBD/THC-A Oil	40	25	52	59	39	58	373
Repackaging Training Program	0	1	0	0	0	0	2
Restricted Manufacturer	1	0	1	0	0	1	44
Third Party Logistics Provider	0	0	1	0	0	1	6
Warehouse	9	0	0	1	3	2	112
Wholesale Distributor	0	0	1	3	0	0	65
<b>Total</b>	<b>900</b>	<b>577</b>	<b>1,113</b>	<b>1,236</b>	<b>898</b>	<b>852</b>	<b>37,225</b>

Virginia Board of Pharmacy  
 Inspection Report  
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Inspections Completed

	12/1/18-2/28/19	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	Total	Virtual
<b>License Type</b>								
Controlled Substances Registration	164	83	145	177	111		145	35
Medical Equipment Supplier	10	11	21	19	36		33	8
Non-restricted Manufacturer	3	1	3	0	0		1	
Permitted Physician	0	0	0	0	1		0	
Physician Selling Drugs Location	30	11	39	30	39		18	1
Restricted Manufacturer	1	0	1	0	0		2	
Third Party Logistics Provider	1	0	1	2	0		3	
Warehouse	10	7	10	7	11		16	3
Wholesale Distributor	9	2	11	7	5		5	1
Pharmacy	227	207	348	284	274		184	8
Pilot	0	1	0	0	0		6	1
Pharmaceutical Processor					6		1	
<b>Total</b>	<b>455</b>	<b>323</b>	<b>579</b>	<b>526</b>	<b>483</b>		<b>414</b>	<b>57</b>

**Pharmacy (0201) Inspections**

Change of Location	0	0	7	5	5		4	2
New	12	6	13	10	10		9	1
Reinspection	14	4	9	15	10		7	
Remodel	40	38	53	49	39		42	5
Routine	159	159	253	193	207		121	
Focus	0	0	2	3	2		1	
Federal Agency	0	0	11	9	0		0	
Compliance	2	0	0	0	1		0	
Pilot	0	0	0	0	0		0	
<b>Total</b>	<b>227</b>	<b>207</b>	<b>348</b>	<b>284</b>	<b>274</b>		<b>184</b>	<b>8</b>

**Pharmacy Routine Inspections**

No Deficiency	57	36%	53	33%	98	39%	64	33%	73	35%	42	35%
Deficiency	55	34%	47	34%	76	34%	66	34%	70	34%	34	28%
Deficiency & IPHCO	47	30%	59	37%	79	31%	63	33%	64	31%	45	37%
<b>Total</b>	<b>159</b>		<b>159</b>		<b>253</b>		<b>193</b>		<b>207</b>		<b>121</b>	

Virginia Board of Pharmacy  
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 Frequently Cited Deficiencies  
 December 2018 - April 2020

<b>Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)</b>	<b>Cumulative Total</b>
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	120
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	60
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)	44
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
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	26
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)	25
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	25
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	23
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)	22
<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)	166
123. Engaging in remote processing not in compliance	95
127. Repackaging records and labeling not kept as required or in compliance	95
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.	92
130a. Compounded products not properly labeled	66
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	66
108. Emergency access alarm code/key not maintained in compliance	62
124. Labels do not include all required information	55
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	46
119. Not properly documenting partial filling of prescriptions	46

Virginia Board of Pharmacy  
Inspection Report  
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Deficiencies 1 - 100  
(Formerly Major Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
<b>Routine Inspections Completed</b>	<b>159</b>	<b>159</b>	<b>253</b>	<b>193</b>	<b>207</b>	<b>121</b>	<b>1092</b>	<b>Repeat</b>	<b>Repeat</b>
<b>Total Deficiencies</b>	<b>60</b>	<b>101</b>	<b>123</b>	<b>119</b>	<b>111</b>	<b>74</b>	<b>588</b>	<b>6</b>	<b>266</b>
<b>Average Deficiencies per Inspection</b>	<b>0.4</b>	<b>0.6</b>	<b>0.5</b>	<b>0.6</b>	<b>0.5</b>	<b>0.6</b>	<b>0.5</b>		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	1	2	0	0	4	1	8		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	6	12	14	7	15	6	60		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	2	5	1	4	4	2	18		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	1	1	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	0	2	6	5	2	15		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	1	0	1	0	2		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	2	5	11	4	2	5	29		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	1	1	0	0	3	0	5		1
9. Alarm not operational or not being set	0	1	0	0	1	1	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)	0	3	2	11	5	1	22		1



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Deficiencies 1 - 100  
(Formerly Major Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	0	4	2	7	3	0	16		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	2	3	1	3	2	12		
12. Storage of prescription drugs not in the prescription department	1	3	5	5	3	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)	0	4	3	2	4	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)	2	3	8	5	4	3	25	1	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)	8	9	6	7	8	6	44		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	16	19	31	19	17	18	120	4	119
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	3	4	4	5	3	6	25		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)	2	1	0	3	0	2	8		
18. Records of dispensing not maintained as required	3	2	1	4	1	0	11		1
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	1	0	2	3	2	1	9		3

Virginia Board of Pharmacy  
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June 16, 2020

Deficiencies 1 - 100  
(Formerly Major Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
20. Pharmacist not checking and documenting repackaging or bulk packaging	0	3	10	5	5	3	26		18
20a. Pharmacist not documenting final verification of non-sterile compounding	1	5	5	1	2	2	16		4
20b. Pharmacist not documenting final verification of sterile compounding	1	3	1	3	4	0	12		16
21. No clean room	0	0	0	0	0	0	0		
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	0	1	0	1	2		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	2	0	0	0	0	1	3		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	0	1	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  
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Deficiencies 1 - 100  
 (Formerly Major Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	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.	2	3	4	5	6	3	23		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	0	1	0	0	1	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	0	1	1	2	0	0	4		1
29. Unlawful compounding for further distribution by other entities	1	0	1	1	0	1	4		
30. Security of after-hours stock not in compliance	0	0	0	0	0	1	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	4	6	4	4	26	1	22
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	1	0	1	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	0	1	0	1		1

Virginia Board of Pharmacy  
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Deficiencies Above 100  
 (Formerly Minor Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
<b>Routine Inspections Completed</b>	<b>159</b>	<b>159</b>	<b>253</b>	<b>193</b>	<b>207</b>	<b>121</b>	<b>1092</b>	<b>Repeat</b>	<b>Repeat</b>
<b>Total Deficiencies</b>	<b>160</b>	<b>150</b>	<b>238</b>	<b>239</b>	<b>208</b>	<b>97</b>	<b>995</b>	<b>6</b>	<b>376</b>
<b>Average Deficiencies per Inspection</b>	<b>1.0</b>	<b>0.9</b>	<b>0.9</b>	<b>1.2</b>	<b>1.0</b>	<b>0.8</b>	<b>0.9</b>		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	0	0	1	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.	7	1	3	1	3	2	17		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	1	0	1	0	4	1	7		7
106. Prescription department substantially not clean and sanitary and in good repair	2	0	2	0	0	0	4		2
107. Current dispensing reference not maintained	6	4	2	2	2	0	16		11
108. Emergency access alarm code/key not maintained in compliance	8	9	20	10	11	4	62		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)	26	23	31	38	37	11	166		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	1	2	0	0	0	0	3		2
112. Biennial taken late but within 30 days	2	2	2	0	1	0	7		
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.	20	14	21	16	15	6	92		63

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 Inspection Report  
 June 16, 2020

Deficiencies Above 100  
 (Formerly Minor Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	0	0	1	2	0	3	6		
115. Other records of distributions not maintained as required	0	2	0	0	1	1	4		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	4	7	12	11	7	5	46		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	0	1	1	0	0	2		
119. Not properly documenting partial filling of prescriptions	5	3	13	10	11	4	46	1	28
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	2	0	0	0	0	0	2		
122. Engaging in alternate delivery not in compliance	6	5	3	13	6	4	37	1	11
123. Engaging in remote processing not in compliance	8	11	25	23	14	14	95	1	10
124. Labels do not include all required information	7	5	12	14	12	5	55		15
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	8	4	8	10	7	2	39		10
126. Special packaging not used or no documentation of request for non-special packaging	0	0	2	1	0	0	3		5
<b>Repackaging, specialty dispensing, compounding:</b>									
127. Repackaging records and labeling not kept as required or in compliance	9	17	20	20	19	10	95	1	38
128. Unit dose procedures or records not in compliance	0	0	0	0	0	0	0		
129. Robotic pharmacy systems not in compliance	0	1	0	0	0	0	1		
130. Required compounding/dispensing/distribution records not complete and properly maintained	4	6	9	8	9	2	38		16
130a. Compounded products not properly labeled	9	9	14	14	15	5	66		17

Virginia Board of Pharmacy  
Inspection Report  
June 16, 2020

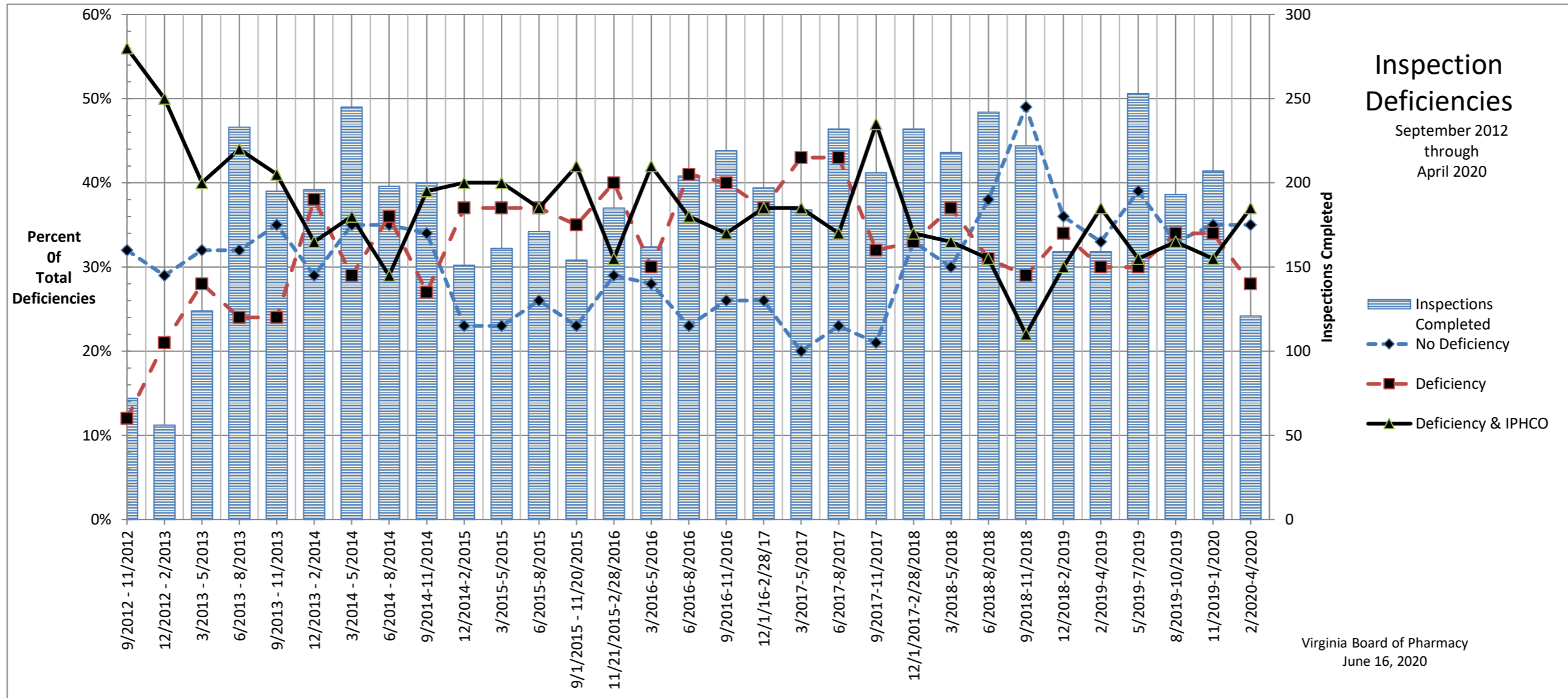
Deficiencies Above 100  
(Formerly Minor Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	3	1	1	7	7	2	21		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	3	8	7	8	6	0	32	1	8
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	1	0	0	1		
<b>Hospital specific or long-term care specific:</b>									
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	1	0	1		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	0	0	1	0	1	2		2
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	1	3	2	3	0	1	10		1
139. Emergency medical services procedures or records not in compliance	0	0	1	2	2	0	5		5
140. Emergency kit or stat-drug box procedures or records not in compliance	0	1	0	3	2	1	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	10	14	14	12	6	66	1	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  
 June 16, 2020

Deficiencies Above 100  
 (Formerly Minor Deficiency)

	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	2/20-4/20	Total	2/20-4/20	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)	1	0	0	1	0	1	3		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)	7	2	11	4	4	6	34		3





**Pharmaceutical Processors Report-June 16, 2020**

- Dharma Pharmaceuticals, LLC (Bristol) completed their first quarterly inspection in May
- Columbia Care Eastern Virginia, LLC (Portsmouth) was awarded their pharmaceutical processor permit on April 6, 2020
- Green Leaf Medical of Virginia, Inc. (Richmond) was awarded their pharmaceutical processor permit on May 12, 2020
- Ongoing work to establish the CBD/THC-A product registration process through the Prescription Monitoring Program and patient verification through Virginia Interactive.
- Legislative changes are being addressed through exempt and emergency regulatory procedures

Pharmaceutical Processors Program-By the Numbers  
As of 5/22/2020

Registered Practitioners	370
Registered Patients	2570
Registered Parents/Guardians	41
Registered Agents	2

# Discipline Program Report

Open Cases as of 5-22-2020:

	PC	APD	Investigation	FH	IFC	Entry	Pending Closure	TOTALS
<b>Patient Care Cases</b>	67	1	70	1	11	1	0	151
<b>Non-Patient Care Cases</b>	100	2	111	2	16	1	6	238
						<b>TOTAL:</b>		<b>389</b>

Notes:

- 1) Patient care cases:
  - We have sixty-seven (67) patient care cases at Probable Cause compared to thirty-one (31) that were reported for February 2020. Twelve (12) of these cases are pending an IFC or FH.
  - We have twenty-five percent (25%) more cases compared to February 2020.
- 2) Non-patient care cases (inspection cases or compliance related cases)
  - The number of cases is approximately double the number last reported.
- 3) Cases greater than 250 work days: We have twenty (22) cases exceeding 250 work days. Of this number, six (6) cases are in criminal activity pending (CAP) status.

Upcoming Disciplinary Proceedings:

June 23, 2020	IFCs	Kris Ratliff/Patricia Richards-Spruill
July 7, 2020	IFCs	Patricia Richards-Spruill/Glenn Bolyard
July 21, 2020	Formal Hearings	Full Board
August 18, 2020	IFCs	Kris Ratliff/Melvin Boone
September 8, 2020	IFCs	Patricia Richards-Spruill/Glenn Bolyard
September 9, 2020	FH/Full Board Mtg	Full Board
September 23, 2020	IFCs	Members to be assigned

Cases Received, Open & Closed  
Agency Summary  
Quarter 3 – Fiscal Year 2020

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	CURRENT Q3 2020
<b>Number of Cases Received</b>	1445	1413	1381	1413	1570	1662	1857	1695	1543	1790	1889	1819	1757
<b>Number of Cases Open</b>	3222	3196	3481	3504	3600	3626	3791	3926	3978	3955	4239	4437	4512
<b>Number of Cases Closed</b>	1593	1495	1143	1426	1542	1718	1622	1447	1474	1846	1554	1620	1709

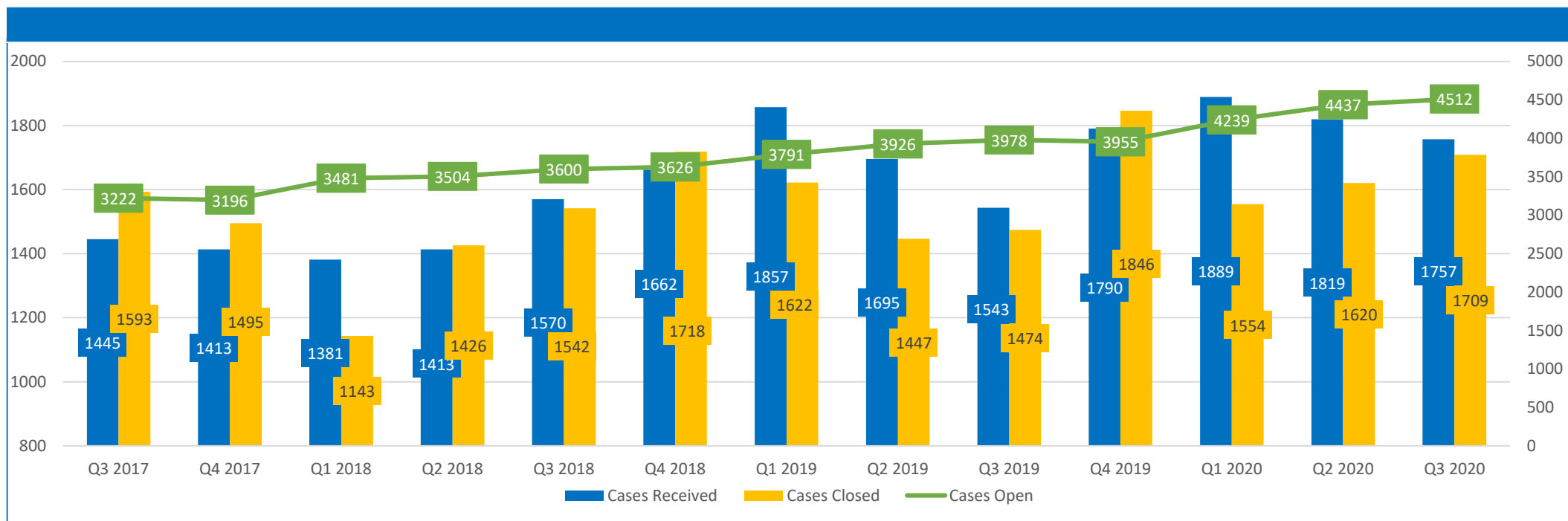
## Cases Received, Open & Closed

### Agency Summary

### Quarter 3 – Fiscal Year 2020

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Cases Received, Open & Closed  
Agency Summary  
Quarter 3 – Fiscal Year 2020

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													CURRENT	
		Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
Audiology/Speech Pathology	Number of Cases Received	5	5	2	5	4	6	17	15	6	5	6	4	0
	Number of Cases Open	22	17	7	12	11	14	23	31	31	23	21	20	18
	Number of Cases Closed	6	10	11	1	5	3	8	7	5	13	8	5	2
Counseling	Number of Cases Received	40	35	28	37	31	45	56	54	76	72	99	81	82
	Number of Cases Open	58	56	61	72	84	102	124	150	176	144	166	207	180
	Number of Cases Closed	60	42	26	29	23	33	29	28	51	103	77	70	80
Dentistry	Number of Cases Received	88	94	84	93	91	124	274	191	100	128	96	123	129
	Number of Cases Open	259	266	277	254	256	249	400	297	313	282	277	310	332
	Number of Cases Closed	93	91	78	119	100	135	115	187	83	150	98	105	106

Cases Received, Open & Closed  
Agency Summary  
Quarter 3 – Fiscal Year 2020

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													CURRENT	
		Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
<b>Funeral Directing</b>	<b>Number of Cases Received</b>	9	22	12	8	12	13	26	23	18	10	20	35	17
	<b>Number of Cases Open</b>	35	39	38	40	35	28	40	57	50	48	48	61	50
	<b>Number of Cases Closed</b>	15	20	14	7	18	24	13	6	25	16	20	21	30
<b>Long Term Care Administrators</b>	<b>Number of Cases Received</b>	9	18	15	24	13	16	31	23	23	14	20	20	15
	<b>Number of Cases Open</b>	58	56	71	90	94	74	91	103	99	100	96	95	86
	<b>Number of Cases Closed</b>	13	20	5	8	8	31	14	11	27	13	25	23	25
<b>Medicine</b>	<b>Number of Cases Received</b>	402	358	423	411	551	541	485	531	472	516	473	509	551
	<b>Number of Cases Open</b>	682	628	755	796	934	902	943	1024	1089	1082	1035	1024	1027
	<b>Number of Cases Closed</b>	401	391	297	407	443	575	434	447	407	483	474	484	558

Cases Received, Open & Closed  
Agency Summary  
Quarter 3 – Fiscal Year 2020

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													CURRENT	
		Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
Nurse Aide	Number of Cases Received	169	165	156	123	118	137	162	143	153	224	199	184	187
	Number of Cases Open	356	370	438	455	301	285	276	261	280	351	369	392	412
	Number of Cases Closed	189	166	94	109	276	158	162	156	134	162	172	164	168
Nursing	Number of Cases Received	412	447	415	427	447	444	507	446	419	457	513	476	442
	Number of Cases Open	1004	1075	1155	1115	1179	1246	1157	1211	1204	1172	1335	1574	1544
	Number of Cases Closed	448	420	352	458	397	414	571	393	429	528	365	295	444
Optometry	Number of Cases Received	10	4	8	9	17	8	7	10	12	9	3	5	12
	Number of Cases open	35	36	26	23	32	31	26	34	34	40	29	27	29
	Number of Cases Closed	4	4	20	12	8	9	12	2	12	4	10	7	10

## Cases Received, Open & Closed

### Agency Summary

### Quarter 3 – Fiscal Year 2020

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													CURRENT	
		Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
Pharmacy	Number of Cases Received	179	146	143	160	171	213	148	126	133	223	211	111	174
	Number of Cases Open	355	309	302	271	287	319	303	306	262	259	310	257	277
	Number of Cases Closed	204	192	148	185	162	199	161	123	177	237	158	164	154
Physical Therapy	Number of Cases Received	7	21	6	15	9	4	13	10	9	7	26	4	13
	Number of Cases Open	28	39	36	44	48	50	46	44	37	32	46	39	35
	Number of Cases Closed	5	9	10	7	2	4	15	11	17	12	13	12	18
Psychology	Number of Cases Received	13	22	23	23	28	26	20	31	38	27	55	31	40
	Number of Cases Open	49	34	46	44	52	57	64	83	75	75	97	100	105
	Number of Cases Closed	52	38	16	24	19	24	13	11	46	29	34	30	35



Cases Received, Open & Closed  
Agency Summary  
Quarter 3 – Fiscal Year 2020

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

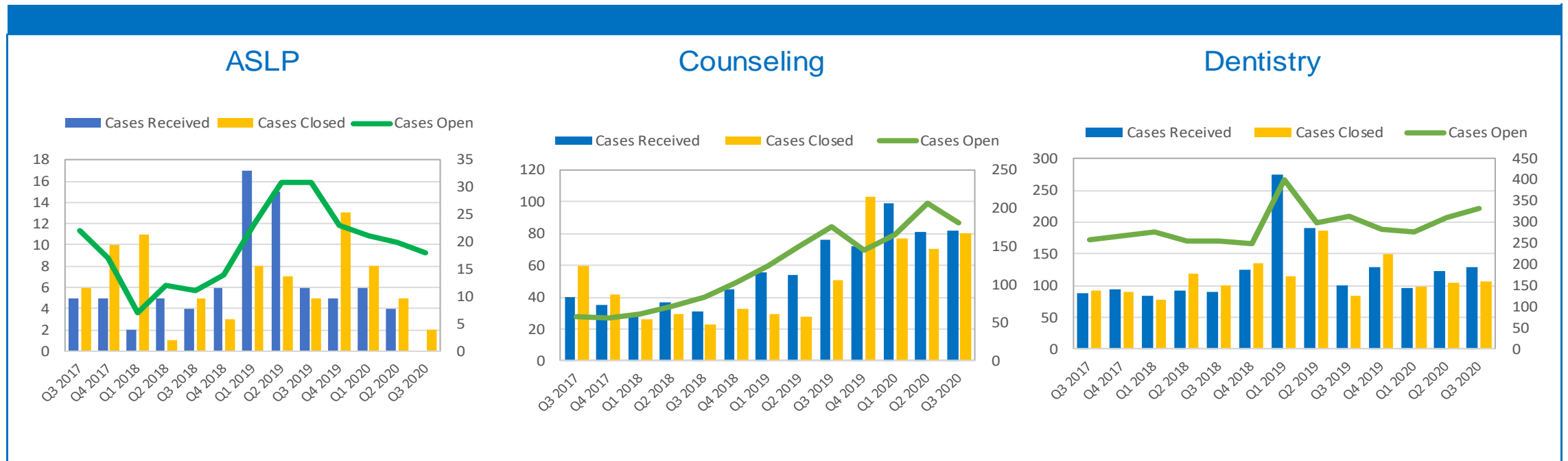
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													CURRENT	
		Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
<b>Social Work</b>	<b>Number of Cases Received</b>	28	21	14	27	15	34	35	25	33	39	27	31	28
	<b>Number of Cases Open</b>	54	39	39	48	52	71	93	95	97	90	88	100	95
	<b>Number of Cases Closed</b>	46	39	15	19	11	18	13	23	31	48	30	19	33
<b>Veterinary Medicine</b>	<b>Number of Cases Received</b>	74	55	52	51	63	51	76	67	51	53	138	204	62
	<b>Number of Cases Open</b>	227	232	230	240	235	198	205	230	231	241	311	288	306
	<b>Number of Cases Closed</b>	57	53	57	41	70	91	62	42	30	47	68	221	45

## Cases Received, Open & Closed Agency Summary Quarter 3 – Fiscal Year 2020

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

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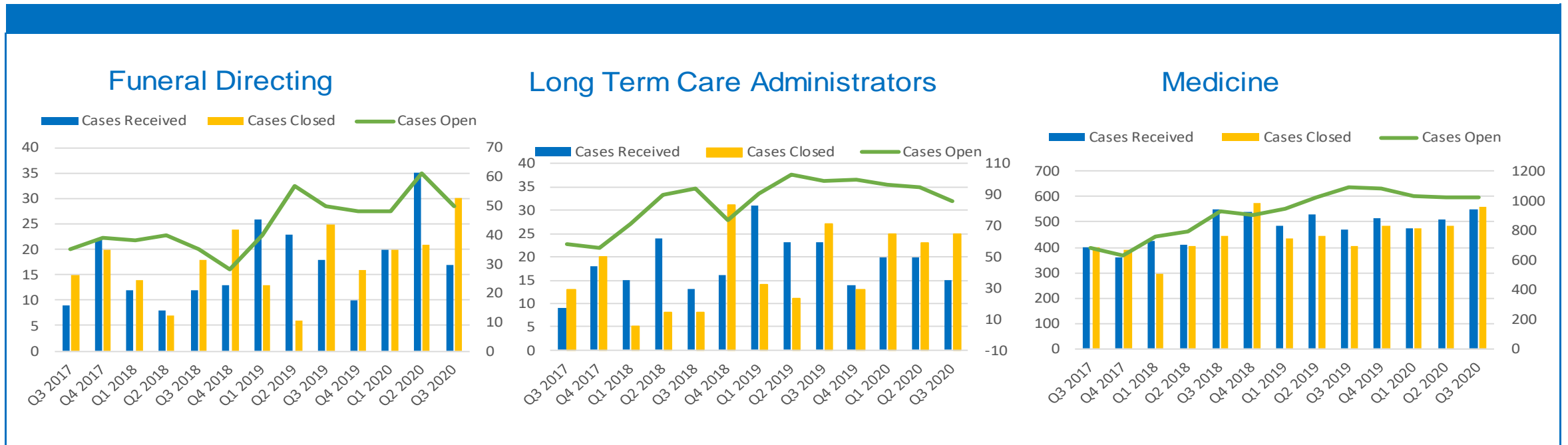
## Cases Received, Open & Closed

### Agency Summary

### Quarter 3 – Fiscal Year 2020

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## Cases Received, Open & Closed

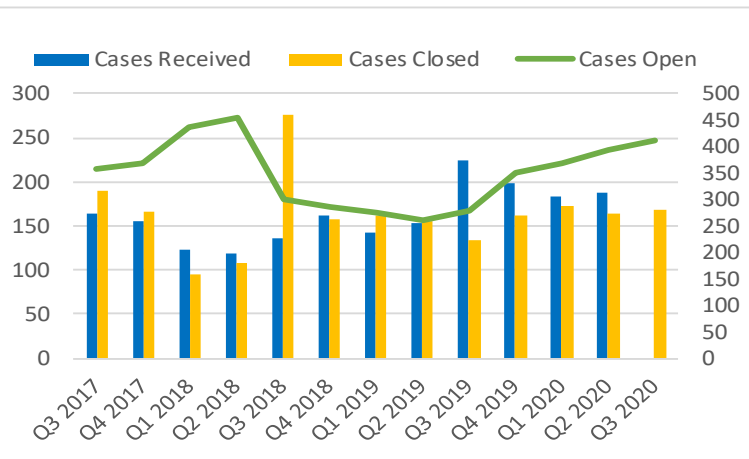
### Agency Summary

### Quarter 3 – Fiscal Year 2020

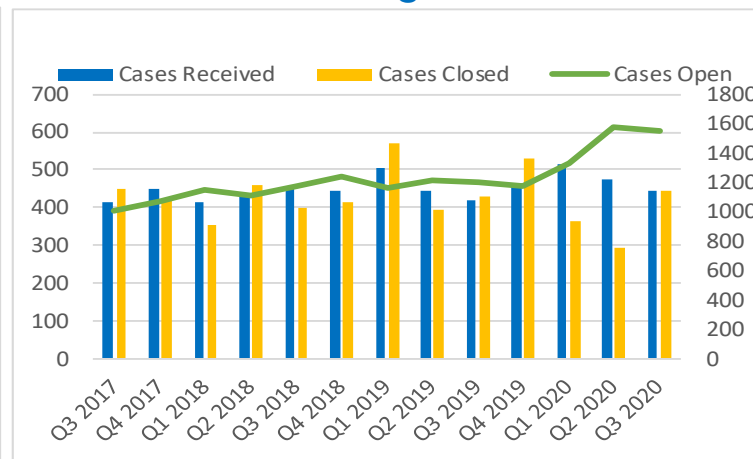
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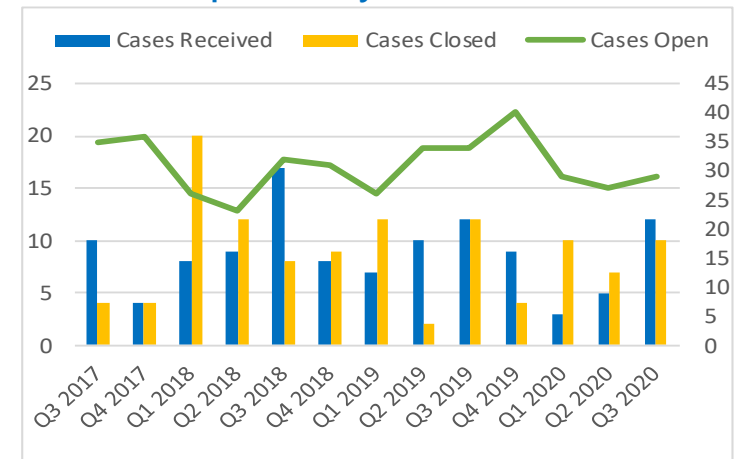
### Nurse Aide



### Nursing



### Optometry



## Cases Received, Open & Closed

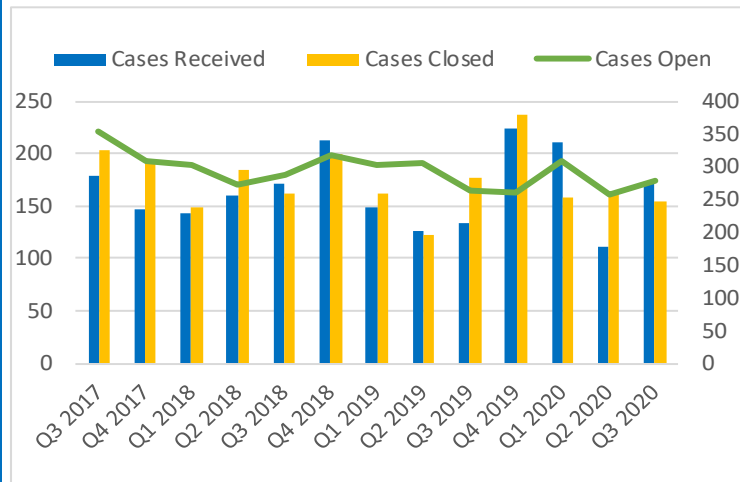
### Agency Summary

### Quarter 3 – Fiscal Year 2020

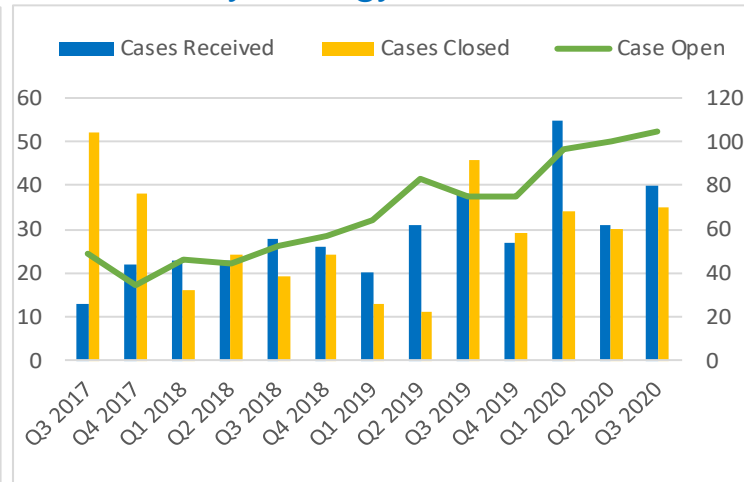
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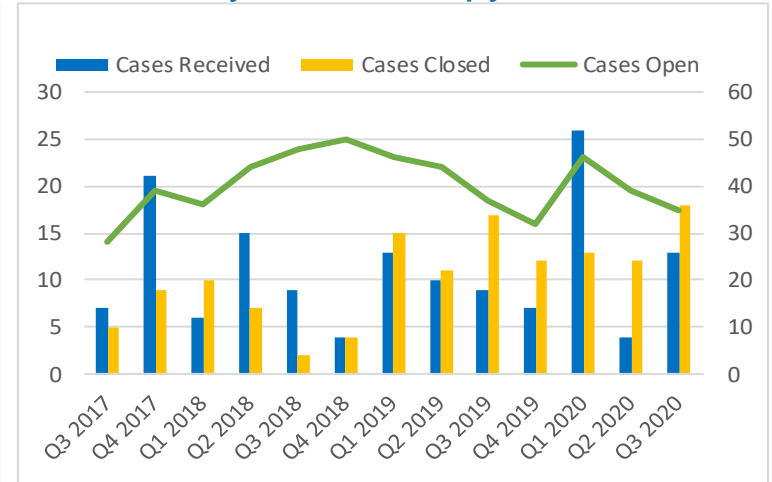
### Pharmacy



### Psychology



### Physical Therapy

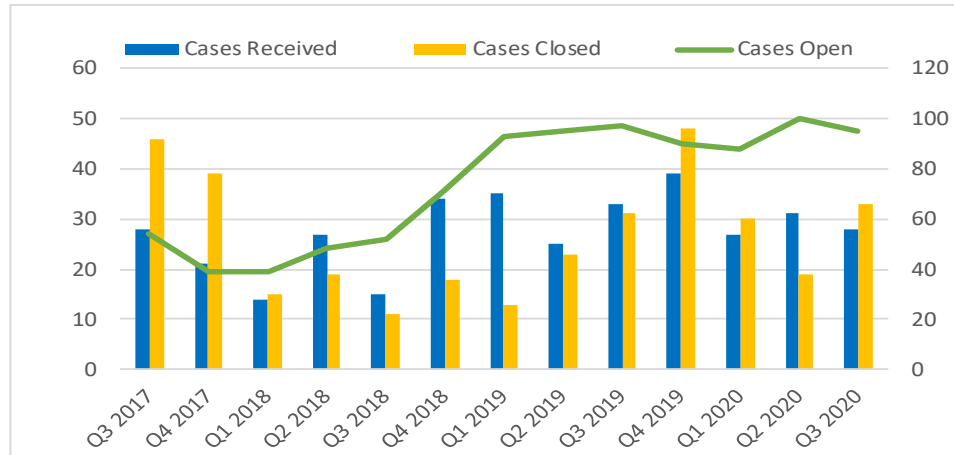


## Cases Received, Open & Closed Agency Summary Quarter 3 – Fiscal Year 2020

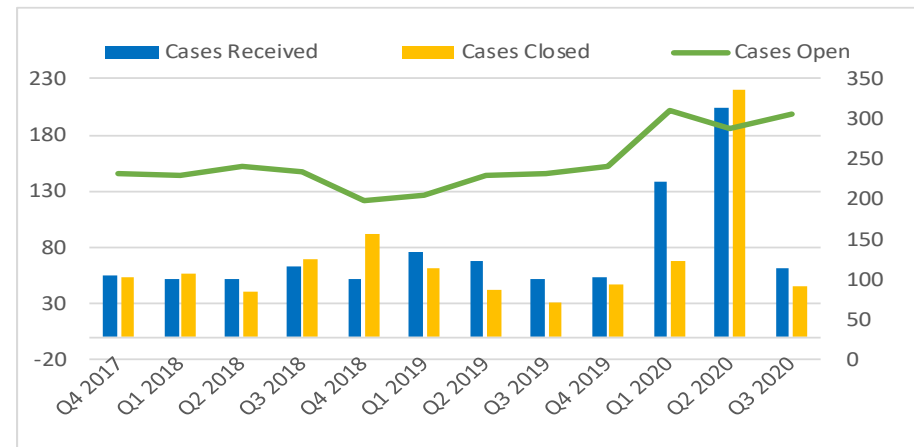
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### Social Work



### Veterinary Medicine





# Virginia Department of Health Professions

## Average Age of Cases Closed


### Quarterly Summary

Quarter 3 - Fiscal Year 2020

The average age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter specified.

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BOARD	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	CURRENT Q3 2020
<b>Audiology</b>	135.3	259.8	255.7	192	179	463.3	97.4	190.3	149	208	241	291	282.5
<b>Counseling</b>	247.9	106.1	251.5	128.2	153.7	185	164.2	161.3	251	279	173	157	293.9
<b>Dentistry</b>	271.2	228.7	337.8	182.9	239.7	165	141.5	83.6	192	395	316	466	270.1
<b>Funeral Directing</b>	295	223.7	229.3	169.1	383.3	211.8	225.7	298.8	116	259	287	180	243.7
<b>Long-Term Care Administrators</b>	282.8	395	171.2	350.6	424.1	395.5	253	396.8	400	433	291	385	553.1
<b>Medicine</b>	135.5	136.9	146.5	135	153.5	133.3	142.1	147.3	240	170	172	238	197.7
<b>Nurse aide</b>	191.4	223.8	297.4	273.3	200.7	235.3	150.1	201.7	204	147	164	226	185.3
<b>Nursing</b>	207.4	202.1	203.6	204.5	215.8	280.3	192.3	198.3	276	3003	300	350	323.8
<b>Optometry</b>	95.3	106.3	557.6	268.1	240	190.7	194.2	506.5	379	129	275	380	411.1
<b>Pharmacy</b>	343.2	192.9	215.4	172.2	173.7	114.1	160.2	152.3	255	116	275	117	105.3
<b>Physical Therapy</b>	102.4	291.3	239.4	112	152.5	412.8	389.3	366.5	467	322	280	174	346.6
<b>Psychology</b>	357.7	252.7	119.5	183.3	118.8	175.2	170.4	228.6	225	153	72	548	226.1
<b>Social Work</b>	366.2	228.8	292.7	123.6	277.5	237.2	113.8	200.7	263	211	271	377	338.6
<b>Veterinary Medicine</b>	283.5	295.6	223	357.7	278.7	376.7	321.9	261.9	293	423	285	79	357.8
<b>Agency total</b>	222.8	194.1	255.7	186.5	196.4	201.1	173.8	169.2	258	204	214	258.4	236.4



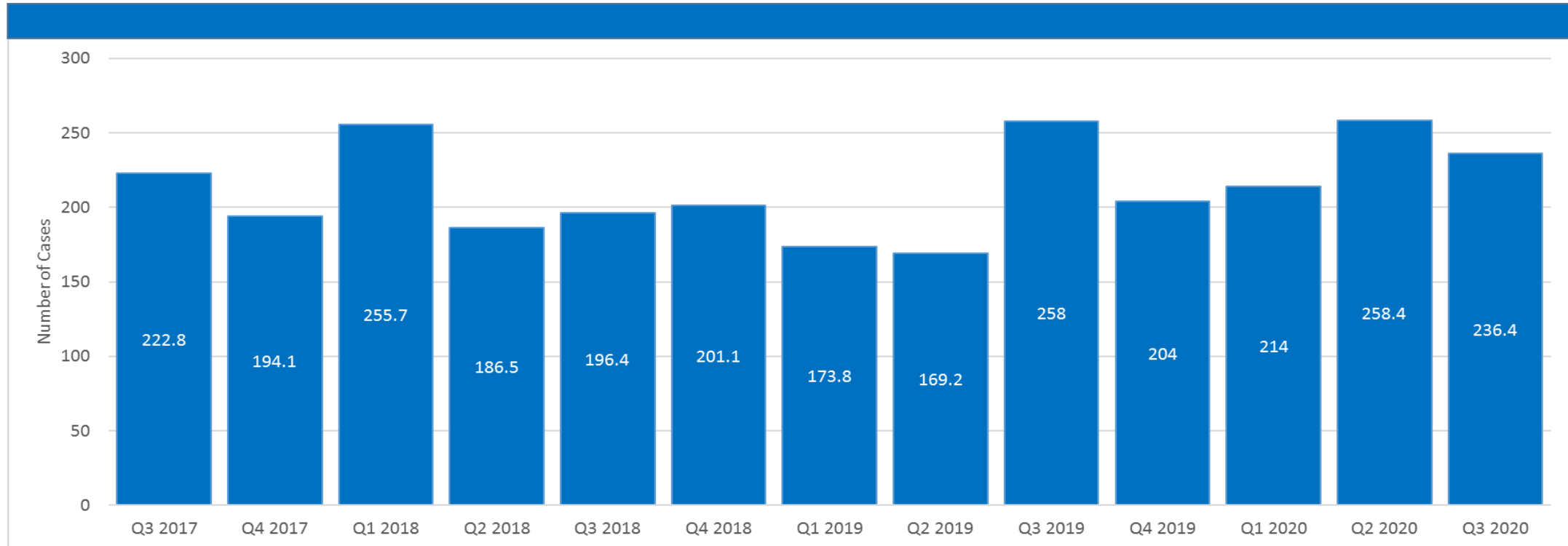
# Virginia Department of Health Professions

## Average Age of Cases Closed

### Quarterly Summary

Quarter 3 - Fiscal Year 2020

The average age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter specified.







# Virginia Department of Health Professions

## Average Age of Cases Closed

### Fiscal Year Summary

Fiscal Year 2019

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Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

BOARD	FY 2014	Change Between FY 15 & FY 14	FY 2015	Change Between FY 16 & FY 15	FY 2016	Change Between FY 17 & FY 16	FY 2017	Change Between FY 18 & FY 17	FY 2018	Change Between FY 19 & FY 18	FY 2019
Audiology/Speech Pathology	59.9	65.4%	99	67.4%	165.8	39.1%	230.5	14.7%	264.5	-57.4%	168.00
Counseling	215.2	20.0%	258.3	22.0%	315	-18.4%	257.2	-30.5%	178.9	15.6%	212.00
Dentistry	317.9	-11.0%	282.9	-1.4%	278.9	-7.4%	258.1	-16.1%	216.5	2.5%	222.00
Funeral Directing	178	-16.7%	148.3	28.2%	190.1	16.4%	221.3	17.8%	260.7	-33.0%	196.00
Long-Term Care Administrators	175.8	7.2%	188.5	12.7%	212.4	45.0%	307.9	14.7%	353.3	18.4%	433.00
Medicine	156.6	9.2%	171	-0.9%	169.5	-17.2%	140.4	-0.3%	139.9	31.8%	205.00
Nurse Aide	203.7	-29.6%	143.4	0.5%	144.2	33.4%	192.2	22.5%	235.6	-11.1%	212.00
Nursing	178.5	8.7%	194	3.4%	200.6	-1.9%	196.8	14.5%	225.2	16.6%	270.00
Optometry	223.6	-23.7%	170.7	19.6%	204.2	-17.7%	168	118.7%	367.4	-19.8%	306.76
Pharmacy	136.7	19.0%	162.6	-20.7%	129	103.5%	262.5	-36.0%	167.9	-24.4%	135.00
Physical Therapy	147.2	22.0%	179.7	-5.9%	169.1	58.9%	268.6	-11.2%	238.5	47.4%	453.00
Psychology	158.3	15.4%	182.7	89.0%	345.2	-8.3%	316.6	-53.1%	148.6	31.5%	217.00
Social Work	172	33.4%	229.4	11.0%	254.7	47.4%	375.3	-40.5%	223.1	-8.8%	205.00
Veterinary Medicine	174.8	31.6%	230	48.4%	341.4	-12.6%	298.2	4.6%	311.8	3.8%	324.00
Agency Total	181.5	3.0%	186.8	4.5%	195.3	6.1%	207.2	-4.2%	198.4	11.8%	225

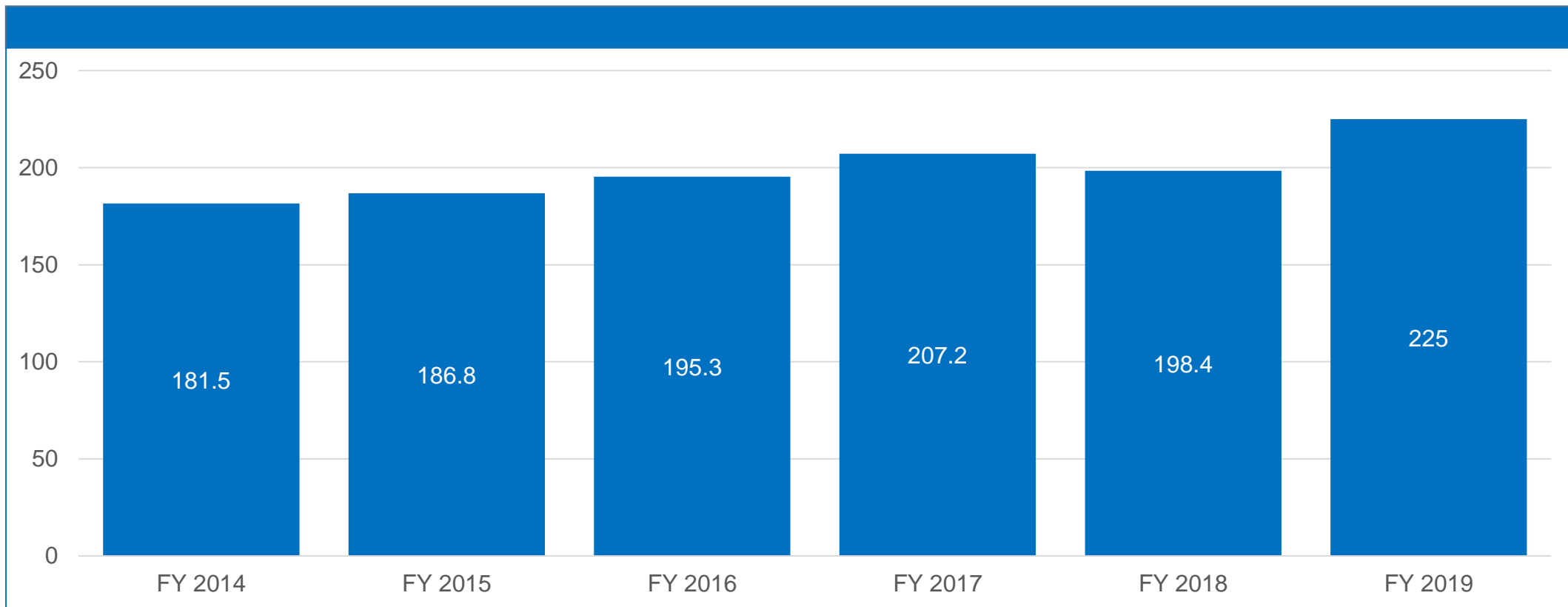


# Virginia Department of Health Professions

## Average Age of Cases Closed Fiscal Year Summary

Fiscal Year 2019

The average age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter specified.





# Virginia Department of Health Professions

## Cases Closed in Less than One Year Quarterly Summary Quarter 3- Fiscal Year 2020

The percent of cases closed in fewer than 365 days shows, from the total of all cases closed during the specified period, from entry to closure. These calculations include only cases closed within the quarter specified.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

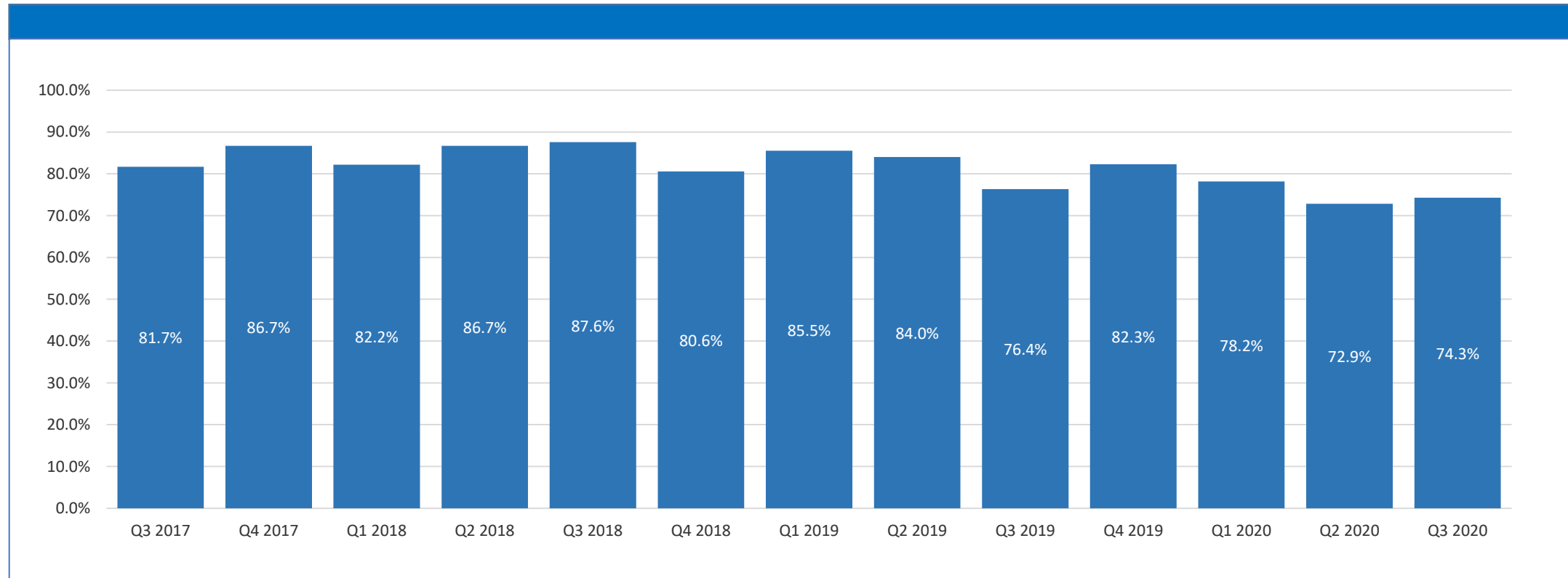
BOARD													CURRENT
	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2 2020	Q3 2020
<b>Audiology/Speech Pathology</b>	100.0%	90.0%	90.9%	100.0%	80.0%	33.3%	100.0%	71.4%	100.0%	84.6%	87.5%	62.5%	50.0%
<b>Counseling</b>	84.7%	97.5%	76.9%	97.0%	91.3%	84.8%	89.7%	89.3%	73.8%	68.0%	84.8%	83.7%	68.5%
<b>Dentistry</b>	73.9%	94.3%	65.4%	89.2%	84.0%	93.3%	90.3%	95.7%	86.9%	71.8%	64.7%	52.4%	76.8%
<b>Funeral Directing</b>	60.0%	70.0%	78.6%	85.7%	61.1%	87.0%	69.2%	83.3%	100.0%	73.3%	80.5%	90.3%	68.1%
<b>Long Term Care Administrator</b>	69.2%	55.0%	80.0%	50.0%	25.0%	29.0%	64.3%	36.4%	42.6%	64.3%	64.4%	41.9%	19.6%
<b>Medicine</b>	93.5%	95.4%	91.6%	93.8%	93.7%	94.6%	93.3%	92.4%	83.9%	93.8%	88.6%	85.2%	86.8%
<b>Nurse Aide</b>	84.0%	77.7%	65.2%	78.9%	93.1%	75.3%	85.2%	78.2%	85.6%	95.3%	87.2%	78.5%	85.6%
<b>Nursing</b>	85.8%	86.4%	83.4%	84.5%	81.0%	62.3%	79.2%	72.5%	69.9%	79.3%	59.6%	44.4%	53.6%
<b>Optometry</b>	100.0%	100.0%	50.0%	66.7%	62.5%	88.9%	83.3%	50.0%	47.8%	100.0%	64.7%	49.5%	35.7%
<b>Pharmacy</b>	71.6%	85.4%	83.1%	87.1%	91.4%	94.0%	90.3%	92.6%	83.4%	95.8%	64.7%	95.8%	92.7%
<b>Physical Therapy</b>	100.0%	44.4%	90.0%	100.0%	100.0%	25.0%	46.7%	45.5%	32.7%	54.5%	54.8%	78.6%	50.0%
<b>Psychology</b>	44.2%	81.6%	92.9%	85.2%	100.0%	90.5%	92.3%	81.8%	86.4%	93.1%	95.7%	36.2%	78.0%
<b>Social Work</b>	41.3%	92.3%	73.3%	100.0%	81.8%	66.7%	84.2%	78.3%	50.9%	70.8%	46.7%	47.9%	37.3%
<b>Veterinary Medicine</b>	73.7%	75.5%	86.0%	51.2%	74.3%	53.8%	64.5%	73.8%	67.1%	44.6%	64.6%	93.8%	51.0%
<b>Agency Total</b>	81.7%	86.7%	82.2%	86.7%	87.6%	80.6%	80.6%	80.6%	80.6%	80.6%	80.6%	72.9%	74.3%



# Virginia Department of Health Professions

## Cases Closed in Less than One Year Quarterly Summary Quarter 3- Fiscal Year 2020

The percent of cases closed in fewer than 365 days shows, from the total of all cases closed during the specified period, from entry to closure. These calculations include only cases closed within the quarter specified.





# Virginia Department of Health Professions

## Cases Closed in Less than One Year

### Fiscal Year Summary

Fiscal Year 2019

The percent of cases closed in fewer than 365 days shows, from the total of all cases closed during the specified period, from entry to closure. These calculations include only cases closed within the quarter specified.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

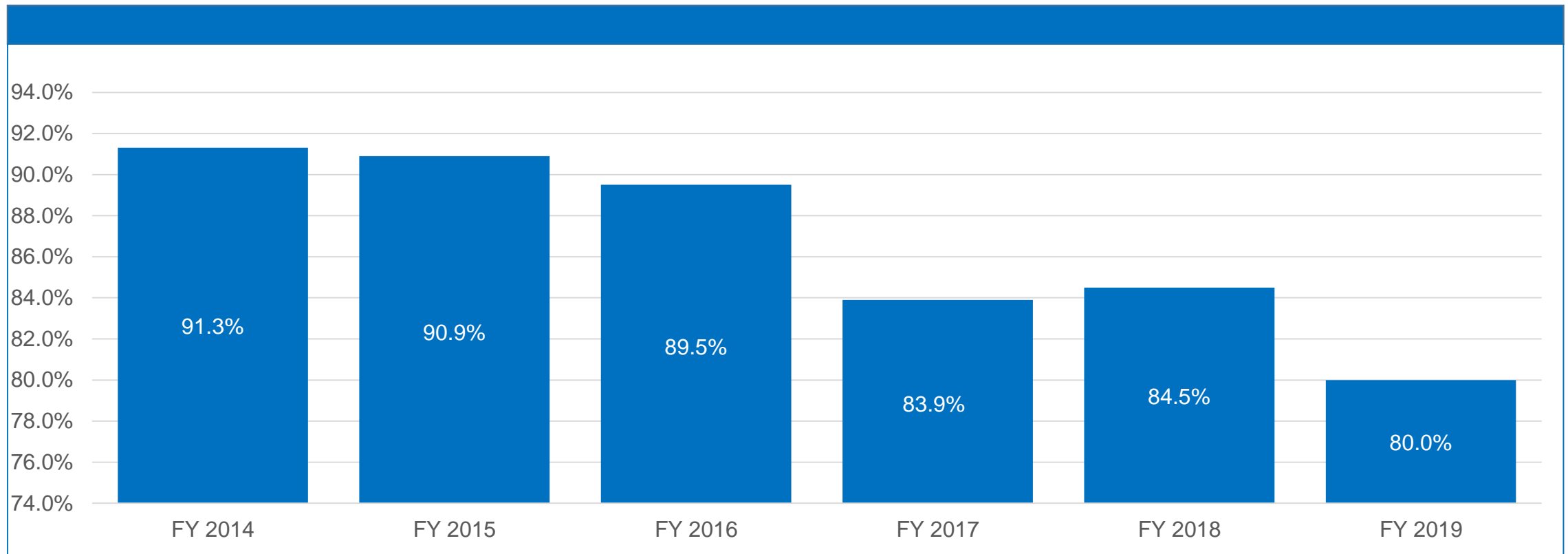
BOARD	FY 2014	Change Between FY 15 & FY 14	FY 2015	Change Between FY 16 & FY 15	FY 2016	Change Between FY 17 & FY 16	FY 2017	Change Between FY 18 & FY 17	FY 2018	Change Between FY 19 & FY 18	FY 2019
<b>Audiology</b>	100.0%	-3.2%	96.8%	3.3%	100.0%	-10.5%	89.5%	-10.6%	80.0%	9.3%	88.2%
<b>Counseling</b>	87.6%	-12.6%	76.6%	-25.8%	56.8%	35.0%	76.8%	13.8%	87.4%	-11.3%	78.5%
<b>Dentistry</b>	65.1%	11.1%	72.4%	0.0%	72.4%	3.4%	74.8%	13.9%	85.2%	-6.1%	80.3%
<b>Funeral Directing</b>	90.8%	5.4%	95.7%	-6.0%	90.0%	-14.4%	77.1%	0.5%	77.4%	8.6%	84.7%
<b>Long-Term Care Administrator</b>	88.6%	1.6%	90.0%	-6.4%	84.2%	-19.0%	68.3%	-38.9%	41.7%	-16.5%	35.8%
<b>Medicine</b>	91.7%	-1.0%	90.8%	-1.7%	89.3%	5.0%	93.7%	0.1%	93.8%	-9.6%	85.6%
<b>Nurse Aide</b>	96.1%	-0.1%	96.0%	-2.2%	94.0%	-9.4%	85.1%	-3.0%	82.5%	-0.4%	82.2%
<b>Nursing</b>	92.3%	-2.2%	90.3%	-4.7%	86.1%	0.7%	86.7%	-9.7%	78.3%	-0.9%	77.6%
<b>Optometry</b>	83.3%	4.0%	86.7%	4.9%	90.9%	-1.4%	89.7%	-29.4%	63.3%	1.1%	64.0%
<b>Pharmacy</b>	92.0%	-4.3%	88.0%	4.4%	91.9%	-15.6%	77.6%	14.6%	89.0%	4.3%	93.0%
<b>Physical Therapy</b>	95.4%	-5.6%	90.0%	3.4%	93.0%	-33.3%	62.1%	25.3%	77.8%	-130.2%	33.8%
<b>Psychology</b>	93.7%	0.1%	93.8%	-49.5%	47.3%	21.8%	57.6%	60.0%	92.2%	-8.2%	85.2%
<b>Social Work</b>	92.7%	-8.3%	85.0%	-28.4%	60.9%	-15.3%	51.5%	57.1%	81.0%	-16.4%	69.6%
<b>Veterinary Medicine</b>	95.2%	5.1%	100.0%	-37.6%	62.4%	16.7%	72.8%	-9.2%	66.2%	-4.7%	63.2%
<b>AGENCY</b>	<b>91.3%</b>	<b>-0.4%</b>	<b>90.9%</b>	<b>-1.6%</b>	<b>89.5%</b>	<b>-6.2%</b>	<b>83.9%</b>	<b>0.7%</b>	<b>84.5%</b>	<b>-5.6%</b>	<b>80.0%</b>



# Virginia Department of Health Professions

## Cases Closed in Less than One Year Fiscal Year Summary Fiscal Year 2019

The percent of cases closed in fewer than 365 days shows, from the total of all cases closed during the specified period, from entry to closure. These calculations include only cases closed within the quarter specified.



# Virginia Department of Health Professions

## Patient Care Disciplinary Case Processing Times (with Continuance Days Removed): Quarterly Performance Measurement, Q3 2016 - Q3 2020

David E. Brown, D.C.

Director

*"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."*  
**DHP Mission Statement**

In order to uphold its mission relating to discipline, DHP continually assesses and reports on performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. These three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload; Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days the case was in the continuance activity. Beginning this quarter, the agency also tracks the Age of Pending Caseload and Time to Disposition based upon a 415 day model (These results are displayed by the green line).

**Clearance Rate** - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

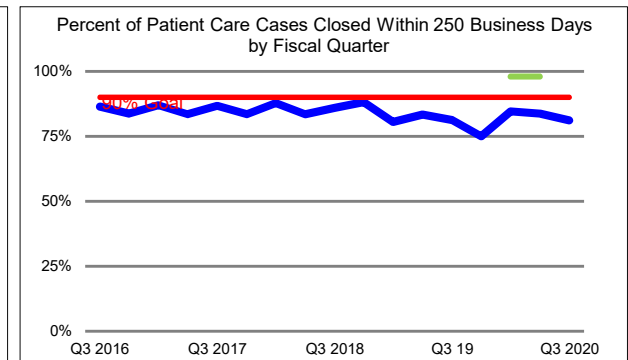
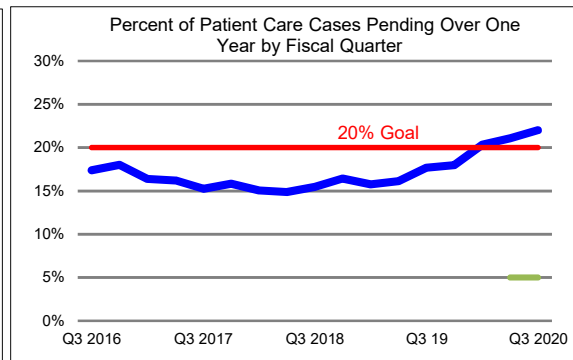
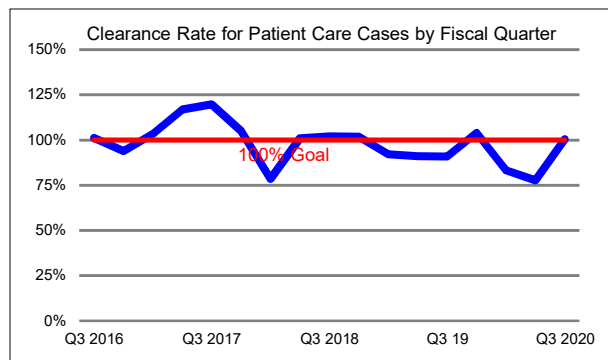
The current quarter's clearance rate is 100%, with 1251 patient care cases received and 1257 closed.

**Age of Pending Caseload** - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 250 business days at no more than 20%.

The current quarter shows 22% patient care cases pending over 250 business days with 3608 patient care cases pending and 794 pending over 250 business days. 192 Cases are pending over 415 business days for a percentage of 5%.

**Time to Disposition** - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 250 business days.

The current quarter shows 80% of patient care cases being resolved within 250 business days with 1198 cases closed and 960 closed within 250 business days. 877 Cases are pending over 415 business days for a percentage of 98%.



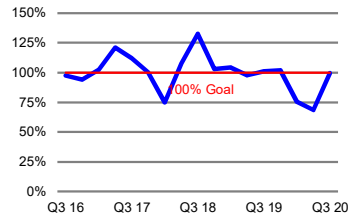
Submitted: 5/13/2020

Prepared by: Department of Health Professions

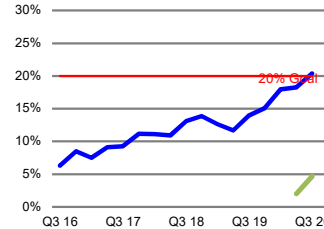
**Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board**

**Nursing**  
**Clearance Rate: 100%**  
 491 Cases Received  
 489 Cases Closed  
**Pending Caseload: 20%**  
 335 Cases Pending over 250 Days  
**Pending Caseload Over 415 Days: 5%**  
 77 Cases Pending over 415 Days  
**Time to Disposition: 72%**  
 340 Cases Closed within 250 Days  
**Time to Disposition within 415 Days: 98%**  
 462 Cases Closed within 415 Days

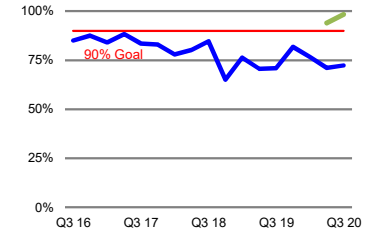
**Clearance Rate**



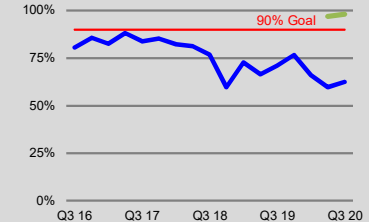
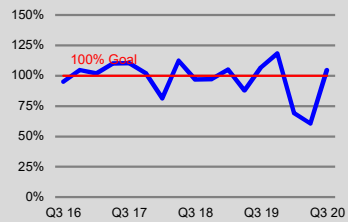
**Age of Pending Caseload**  
 (percent of cases pending over one year)



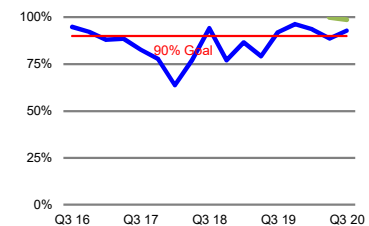
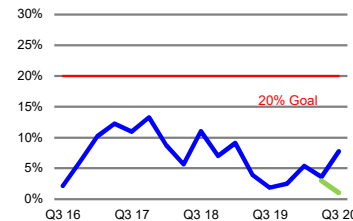
**Time to Disposition**



**Nurses**  
**Clearance Rate: 105%**  
 320 Cases Received  
 335 Cases Closed  
**Pending Caseload: 24%**  
 307 Cases Pending over 250 Days  
**Pending Caseload Over 415 Days: 6%**  
 73 Cases Pending over 415 Days  
**Time to Disposition: 62%**  
 198 Cases Closed within 250 Days  
**Time to Disposition within 415 Days: 98%**  
 311 Cases Closed within 415 Days



**CNA**  
**Clearance Rate: 90%**  
 171 Cases Received  
 154 Cases Closed  
**Pending Caseload: 8%**  
 28 Cases Pending over 250 Days  
**Pending Caseload Over 415 Days: 1%**  
 4 Cases Pending over 415 Days  
**Time to Disposition: 93%**  
 142 Cases Closed within 250 Days  
**Time to Disposition within 415 Days: 99%**  
 151 Cases Closed within 415 Days





Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

**Medicine**

**Clearance Rate: 100%**

449 Cases Received

451 Cases Closed

**Pending Caseload: 16%**

144 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 10%**

89 Cases Pending over 415 Days

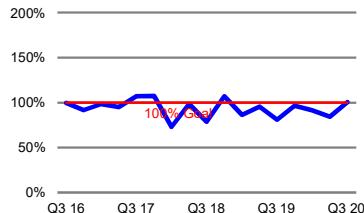
**Time to Disposition: 94%**

410 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

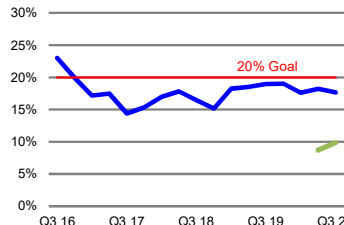
434 Cases Closed within 415 Days

**Clearance Rate**

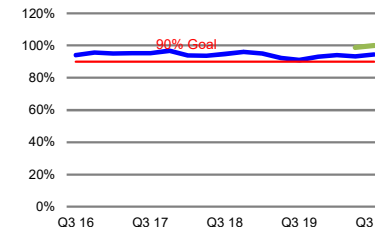


**Age of Pending Caseload**

(percent of cases pending over one year)



**Time to Disposition**



**Dentistry**

**Clearance Rate: 90%**

86 Cases Received

77 Cases Closed

**Pending Caseload: 26%**

59 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 10%**

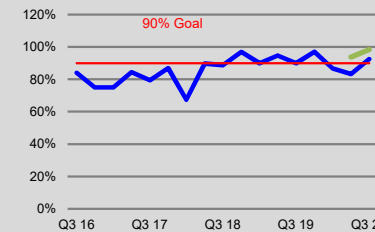
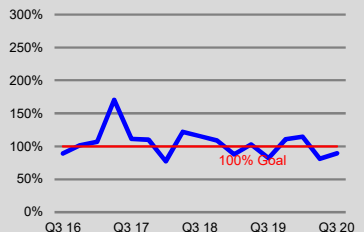
23 Cases Pending over 250 Days

**Time to Disposition: 92%**

61 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 98%**

65 Cases Closed within 415 Days



**Pharmacy**

**Clearance Rate: 75%**

72 Cases Received

54 Cases Closed

**Pending Caseload: 11%**

18 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 3%**

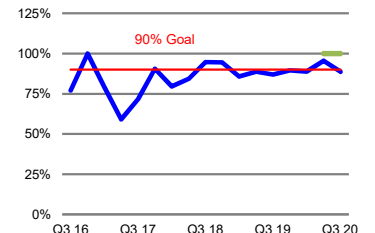
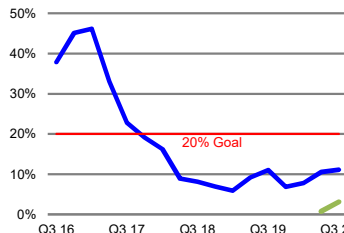
5 Cases Pending over 415 Days

**Time to Disposition: 89%**

47 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

53 Cases Closed within 415 Days



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

**Veterinary Medicine**

**Clearance Rate: 97%**

29 Cases Received

28 Cases Closed

**Pending Caseload: 50%**

100 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 17%**

34 Cases Pending over 415 Days

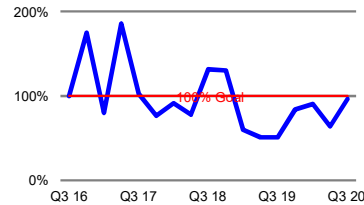
**Time to Disposition: 50%**

10 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

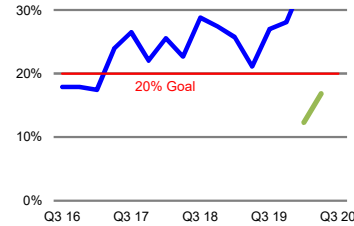
20 Cases Closed within 415 Days

**Clearance Rate**

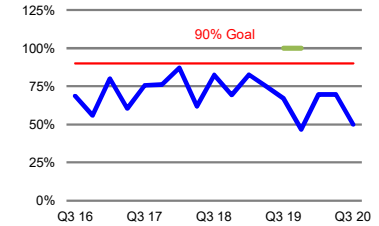


**Age of Pending Caseload**

(percent of cases pending over one year)



**Time to Disposition**



**Counseling**

**Clearance Rate: 109%**

45 Cases Received

49 Cases Closed

**Pending Caseload: 16%**

22 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 2%**

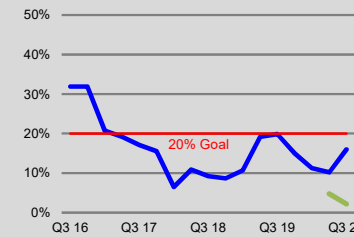
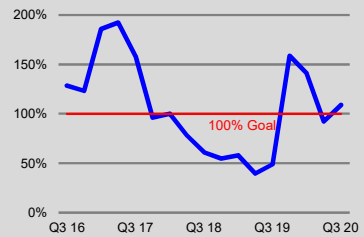
3 Cases Pending over 415 Days

**Time to Disposition: 88%**

45 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

51 Cases Closed within 415 Days



**Social Work**

**Clearance Rate: 139%**

18 Cases Received

25 Cases Closed

**Pending Caseload: 42%**

33 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 14%**

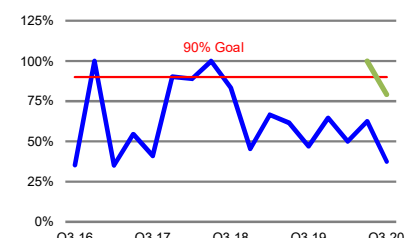
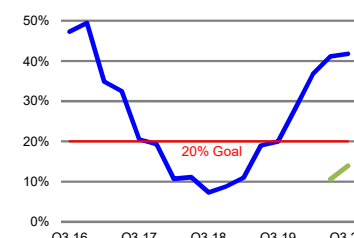
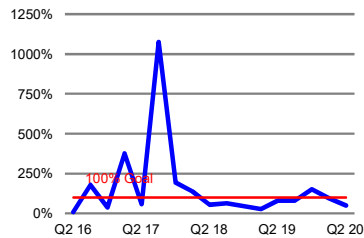
11 Cases Pending over 415 Days

**Time to Disposition: 38%**

9 Cases Closed within 250 Days

**Time to Disposition within 415 days: 79%**

19 Cases Closed within 415 Days



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

**Psychology**

**Clearance Rate: 104%**

27 Cases Received  
28 Cases Closed

**Pending Caseload: 27%**

24 Cases Pending over 250 Days

**Pending Caseload over 415 Days: 10%**

9 Cases Pending over 415 Days

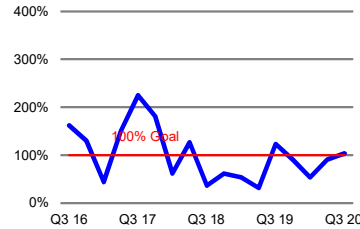
**Time to Disposition: 74%**

20 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 96%**

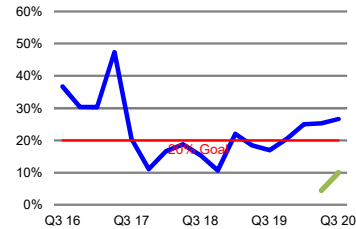
26 Cases Closed within 415 Days

**Clearance Rate**

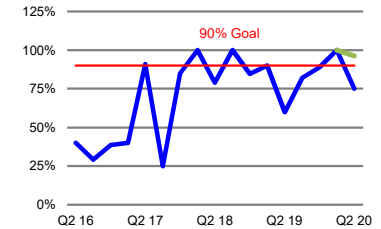


**Age of Pending Caseload**

(percent of cases pending over one year)



**Time to Disposition**



**Long Term Care**

**Clearance Rate: 200%**

9 Cases Received  
18 Cases Closed

**Pending Caseload: 49%**

34 Cases Pending over 250 Days

**Pending Caseload over 415 Days: 12%**

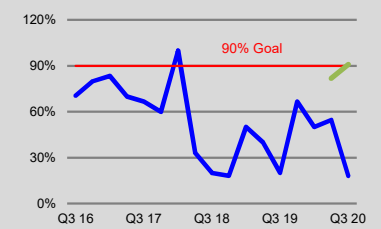
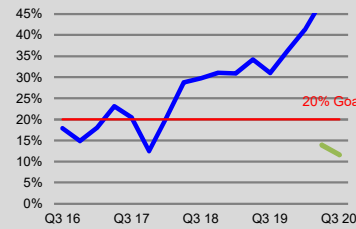
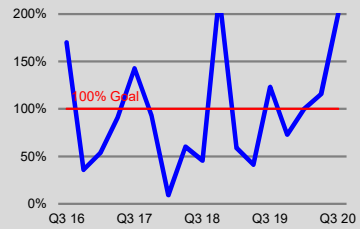
8 Cases Pending over 415 Days

**Time to Disposition: 18%**

2 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 91%**

10 Cases Closed within 415 Days



**Optometry**

**Clearance Rate: 100%**

4 Cases Received  
4 Cases Closed

**Pending Caseload: 28%**

5 Cases Pending over 250 Days

**Pending Caseload over 415 Days: 11%**

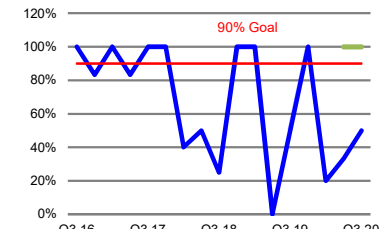
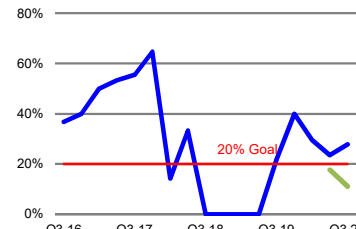
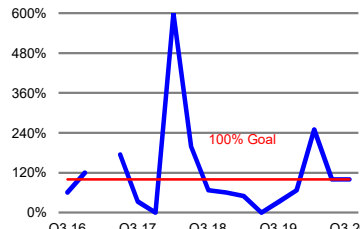
2 Cases Pending over 415 Days

**Time to Disposition: 50%**

1 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

3 Cases Closed within 415 Days



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

**Physical Therapy**

**Clearance Rate: 136%**

11 Cases Received

15 Cases Closed

**Pending Caseload: 24%**

8 Cases Pending over 250 Days

**Pending Caseload Over 415 Days: 3%**

1 Cases Pending over 415 Days

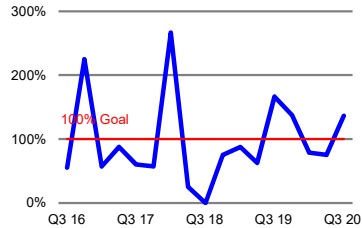
**Time to Disposition: 50%**

7 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 86%**

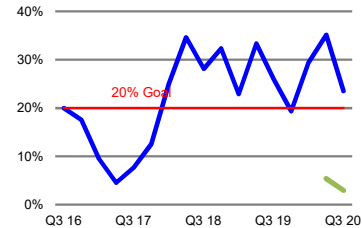
12 Cases Closed within 415 Days

**Clearance Rate**

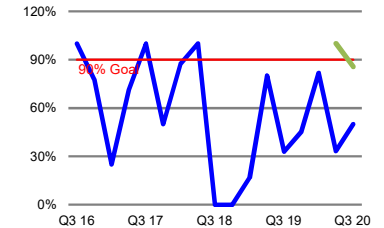


**Age of Pending Caseload**

(percent of cases pending over one year)



**Time to Disposition**



**Funeral**

**Clearance Rate: 110%**

10 Cases Received

11 Cases Closed

**Pending Caseload: 14%**

4 Cases Pending over 250 Days

**Pending Caseload over 415 Days: 0%**

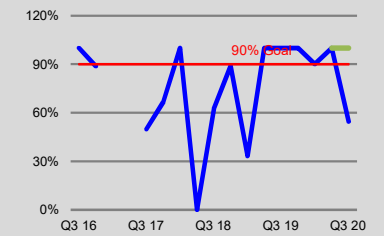
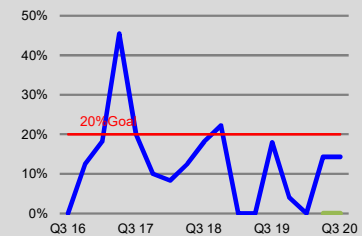
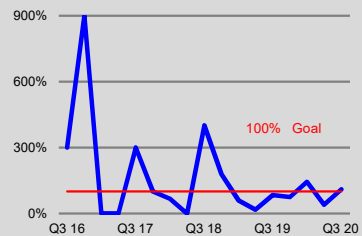
0 Cases Pending over 415 Days

**Time to Disposition: 55%**

6 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

11 Cases Closed within 415 Days



**Audiology**

**Clearance Rate: -**

0 Cases Received

2 Cases Closed

**Pending Caseload: 50%**

8 Cases Pending over 250 Days

**Pending Caseload over 415 Days: 44%**

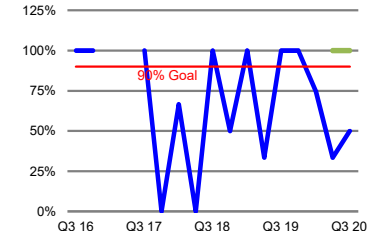
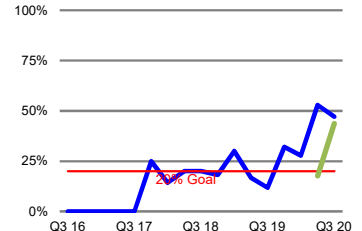
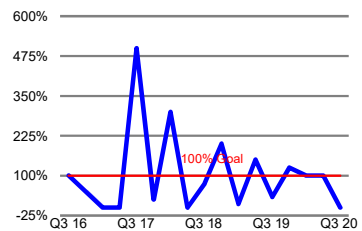
7 Cases Pending over 415 Days

**Time to Disposition: 50%**

1 Cases Closed within 250 Days

**Time to Disposition within 415 Days: 100%**

2 Cases Closed within 250 Days



**Executive Director's Report** – June 16, 2020

*Board Member Terms Expiring June 30, 2020:*

- ❖ Rebecca Thornbury
- ❖ Cynthia Warriner

*Recent Meetings:*

- ❖ COVID-19 Pharmacy Services Subcommittee of the Healthcare Coordination Committee Call – *ongoing*
- ❖ VDH/VHHA Healthcare Coordination Committee Call – *ongoing*
- ❖ COVID Partner Call - *ongoing*

*Upcoming Meetings:*

- ❖ June 23, 2020, Special Conference Committee (in-person)
- ❖ July 7, 2020, Special Conference Committee (in-person)
- ❖ July 21, 2020, Formal Hearing (virtual or in-person TBD)

*Staffing:*

- ❖ Continuing to telework with limited hours on-site
- ❖ Recruitment initiated for vacant licensing administrative assistant position

*Emergency Waivers:*

- ❖ Currently remain in effect
- ❖ Update

*Miscellaneous Updates*