COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearing and Full Board Meeting
June 5, 2019
9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Increase in Fees: Rafael Saenz, Chairman • Welcome & Introductions • Reading of Emergency Evacuation Script	
Public Hearing: • Increase in fees	1-9
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Rafael Saenz, Chairman • Approval of Agenda • Approval of Previous Board Meeting Minutes: o March 26, 2019, Full Board Meeting o March 26, 2019, Public Hearing for Chemicals and Pharmaceutical Processor Regs o March 28, 2019, Special Conference Committee o April 16, 2019, Board Retreat o April 17, 2019, Special Conference Committee o May 3, 2019, Regulation Committee o May 14, 2019, Special Conference Committee	10-42
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	43-44
DHP Director's Report: David Brown, DC	
Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran • Update on Regulatory/Policy Actions • Revenue and Expenditure Analysis • Report on Regulation Committee Meeting: o Recommendation on Proposed Regulations for Labeling Dispensed Prescriptions o Recommendation to Adopt Final Regulations for Pharmaceutical Processors o Recommendation on Number of Patients associated with Registered Agent – Emergency/Exempt Actions – Regulations for Pharmaceutical Processors o Consideration of Possible 2020 Legislative Proposals ▪ Pharmacy Technician Education Standards ▪ Compounding of Essentially Copies ▪ Telepharmacy	45-47 48 49-55 56-148 149-151 152-154

New Business:

Reports:

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

Adjourn

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

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

Proposed regulations

Public comment period: May 27, 2019 to July 26, 2019

Public hearing: June 5, 2019

Increase in fees

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	~~$180~~ $235
2. Pharmacy intern registration	~~$15~~ $20
3. Pharmacy technician registration	~~$25~~ $35
4. Pharmacy permit	~~$270~~ $500
5. Permitted physician licensed to dispense drugs	~~$270~~ $500
6. Medical equipment supplier permit	~~$180~~ $235
~~7. Humane society permit~~	~~$20~~
~~8.~~7. Outsourcing facility permit	~~$270~~ $350
~~9.~~8. Nonresident pharmacy registration	~~$270~~ $350
~~10.~~9. Nonresident outsourcing facility registration	~~$270~~ $350
~~11.~~10. Controlled substances registrations	~~$90~~ $120
~~12.~~11. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	~~$250~~ $325

~~13.~~12. Approval of a pharmacy technician training program	~~$150~~ $200
~~14.~~13. Approval of a continuing education program	~~$100~~ $130
~~15.~~14. Approval of a repackaging training program	~~$50~~ $65

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	~~$90~~ $120
2. Pharmacist inactive license – due no later than December 31	~~$45~~ $60
3. Pharmacy technician registration – due no later than December 31	~~$25~~ $35
4. Pharmacy permit – due no later than April 30	~~$270~~ $350
5. Physician permit to practice pharmacy – due no later than February 28	~~$270~~ $350
6. Medical equipment supplier permit – due no later than February 28	~~$180~~ $235
~~7. Humane society permit – due no later than February 28~~	~~$20~~
~~8.~~7. Outsourcing facility permit – due no later than April 30	~~$270~~ $350
~~9.~~8. Nonresident pharmacy registration – due no later than the date of initial registration	~~$270~~ $350
~~10.~~9. Nonresident outsourcing facility registration – due no later than the date of initial registration	~~$270~~ $350
~~11.~~10. Controlled substances registrations – due no later than February 28	~~$90~~ $120
~~12.~~13. Innovative program continued approval based on board order not to exceed ~~$200~~$260 per approval period.	
~~13.~~14. Approval of a pharmacy technician training program	~~$75~~ $100 every two years
~~14.~~15. Approval of a repackaging training program	~~$30~~ $40 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of

a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	~~$30~~ $40
2. Pharmacist inactive license	~~$15~~ $20
3. Pharmacy technician registration	~~$10~~ $15
4. Pharmacy permit	~~$90~~ $120
5. Physician permit to practice pharmacy	~~$90~~ $120
6. Medical equipment supplier permit	~~$60~~ $80
~~7. Humane society permit~~	~~$5~~
~~8.~~7. Outsourcing facility permit	~~$90~~ $120
~~9.~~8. Nonresident pharmacy registration	~~$90~~ $120
~~10.~~9. Nonresident outsourcing facility registration	~~$90~~ $120
~~11.~~10. Controlled substances registrations	~~$30~~ $40
~~12.~~11. Approval of a pharmacy technician training program	~~$15~~ $20
~~13.~~12. Approval of a repackaging training program	~~$10~~ $15

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

1. Pharmacist license	~~$210~~ $275
2. Pharmacist license after revocation or suspension	~~$500~~ $650
3. Pharmacy technician registration	~~$35~~ $45
4. Pharmacy technician registration after revocation or suspension	~~$125~~ $165

5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	~~$240~~ $315
b. Physician permit to practice pharmacy	~~$240~~ $315
c. Medical equipment supplier permit	~~$210~~ $275
~~d. Humane society permit~~	~~$30~~
~~e.~~d. Outsourcing facility permit	~~$240~~ $315
~~f.~~e. Nonresident pharmacy registration	~~$115~~ $150
~~g.~~f. Nonresident outsourcing facility registration	~~$240~~ $315
~~h.~~g. Controlled substances registration	~~$180~~ $235
~~i.~~h. Approval of a pharmacy technician training program	~~$75~~ $100
~~j.~~i. Approval of a repackaging training program	~~$50~~ $65

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	~~$50~~ $65
2. Change of ownership for any facility	~~$50~~ $65
3. Inspection for remodeling or change of location for any facility	~~$150~~ $300
4. Reinspection of any facility	~~$150~~ $300
5. Board-required inspection for a robotic pharmacy system	~~$150~~ $300
6. Board-required inspection of an innovative program location	~~$150~~ $300
7. Change of pharmacist responsible for an approved innovative program	~~$25~~ $35

H. Miscellaneous fees.

1. Duplicate wall certificate	~~$25~~ $50
2. Returned check	$35
3. Duplicate license or registration	~~$10~~ $15

4. Verification of licensure or registration ~~$25~~ $35

18VAC110-20-121. Innovative program approval.

A. An informal conference committee of the board may approve an innovative or pilot program in accordance with § 54.1-3307.2 of the Code of Virginia upon receipt of an application and fee specified in 18VAC110-20-20.

B. If the informal conference committee determines that an inspection is necessary to adequately consider an application, it may require that the applicant pay a fee specified in 18VAC110-20-20 to cover the cost of the inspection.

C. If the informal conference committee determines that a technical consultant is necessary in order for the board to make an informed decision on approval of a program, the applicant shall pay a consultant fee, not to exceed the actual cost of the consultation.

D. In the initial order granting approval of a program, the informal conference committee shall set the approval period with a schedule for submission of required reports and outcome data. The frequency of required reports shall not exceed four times a year.

E. The informal conference committee shall determine the appropriate fee for continued approval of the program based on the requirements for review and monitoring. Such renewal fee shall not exceed ~~$200~~ $260 per approval period.

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$180~~ $235.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$240~~ $315.

C. Annual renewal fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$90~~ $120.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$240~~ $315.

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substances: ~~$30~~ $40.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$40~~ $50.

E. Reinstatement fees. Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$150~~ $195.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$240~~ $315.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: ~~$500~~ $650.

F. 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 a facility permit. Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.

G. The fee for reinspection of any facility shall be ~~$150~~ 300.

H. The fee for a returned check shall be $35.

18VAC110-50-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

1. Nonrestricted manufacturer permit	~~$270~~ $350
2. Restricted manufacturer permit	~~$180~~ $235
3. Wholesale distributor license	~~$270~~ $350
4. Warehouser permit	~~$270~~ $350
5. Nonresident wholesale distributor registration	~~$270~~ $350
6. Controlled substances registration	~~$90~~ $120
7. Third-party logistics provider permit	~~$270~~ $350
8. Nonresident manufacturer registration	~~$270~~ $350

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	~~$270~~ $350
2. Restricted manufacturer permit	~~$180~~ $235
3. Wholesale distributor license	~~$270~~ $350
4. Warehouser permit	~~$270~~ $350
5. Nonresident wholesale distributor registration	~~$270~~ $350
6. Controlled substances registration	~~$90~~ $120
7. Third-party logistics provider permit	~~$270~~ $350
8. Nonresident manufacturer registration	~~$270~~ $350

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

1. Nonrestricted manufacturer permit	~~$90~~ $120
2. Restricted manufacturer permit	~~$60~~ $80
3. Wholesale distributor license	~~$90~~ $120
4. Warehouser permit	~~$90~~ $120
5. Nonresident wholesale distributor registration	~~$90~~ $120

6. Controlled substances registration	~~$30~~ $40
7. Third-party logistics provider permit	~~$90~~ $120
8. Nonresident manufacturer registration	~~$90~~ $120

E. Reinstatement fees.

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

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit	~~$240~~ $315
b. Restricted manufacturer permit	~~$210~~ $275
c. Wholesale distributor license	~~$240~~ $315
d. Warehouser permit	~~$240~~ $315
e. Nonresident wholesale distributor registration	~~$240~~ $315
f. Controlled substances registration	~~$180~~ $235
g. Third-party logistics provider permit	~~$240~~ $315
h. Nonresident manufacturer registration	~~$240~~ $315

F. Application for change or inspection fees.

1. Reinspection fee	~~$150~~ $300
2. Inspection fee for change of location, structural changes, or security system changes	~~$150~~ $300

3. Change of ownership fee	~~$50~~ $65
4. Change of responsible party	~~$50~~ $65

G. The fee for a returned check shall be $35.

H. The fee for verification of license, permit, or registration shall be ~~$25~~ $35.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

March 26, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:25 am

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT: James L. Jenkins, Jr.

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

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

APPROVAL OF AGENDA: The agenda was unanimously approved as presented. (Motion by Warriner, second by Boone)

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

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

- **December 18, 2018 Full Board Meeting**
- **December 18, 2018 Public Hearing to Schedule Certain Chemicals**

in Schedule I

- **December 18, 2018 Formal Hearing**
- **January 9, 2019 Formal Hearing**
- **January 9, 2019 Public Hearing**
- **January 25, 2019 Special Conference Committee**
- **February 13, 2019 Special Conference Committee**
- **February 27, 2019 Formal Hearing**
- **February 28, 2019 Special Conference Committee**

(motion by Bolyard, second by Boone)

PUBLIC COMMENTS:

Bill Cropper, President of VACDS, commented that the board should consider eliminating the pharmacist to pharmacy technician ratio in a future regulatory activity as pharmacists should be able to determine how many pharmacy technicians they are able to supervise. He stated the ratio limits quality of care, that there is a national trend to relax or eliminate ratios, that other professional groups do not limit the amount of support they may have, and that it would improve healthcare and costs.

Ken Hutchinson, representing National Healthcareer Association, provided comment on the draft 2020 legislative proposal regarding pharmacy technician educational standards. He expressed support for the idea of revisiting pharmacy technician educational standards, but is concerned that the draft changes would prohibit many individuals from meeting the requirements, have a negative impact on the workforce, and create a financial hindrance for those entering the workforce. Written comment was also provided as a handout.

Janet Sylvester, Vice President of Accreditation Services at the American Society of Health-System Pharmacists, offered comment in support of the draft 2020 legislative proposal on pharmacy technician educational standards, She stated that appropriately educated and accredited pharmacy technicians are needed to improve patient safety, and that public safety depended on uniform educational standards. She added that the Joint Commission of Pharmacy Practitioners voted to adopt national standards, and that currently there are 4 distance learning programs and 2 physical learning programs accredited by ASHP-ACPE in the Commonwealth.

Cindy Williams, Vice President/Chief Pharmacy Officer of Riverside Health System and President of VSHP, commented on the draft 2020 legislation regarding pharmacy technicians. She stated that VSHP supports the draft proposal. She stated she has had difficulty in hiring and retaining well-trained pharmacy technicians. She stated the pharmacy technicians who complete the board-approved pharmacy technician programs, which can be costly to the applicant, do not always have the skills to be successful in their organization.

Jeenu Phillip, member of the Florida Board of Pharmacy and Senior Manager, Pharmacy Affairs, Walgreens offered comment regarding the draft 2020 pharmacy technician legislative proposal. He shared that ASHP/ACPE provides students with a high level of education, but does not focus on the pharmacy technicians' area of practice. He said that shifting to require this

certification would limit the number of training programs available. Mr. Phillip commented that federal programs should be added and that NABP model language should be reviewed as it does not specify the ASHP-ACPE accreditation requirement. He also recommended reviewing the Florida Board of Pharmacy regulations on board-approved pharmacy technician training programs which was recently amended.

Christina Barrille, Executive Director of the Virginia Pharmacists Association commented that she recently attended the American Pharmacists Association convention, which focused on "moving pharmacy forward". She provided information on HB2561 regarding mandatory best practices for pharmacy audits and HJ662 regarding a Joint Commission on Healthcare study which includes a review of the pharmacist's role in prescribing, dispensing, and administering drugs and devices pursuant to collaborative practice agreements, standing orders, and statewide protocols. She also shared that WV has experienced significant savings after undergoing a Medicaid readjustment. Additionally, she asked the board to clarify its position on use of temperature monitoring devices when mailing dispensed drugs. A handout of written comment was also provided to the board.

Angela Cassano, pharmacist, commented in support of the draft 2020 legislative proposal regarding pharmacy technician training programs. She offered that pharmacy technician training programs are not currently in line with other types of programs such as radiology technicians, dental assistants, and cosmetologists. She added that the training programs offered by Walgreens, CVS, and Rite Aid are already ASHP-ACPE accredited.

Michelle Green-Wright, with the Virginia Department of Education (DOE), offered support for the draft legislative proposal for pharmacy technicians. She stated that the DOE currently has 17 high school training programs accommodating 1600 students. The programs prepare the students to take either the ExCPT or PTCB exam. She requested a grace period of two years, if the changes are approved, to accommodate the program's grant funding cycle and to allow time for the instructors to incorporate the new standards into their program. Currently, the DOE's program meets the entry-level ASHP/ACPE requirements and meets many of the advanced-level requirements.

Ms. Juran shared with the board members that a handout of written comment was provided to them at their sit that came from the National Community Pharmacists Association. The comment outlined their concerns for the draft 2020 legislative proposal regarding pharmacy technician educational standards.

DHP DIRECTOR'S REPORT:

Dr. Brown stated that the new DHP website is anticipated to be rolled out soon. He added that the new website design should make it easier to locate information, and will also include functionality for the boards to update their own content to the website. He also shared that there will be a number of legislatively mandated workgroups convened this summer to discuss barriers to licensing foreign trained physicians, telemedicine, licensure of music therapists, and if performing body composition analyses should be regulated. A budget amendment will require the Board of Pharmacy to report to the Joint Commission on Healthcare on proper drug disposal issues. The Secretaries of

Agriculture and Health and Human Resources will report on appropriate standards, if any, for the production of hemp-derived cannabidiol oil. Dr. Brown also expressed concerns for a CDC grant impacting the PMP program as it would require connecting to a new hub for transmitting data.

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Report of the 2019 General Assembly

Ms. Yeatts provided a summary overview of the materials in the agenda packet regarding passed legislation.

Regulatory Update

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet.

Adoption of Exempt Regulation to Schedule Certain Chemicals in Schedule I

There was a public hearing conducted at 9:10AM pursuant to requirements of §54.1-3443 of the Drug Control Act to receive comment on scheduling certain chemicals in Schedule I.

MOTION:

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

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

1. Synthetic opioid.

a. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation

2. Research chemicals.

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

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

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

Adoption of proposed regulations on delivery of dispensed prescription devices

MOTION: **The board voted unanimously to adopt the proposed regulations as presented. (motion by Williams, second by Nelson)**

Presentation on Telepharmacy

To accommodate travel arrangements, the chairman recommended that the Board move the presentation on telepharmacy up on the agenda schedule. Jessica Adams, PharmD, Manager of Regulatory Affairs with TelePharm provided a presentation to discuss the benefits of the use of telepharmacy in rural areas that may not have a pharmacy within close proximity. The slides were included in the agenda packet. No action was taken by the Board. The subject will be discussed at the Regulation Committee meeting in May.

Consideration of comment on periodic review regulations and adoption of final amendments

A 60-day public comment period on the proposed regulations resulting from the periodic regulatory review of chapters 20 and 50 ended February 22, 2019. To aid the board in its deliberations, Ms. Yeatts provided a handout that highlighted sections of regulations for which comment was received. The board discussed each section to determine if the proposed language needed to be amended prior to adopting final regulations.

The Board received a significant amount of comment regarding whether live or real-time interactive continuing education (CE) should be required. It was clarified that live webinars that offered the ability to interact with the presenter would satisfy the requirement for "live or real-time interactive" CE, but that recorded webinars that did not offer the opportunity to interact with the presenter would not satisfy the requirement. There was much discussion regarding this issue and the required number of hours.

MOTION: **The Board voted unanimously to amend the proposed language in 18VAC110-21-120 subsection C by decreasing "five" hours to "three" hours of live or real-time interactive continuing education. (motion by Warriner, second by Richards-Spruill)**

MOTION: **The Board voted unanimously to amend the proposed language in 18VAC110-20-425 by removing reference to a "root cause analysis" and have subsection (4)(h) read, "Appropriately performing analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system" and subsection (6) read, "If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in**

compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format." (motion by Warriner, second by Logan)

MOTION: **The Board voted 3:6 to amend the proposed language in 18VAC110-20-110 regarding a minimum number of years of experience required for eligibility to serve as a pharmacist-in-charge by decreasing the proposed "two" years to "one" year. Motion failed due to a lack of votes. (motion by Bolyard, second by Thornbury; opposed by Warriner, Logan, Boone, Nelson, Ratliff, Richards-Spruill)**

MOTION: **The Board voted 7:2 to adopt as presented the proposed language in 18VAC110-20-110 requiring "a minimum of two years of experience practicing in Virginia or another US jurisdiction" and allowing for the granting of exceptions "for good cause shown". (motion by Nelson, second by Boone; opposed by Thornbury and Bolyard)**

MOTION: **The Board voted unanimously to amend the proposed language in 18VAC110-20-270 by inserting at the end of subsection A, "In cases of failed electronic prescriptions, Schedule VI prescriptions transmitted electronically may be routed to the pharmacy's facsimile machine and may bear an electronic signature". (motion by Warriner, second by Thornbury)**

MOTION: **The Board voted unanimously to amend the first sentence of proposed subsection E in 18VAC110-20-270 by deleting "on-duty" and changing "the pharmacist" to "a pharmacist" and having it read, "An on-hold prescription shall be entered into the automated date procession system if such system is employed by the pharmacy, and a pharmacist shall verify the accuracy of the date entry at that time." (motion by Saenz, second by Nelson)**

MOTION: **The Board voted unanimously to amend the proposed subsection B of 18VAC110-20-530 to read: "A pharmacist employed by or contracted with a pharmacy providing services to a long-term care facility may share a copy of a Schedule VI prescription or order with a pharmacist at another pharmacy for the purpose of dispensing an immediate supply of drugs, not to exceed a seven-day supply, without transferring the prescription pursuant to 18VAC110-20-360". (motion by Warriner, second by Thornbury)**

MOTION: **The Board voted unanimously to adopt the final regulations for periodic review of chapters 20 and 50, and to adopt new chapters 21 and 15, as presented and amended. (motion by Warriner, second by Logan)**

Preliminary Discussion of 2020 Legislative Proposals:

Ms. Juran highlighted the draft legislative proposals in the agenda packet. The board did not engage in discussion, but referred the matter to the Regulation Committee for consideration.

Pharmacy Technician Training Requirements

Compounding of Essentially Copies

OLD BUSINESS

Request from Gates Healthcare Associates, Inc. regarding cGMP Inspections

Ms. Juran stated she has communicated with Gates Healthcare Associates (GHA) and was informed that Gates does not have additional information to provide at this time. Because the Board's needs for recognizing an outside entity to perform cGMP inspections is very limited and is currently being met, GHA will withdraw its request for consideration. However, GHA would like to remain as a consideration in the future should the need arise.

NEW BUSINESS

Overview of Pharmacist and Pharmacy Technicians Workforce Survey Reports

Elizabeth Carter, PhD, Director of DHP Healthcare Workforce Date Center (HWDC) and Yetty Shobo, PhD, Deputy Director of DHP HWDC provided an overview of the 2018 Virginia Pharmacist and Pharmacy Technician Workforce Survey Reports provided as attachments to the meeting agenda. A handout of their slides regarding the key findings of the workforce surveys was provided to the Board. Key findings for pharmacists included: 26% increase in licensees, 11% increase in state workforce numbers, but full time equivalency declined; percent female increasing, median age is 44; percent with educational debt increasing overall; and, income stable for past two years. Key findings for pharmacy technicians included: 7% increase in licensees, 7% increase in state workforce numbers, but full time equivalency units declined; percent female stable with percent younger than 40 years old increasing; percent with educational debt increased slightly; income increasing although stable recently. Overall, there is a declining proportion of pharmacists in the state workforce, increasing median education debt, and over 20% of pharmacists and 14% of pharmacy technicians plan to retire in a decade. Three other handouts were provided to the Board. One handout from the US Bureau of Labor Statistics Estimates and Projections (www.projectionscentral.come/projections/longterm) displayed the percent of employment growth 2016-2026 in the US vs. Virginia and nearby states, base vs. projected jobs, and annual average job openings for pharmacists and pharmacy technicians. Projected jobs for pharmacy technicians are higher than base with 870 projected annual average job openings. Projected jobs for pharmacists are higher than base with 360 projected annual average job openings. The second handout was from VirginiaLMI.com and demonstrated supply and demand. As of 3/14/19, there were 0.29 pharmacy technician

candidates available per job opening, or 544 jobs for 159 candidates. While the potential number of candidates is spread throughout the Commonwealth, the density of job openings is found in select areas of the Commonwealth. For pharmacists, there were 0.37 candidates available per job opening as of 3/14/19, or 160 jobs available for 59 candidates. While potential candidates are located in certain areas of the Commonwealth, the density of job openings also exist in select areas of the Commonwealth. The third handout listed the 2018 Data Products produced by the Healthcare Workforce Data Center.

Presentation on HPMP

Because the Board has five new board members as of last year, Ms. Peggy Wood, Program Manager of the Virginia Health Practitioners Monitoring Program (HPMP), provided a training overview of the HPMP program. A one-page flyer regarding referrals to the program was provided as a handout.

Training on disciplinary process and conduct during informal conferences and formal hearings

To expand on information provided during the new board member orientation, Ms. Shinaberry provided an overview of the disciplinary process, from the time the Enforcement Division receives a complaint through the appeals process. A one-page flowchart outlining the steps was provided to the Board. A video outlining the process for performing probable cause review was shown to the Board. However, due to technical difficulties with the sound, staff stopped the video and Ms. Juran completed the training with a verbal overview. A handout regarding sample motions for disciplinary proceedings was also provided. Mr. Rutkowski then discussed appropriate conduct for Board members when participating in informal conferences and formal hearings. A handout of his slides was also provided to the board.

REPORTS

Chairman's Report

Mr. Saenz provided a brief oral report which included information on a recent Leadership Forum that focused on pharmacy technicians.

Report on Board of Health Professions

Mr. Logan shared that he attended a Board of Health Professions meeting February 25, 2019. He added that policies and procedures were adopted for reviewing emerging health professions and that the agency disciplinary case disposition time is under review.

Report on Inspection and Licensure Program

Ms. O'Halloran reported the Board currently licenses 35,414 individuals and facilities. The Board issued 900 licenses and registrations for the period of December 1, 2018 through February 28, 2019. Inspectors conducted 455 facility inspections including 159 routine inspections of pharmacies: 57 (36%) resulted in no deficiency, 55 (34%) with deficiencies and 47 (30%) with deficiencies and a consent order.

Report on Disciplinary Program

Ms. Shinaberry provided a statistical update regarding the disciplinary program by reviewing the information provided in the agenda packet.

Executive Director's Report

Ms. Juran provided a verbal overview of recent meetings and presentations attended, as well as upcoming meetings that staff will be attending. She stated she attended a Congressional Briefing on February 27, 2019 on cannabinoid research. She shared some highlights of the briefing with the Board.

Regarding the Board Retreat on April 16, 2019, she stated that Carmen Catizone, Executive Director/Secretary of NABP will present on standard of care regulations, Peter Vlasses, Executive Director of ACPE will present on pharmacy technician educational standards, and Al Domeika, pharmacist-in-charge of Prime Wellness of CT will present on treating patients with medical marijuana. Lastly, she encouraged board members to attend the NABP annual meeting in May in MN.

ADJOURN: With all business concluded, the meeting adjourned at 4:10pm.

_____ _____

Rafael Saenz, Chairman Caroline D. Juran, Executive Director

_____ _____

DATE: DATE:

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARINGS FOR PHARMACEUTICAL PROCESSOR REGULATIONS AND TO SCHEDULE CERTAIN CHEMICALS IN SCHEDULE I

March 26, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The public hearings were called to order at 9:10 a.m.

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT: James L. Jenkins, Jr.

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

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

A powerful synthetic opioid:

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

Research chemicals:

- alpha-pyrrolidinoisohexiophenone (other name: alpha-

PiHP)

- 1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP)

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

PULIC COMMENT:

Scott May, Chemistry Program Manager with the Department of Forensic Science provided information on the 3 chemicals the department has identified for the Board's consideration to place into Schedule I.

No other comment on this subject was provided.

CALL FOR PUBLIC COMMENT:

Mr. Saenz then call for public comment on the proposed regulations for pharmaceutical processors. Copies of the proposed regulations were provided to the board members and on the back table for the public.

PUBLIC COMMENT:

Caley Crawford, with Virginia Medical Cannabis Coalition which represents the five pharmaceutical processors, offered comment that their mission is to ensure all laws and regulations are aligned with the goal of patient safety. Ms. Crawford commended the board and added that she is pleased with the passage of SB 1557 and SB 1719 that increases access, formulations, and labeling, and offered to serve as a resource to the board.

Aaron Lopez, representing Dalitso, made comment asking the board to remain vigilant in the unregulated sales of over-the-counter CBD products. He offered that the unregulated sale of CBD is confusing to the public and that the CBD suppliers are not being held accountable to the same standards as the pharmaceutical processors.

Jean Michelle Pedini, Executive Director of Virginia NORML thanked the board for allowing Virginians to access CBD. She expressed concern over unregulated products, patient safety, access, and affordability.

Dylan Bishop, Virginia Cannabis Association, offered support to the board.

ADJOURN:

The public hearing adjourned at 9:25am.

_____	_____
Rafael Saenz, Chairman	Caroline D. Juran, Executive Director
_____	_____
Date	Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, March 28, 2019
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 09:05 a.m.
PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Ileita Redd, Discipline Program Specialist
MARTIN'S PHARMACY Permit No. 0201-000443	William Hale, Pharmacist and owner, Eddie Hale, Pharmacist, Aaron Houchens, Attorney and Richard Wall, Attorney, appeared on behalf of Martin's Pharmacy to discuss allegations that Martin's Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 17, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Dr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Martin's Pharmacy. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded Dr. Saenz, the Committee voted unanimously to dismiss the matter.
HAGUE PHARMACY Permit No. 0201-002286	No one appeared on behalf of Hague Pharmacy to discuss allegations that Hague Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 5, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Dr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Hague Pharmacy. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Dr. Saenz, the Committee voted unanimously to enter an Order to assess a monetary penalty.
EBONI RAMSEY License No. 0202-216114	Eboni Ramsey, Pharmacist, appeared on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 13, 2018 Notice.

Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Dr. Saenz, the Committee voted unanimously to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Eboni Ramsey. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Dr. Saenz, the Committee voted unanimously to enter an Order with terms and conditions.
PHARMACY AT GREAT FALLS Permit No. 020201-004791	No one appeared on behalf of the Pharmacy at Great Falls to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 21, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Dr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of the Pharmacy at Great Falls. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded by Dr. Saenz, the Committee unanimously voted to enter an Order with no sanction imposed.
ROYAL CARE PHARMACY Permit No. 0201-004652	Steven S. Yi, Pharmacist in Charge, and Hunter Jamerson, Attorney appeared on behalf of Royal Care Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 2, 2019 Notice.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Dr. Saenz, the Committee unanimously voted to enter an Order to impose a monetary penalty and place Royal Care Pharmacy on probation for two years with certain terms and conditions.
ADJOURNED:	2:46 PM

_____	_____
Rafael Saenz, Chair	Ellen B. Shinaberry Deputy Executive Director
_____	_____
Date	Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD RETREAT

April 16, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:05 am

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT:
James L. Jenkins, Jr.
Ryan Logan

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

GUEST SPEAKERS:
Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy
Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education
Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy
Al Domeika, Pharmacist-in-Charge, Prime Wellness of Connecticut

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

APPROVAL OF AGENDA: The agenda was unanimously approved as presented.

PURPOSE OF MEETING:	Learning session for the Board of Pharmacy members to provide education on topics of Standards of Care, Pharmacy Technician Education Standards, Endocannaboid System and Cannaboid Research, and Medical Marijuana Dispensary Operations. Board members asked questions of the presenters following each presentation.
PRESENTATIONS:	
STANDARDS OF CARE REGULATORY APPROACH (ATTACHMENT 1)	Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy provided a presentation on the topic of Standard of Care Regulatory Approach.
PHARMACY TECHNICIAN EDUCATION STANDARDS (ATTACHMENT 2)	Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education, provided a presentation on the topic of Pharmacy Technician Education Standards.
ENDOCANNABINOID SYSTEM AND CANNABIS RESEARCH (ATTACHMENT 3)	Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy, provided a presentation discussing the topic Endocannabinoid System and Cannabis Research.
MEDICAL MARIJUANA DISPENSARY OPERATIONS (ATTACHMENT 4)	Al Domeika. Pharmacist-in-Charge provided a presentation on the topic of Medical Marijuana Dispensary Operations.
UPDATE ON IMPLEMENTATION OF PHARMACEUTICAL PROCESSOR PROGRAM	Ms. Juran, Mr. Johnson, and Melody Morton provided a brief presentation to update the board on the status of the pharmaceutical processor program.
ADJOURN:	With all business concluded, the meeting adjourned at 3:15 pm.

_____ _____

Rafael Saenz, Chairman Caroline D. Juran, Executive Director

_____ _____

DATE: DATE:

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, April 17, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 09:07 a.m.
PRESIDING:	Cindy Warriner, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Ileita Redd, Discipline Program Specialist
CVS PHARMACY #1416 Permit No. 0201-000574	No one appeared on behalf of CVS Pharmacy #1416 to discuss allegations that CVS Pharmacy #1416 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 8, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS Pharmacy #1416 . Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee voted unanimously enter an Order to assess a monetary penalty.

ROSS WILLIAM LARKIN Registration No. 0230-022264	Ross William Larkin, Pharmacy Technician, appeared on his behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 11, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Ross W. Larkin. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	The Committee deferred a decision in this matter.
TERESSA ANN ANTHONY License No. 0202-011697	Teresa Ann Anthony, Pharmacist, appeared on her behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 8, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee voted unanimously to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(16) for the purpose of discussion of medical records, substance abuse treatments records, or mental health records. Additionally, he moved that Ellen Shinaberry, Claire Foley, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Teressa A. Anthony. Additionally, he moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee voted unanimously to refer the matter to the full Board or a panel thereof for a formal hearing.
ADJOURNED:	11:50 AM

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

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

May 3, 2019
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:03AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT: Rafael Saenz
Glen Bolyard, Jr.
Kristopher Ratliff

STAFF PRESENT: Caroline D. Juran, Executive Director
Barbara Allison-Bryan, M.D., Chief Deputy Director, DHP (Exited 11:19AM)
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

QUORUM:

With four members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: Agenda was approved as provided.

PUBLIC COMMENT: Christina Barille, Executive Director of Virginia Pharmacist Association (VPhA), provided comment to the committee on behalf of VPhA and VSHP (Virginia Society of Health-System Pharmacists). Ms. Barille provided support of legislation requiring completion of an accredited pharmacy technician training program. She offered a suggested amendment to §54.1-3321 in the legislative proposal option 2 provided in the agenda packet (pp. 98-100). She said that this option accomplishes the goal of requiring completion of either an accredited training program or a widely accepted federal or state-provided program, allowing the board to retain control over training criteria, and avoiding overly specific or restrictive accreditation or training standards in the Code of Virginia. Ms. Barille also expressed opposition to a legislative proposal authorizing telepharmacy at this time. She expressed concerns regarding the lack of pharmacist personal supervision. She shared that VPhA is currently working with VDH to research access issues and that a report will be published next year to provide findings. She also expressed opposition for any possible discussions to eliminate the current pharmacist to

pharmacy technician ratio as VPhA believes the ratio is there to keep the patients safe. Handout from VPhA-VSHP provided.

Jessica Langley, Executive Director of Education and Advocacy for the National Healthcareer Association (NHA), provided comment in support of advancement of pharmacy technician education and employer-based training programs. She shared concerns for the draft legislative proposals which could result in a decline in access to training programs.

Jan Kuhn, Assistant Professor at VCU, provided comment to the committee regarding the topic of brown bagging and its impact on the treatment of hemophilia. She expressed concern with the recommended language for 18VAC110-20-275 subsection G that reads: "An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment." She shared that some hemophilia treatments are not blood factor treatments. She also provided examples of when blood factor medications are given in a non-emergent outpatient setting, as a part of best practice. She recommended deleting the word "emergent" and changing "blood factor treatment" to "hemophilia medication". Staff encouraged her to please submit formal comment on the subject during the next open public comment period on this regulatory action.

John Beckner, Senior Director of Strategic Initiative for the National Community Pharmacist Associations (NCPA) shared comment with the committee regarding pharmacy technician training requirements. He shared that they currently represent 353 pharmacies in Virginia and that the requirement for pharmacy technician training programs to be ACPE/ASHP-accredited would be too restrictive. He said that imposing this requirement would create access issues for pharmacy technician training. Instead, he asked that the committee expand the regulatory language to include military, Department of Education, and employer-based pharmacy technician training programs, as well as recognize prior pharmacy technician work experience from other states.

Jeenu Phillip, Senior Manager of Pharmacy Affairs for Walgreens and member of the Florida Board of Pharmacy, supported comments provided by Ms. Langley and Mr. Beckner. Mr. Phillip expressed concerned over limitations the board may encounter if only allowing programs that have been accredited through ASHP/ACPE. He asked that the committee discuss available options. He suggested the board not eliminate employer-based programs, but rather beef them up.

Lauren Paul, Senior Director of Pharmacy Regulatory Affairs for CVS Health, offered comment in support of the petition for rulemaking regarding labeling of dispensed prescriptions and requested the committee move forward with the proposed language amending 18VAC110-20-275. She said that this would decrease patient confusion.
Natalie Nguyen, Legislative Committee Chairman for Virginia Society of Health-System Pharmacists (VSHP) offered comment in support of the

legislative proposal requiring completion of an ASHP/ACPE-accredited pharmacy technician training program. She commented that the standards represent minimum standards.

Dylan Bishop, Esq., representing Cannabis Business Association of Virginia (CBAV), provided comment to the committee on the pharmaceutical processor regulations. He requested the committee remove the prohibition to use telemedicine when initially consulting a patient on use of CBD or THC-A oil and in the first year of treatment. CBVA also recommended that the proposed regulations surrounding laboratory testing require Cannabis plant materials be tested once processed and ready for human consumption. With respect to 18VAC110-60-30, CBVA suggested requiring all labs used by pharmaceutical processors to be accredited and registered by the board. CBAV provided recommended changes with regard to 18VAC110-60-300. Handout provided.

Staff provided the Committee with written comments submitted by Political Capital and by Virginia Medical Cannabis Coalition regarding the pharmaceutical processor proposed regulations and NACDS opposing standardized pharmacy technician training programs.

Update on Regulatory/Policy Actions

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

- Brown Bagging and White Bagging- under review by DPB
- E-Profile ID Requirement to go into effect June 26, 2019
- Scheduling of Chemicals into Schedule I effective June 26, 2019
- Delivery of Prescriptions- under review by DPB

Ms. Juran added that the drug gabapentin will change from a Schedule VI drug to a Schedule V drug effective July 1, 2019. She also advised the Committee that law authorizing the registration of nurse practitioners and physician assistants for issuing written certifications takes effect July 1, 2019. Ms. Yeatts also shared that legislative action requiring the board to promulgate emergency regulations on the pharmaceutical processor regulations cannot be addressed until the final replacement regulations become effective later this year. She shared that the emergency regulations will expire in August and that discussions regarding the promulgation of emergency regulations would likely not occur prior to the September board meeting.

Recommendation on Proposed Regulations for Labeling Dispensed Prescriptions

The draft proposed regulations provided in the agenda packet amended 18VAC110-25-275(B) to clarify requirements for the policies and procedure manual when a pharmacy delivers a dispensed drug to another pharmacy. Additionally, it stated that the identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the prescription label when that pharmacy has not shared in other filling or dispensing functions. Mr. Bolyard recused himself

from the discussion and vote since he is employed by CVS Pharmacy and the petition for rulemaking was submitted by CVS. There was much discussion regarding whether both pharmacies' names should be listed on the label or not. It was determined that the pharmacy holding the drug for delivery to the patient, that did not otherwise have a role in the dispensing of the drug, did not need to have its name listed on the prescription label.

- **MOTION:**

The committee voted unanimously to recommend to the full board that it adopt the proposed regulatory amendment as presented. (motion by Saenz, second by Ratliff)

Recommendation on Final Regulations for Pharmaceutical Processors

Ms. Yeatts reminded the Committee that a public comment period is open on this subject until May 17, 2019, but that they could consider the comment received thus far. Ms. Juran and the Committee reviewed recommendations offered by staff in the agenda packet and took written comment received thus far into consideration. Additionally, Ms. Juran provided a handout of other recommended amendments based on written comments received the day before the meeting. Many recommendations were offered by the board.

The committee also had discussion regarding 18VAC110-60-60(A)(6) and whether a violation of law pertaining to marijuana should be incorporated into the language. It was determined that no action is necessary at this time.

There was a brief discussion regarding use of perimeter alarms. It was determined that no changes to security system requirements were needed at this time.

- **MOTION:**

The committee voted unanimously to recommend to the full board that it adopt the following recommendations:

- **18VAC110-60-310(2) – change the record-keeping requirement for maintaining the patient's self-assessment of the use of the oils from two years to three years to be consistent with other recordkeeping requirements;**
- **18VAC110-60-10, "90-day supply" – strike "which cannot exceed 60 fluid ounces";**
- **18VAC110-60-20(D) – insert fee for "change of ownership not requiring criminal background check" equal to $100 and fee for "change of ownership requiring criminal background check" equal to $250;**
- **18VAC110-60-285:**
  - **Strike (A)(5) that reads "5. Any other active ingredient that constitutes at least 1% of the batch used in the product";**
  - **In (B), change "97% to 103%" to "90% to 110%" to be consistent with statutory change involving range**

for THC;

- **18VAC110-60-290(2)(e) - insert at the end "based on stability testing";**
- **18VAC110-60-295 – strike all language as it is duplicative with 18VAC110-60-310**
- **18VAC110-60-300:**
  - **In (B), insert at the end "and terpenes profile."**
  - **In (B), insert "1. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:**
    - **Tetrahydrocannabinol (THC);**
    - **Tetrahydrocannabinol acid (THCA);**
    - **Cannabidiols (CBD); and**
    - **Cannabidiolic acid (CBDA)";**
  - **In (D), strike "include Cannabis in a cannabidiol oil or THC-A oil product or" and insert after "sell", "cannabidiol oil or THC-A oil product" and strike "it" after "product";**
  - **In (F)(2), strike "Cannabis" and insert after "sample", of cannabidiol oil or THC-A oil product";**
  - **In (F)(3), strike "Cannabis" and insert after "sample", of cannabidiol oil or THC-A oil product";**
  - **In (F)(3), in the chart, change "Limits uG/KG BW/Day" to "Limits parts per million (ppm)" and change the limit of Arsenic to "<10 ppm", change the limit of Cadmium to "<4.1 ppm", change the limit of Lead to "<10 ppm", and change the limit of Mercury to "<2 ppm";**
  - **In (F)(4), replace "Cannabis" with "cannabidiol oil or THC-A oil product";**
- **18VAC110-60-310:**
  - **In (C)(2), strike "or kind of" and insert after "THC-A oil", "that was registered with the board pursuant to 18VAC110-60-285";**
  - **In (C), insert a new (6) that reads "A terpenes profile and a list of all active ingredients, including:**
    - **Tetrahydrocannabinol (THC);**
    - **Tetrahydrocannabinol acid (THCA);**
    - **Cannabidiols (CBD); and**
    - **Cannabidiolic acid (CBDA)";**
  - **In (C), insert a new (7) that reads "A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis;"**
  - **In (C)(12) which will be renumbered to (14), after "based on", insert "stability testing and";**
  - **Insert a new (D) that reads "D. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants**

have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.;

- **Staff should also draft language for consideration in June that incorporates salmonella testing similar to Louisiana's requirement, a requirement for residual solvent testing, and further clarify requirements for establishing an expiration date based on stability testing and for complying with §54.1-3442.7(D) regarding requirements for THC-A products.**

(motion by Ratliff, second by Bolyard)

Recommendation on Number of Patients associated with Registered Agents Emergency/Exempt Actions-Regulations for Pharmaceutical Processors

Ms. Yeatts explained that emergency regulations may not be promulgated until the legislative changes and the final replacement regulations are in effect. The Committee deferred this discussion to a later meeting.

Consideration of Possible 2020 Legislative Proposals

Pharmacy Technician Education Standards

After much discussion, the Committee agreed that there should be a standard in place for pharmacy technician training and that military education should be permissible. Ms. Warriner shared her support of education standards.

MOTION:

The Committee voted unanimously to recommend to the full Board to adopt the draft legislative proposal option #1 regarding pharmacy technician education standards with the following amendments:

- **§54.1-3321(C) should read: "To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education or other Board-approved accrediting body with substantially similar standards or federal services pharmacy technician training program and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~."**
- **Staff should draft language for consideration in June,**

authorizing issuance of a pharmacy technician registration to an out-of-state applicant through credentialing as detailed in regulation which could specify a minimum number of years of experience practicing as a pharmacy technician combined with national certification.
(motion by Saenz, second by Bolyard)

Compounding of Essentially Copies

Ms. Juran shared that the draft legislative proposal attempted align state law with current federal requirements that prohibit the compounding of essentially copies of commercially available drug products.

- **MOTION:**

The committee voted unanimously to recommend to the full Board to adopt the legislative proposal on compounding of essentially copies as presented. (motion by Ratliff, second by Bolyard)

Telepharmacy

Ms. Warriner shared her concerns and that she would like to review the population study report on access that will result from the work between VPhA and VDH prior to endorsing telepharmacy. Mr. Saenz said that he would feel more confident with telephamacy if pharmacy technician education standards were enhanced. Mr. Bolyard said that it was too soon to move forward on the subject. Mr. Ratliff said that he currently lives in a rural area and does not see an immediate need for telepharmacy at this time.

- **MOTION:**

The Committee voted unanimously to recommend to the Board to take no action at this time. (motion by Bolyard, second by Ratliff)

White Bagging/Brown Bagging

There was some discussion that a legislative proposal may not be needed on this subject at this time, but that staff could send a letter to pharmacies when the final regulations are effective on white bagging/brown bagging to highlight the need for compliance.

- **MOTION:**

The Committee voted unanimously to recommend to the full Board to take no action on a legislative proposal regarding white bagging/brown bagging at this time. (motion by Saenz, second by Bolyard)

ACTION ITEM:

Staff should send a letter to pharmacies when the final regulations on white bagging/brown bagging are effective to highlight the need for compliance.

Consideration of Comments Received during Periodic

Ms. Yeatts indicated that the Board currently has thirteen regulatory packets under administrative review and that it may be advisable to not

Regulatory Review that Exceeded the Scope of the NOIRA	adopt another Notice of Intended Regulatory Action until some of the current regulatory actions have become final. She also shared that the Board had previously received comment that Pharmacy was the only board with regulatory restrictions regarding the number of people that could be supervised. She then reviewed the information on pages 126 and 127 of the agenda packet that referenced other boards with similar supervisory restrictions. The Committee then reviewed the list of comments on page 125 of the agenda packet that were received during the periodic review regulatory public comment period that were deemed outside of the scope of the Notice of Intended Regulatory Action for the periodic review process. Ms. Juran clarified that the list should have also included a request to change the deadline for pharmacist-in-charge changes from 14 days to 28 days. Mr. Ratliff recommended including on the list an ability for a pharmacist to change a dosage form, e.g., capsules to tablets, without a requirement to contact the prescriber. There was brief discussion of the following subjects, in particular: In section 10, amend the definition of "faxed prescription" to allow an electronic image; In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription to change dosage form; and, Consider amending change of PIC requirements from 14 days to 28 days. There was general consensus that the Regulation Committee will consider the topics on the list at a future meeting.
ADJOURN:	With all business concluded, the meeting adjourned at approximately 2:56 pm.

_____	_____
Rafael Saenz, Chairman	Caroline D. Juran, Executive Director
_____	_____
DATE	DATE

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, May 14, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 0934.

PRESIDING: Kris Ratliff, Committee Chair

MEMBERS PRESENT: Patricia Richards-Spruill, Committee Member

STAFF PRESENT: Ellen B. Shinaberry, Deputy Executive Director
Claire Foley, DHP Adjudication Specialist
Mykl Egan, DHP Adjudication Specialist
Ileita Redd, Discipline Program Specialist

DAVINDER P. KAHLON
License No. 0202-214712

Davinder P. Kahlon, pharmacist, appeared on his own behalf along with Lindsay Walton, attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 15, 2019 Notice.

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

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

Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order for Probation with certain terms and conditions.
GAINESVILLE PHARMACY Permit No. 0201-004481	Davinder P. Kahlon, pharmacist and owner, appeared on behalf of Gainesville Pharmacy, along with Lindsay Walton, attorney, to discuss allegations that Gainesville Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 27, 2019 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Gainesville Pharmacy. Additionally, she moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order to issue a Reprimand and a Monetary Penalty.
KEVIN LEE License No. 0202-211781	No one appeared on behalf of Kevin Lee to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 30, 2019 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the

	purpose of deliberation to reach a decision in the matter of Kevin Lee. Additionally, she moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order to issue a Reprimand.
TIDEWATER DRIVE CENTER Permit No: 0201-001628	Donna Rogers, pharmacist, appeared on behalf of Tidewater Drive Center to discuss allegations that Tidewater Drive Center may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 13, 2019 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Tidewater Drive Center. Additionally, she moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order to issue a Monetary Penalty.

DANIEL NGEMBUS License No: 0202-214122	Daniel Ngembus, pharmacist, appeared on his own behalf along with Keyondra White, pharmacy technician, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 29, 2019 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Daniel Ngembus. Additionally, she moved that Ellen Shinaberry and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order to issue a Reprimand with certain terms and conditions.
ADJOURNED:	16:10

Kris Ratliff, Chair	Ellen B. Shinaberry Deputy Executive Director
Date	Date

VIRGINIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
EDUCATE. ADVOCATE. COLLABORATE.

VPhA
VIRGINIA PHARMACISTS ASSOCIATION

May 22, 2019

Virginia Board of Pharmacy
Attention: Caroline Juran, Executive Director, Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
caroline.juran@dhp.virginia.gov

Dear Ms. Juran, Chairman Saenz and members of the Board of Pharmacy:

The Virginia Society of Health-System Pharmacists (VSHP) and Virginia Pharmacists Association (VPhA) reiterate our support for legislation requiring pharmacy technician licensees to complete an accredited training program. Additionally, the Board of Pharmacy (the Board) should recognize established training programs provided by a federal agency or the Virginia Department of Education. The Board should also include a grandfathering provision for pharmacy technicians currently registered in Virginia, and a reasonable implementation date to allow current training programs to be accredited and to meet Board standards. Accredited technician education is vital to improving pharmacy practice, and there is wide consensus from the pharmacy community that training requirements need to be established.

On May 3, 2019, the Board's Regulation Committee voted to recommend a legislative proposal that includes a requirement that to be licensed in Virginia, a pharmacy technician successfully complete a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education or other Board-approved accrediting body with substantially similar standards or federal services pharmacy technician training program. The Regulation Committee also requested that staff provide language authorizing issuance of a pharmacy technician registration to an out-of-state applicant through credentialing as detailed in regulation which could specify a minimum number of years of experience practicing as a pharmacy technician combined with national certification.

We support conceptually certain aspects of the Regulation Committee's recommendation. It requires completion of an accredited training program, sets forth a clear benchmark of minimum entry-level accreditation standards, provides for multiple accrediting bodies, recognizes federal training programs, and contemplates out-of-state technicians. We note that many of the major chain pharmacies in Virginia already offer accredited training programs to their pharmacy technician employees.

However, we strongly suggest that the Board consider legislation that empowers the Board to determine accreditation standards through Board action rather than in statute. VSHP and VPhA also acknowledge the concerns that some pharmacy stakeholders have expressed with specific aspects of the legislative proposal presented at the March 26, 2019 Board meeting and the adopted recommendation of the Regulation Committee at the May 3 meeting. We understand these concerns and the need to balance training standards with flexibility.

We respectfully suggest the following amendments to § 54.1-3321, based on legislative proposal Option #2 in the Regulation Committee's May 3 meeting agenda packet (pp. 98-100):

VIRGINIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
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VPhA
VIRGINIA PHARMACISTS ASSOCIATION

C. To be registered as a pharmacy technician, a person shall submit to the Board: (i) an application and fee established in regulation to obtain a pharmacy technician registration, (ii) satisfactory evidence that he successfully completed a training program that is either (1) an accredited training program that meets the accreditation standards approved by the Board, or (2) operated through a federal agency or the Virginia Department of Education and (iii) satisfactory evidence that he successfully passed a national examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association.

Additionally, the Board should include provisions to grandfather current licensees and enrolled trainees, and delay implementation in order to allow a reasonable timeframe for current training programs to adjust if necessary.

The suggested language, a version of which was sent to the Regulation Committee in a letter dated May 2, 2019, accomplishes the goals of requiring completion of either an accredited training program or a widely accepted federal- or state-provided program, allowing the Board to determine accreditation standards, and avoiding overly specific or restrictive accreditation or training standards in the Code of Virginia.

VSHP and VPhA emphasize that the role of pharmacy technicians has continued to be leveraged beyond traditional dispensing to support pharmacists in a diversity of settings. These roles include but are not limited to: prior authorizations specialists, sterile and non-sterile compounding, medication histories, informatics, pharmacy purchasers, tech-check-tech models, medication access advocates, controlled substance diversion, and soon in pharmaceutical processors.

The legislative proposal allows for ensuring that minimum competencies prepare technicians for standardized technician qualifications and encourages the opportunity to build upon a core foundation of knowledge and skills to move into more advanced roles within the career field. Additionally, the proposed language meets public expectations ensuring that technicians have received the proper education and training. All pharmacy stakeholders want to guarantee the utmost safety in the preparation and dispensing of medications.

We urge the Board to consider the value that technician education will play in the greater goal of allowing pharmacists and technicians to practice to the full extent of their education and training in order to help patients live healthier lives. Please support requiring that pharmacy technicians complete an accredited training program or a federal/state training program.

We look forward to working with the Board and stakeholders on this issue. Thank you for your consideration.

Sincerely,

Cindy Williams, BS Pharm, FASHP
President, VSHP

Christina Barrille
Executive Director, VPhA

Board of Pharmacy
Chart of Regulatory Actions as of May 8, 2019

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *Register Date: 10/29/18* [Stage 8346] Board to adopt proposed 6/5/19
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed – *Register Date: 5/27/19* *Comment until 7/26/19* *Public hearing: 6/5/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *At DPB for 7 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for pharmacy to be operational within 90 days [Action 5080] Fast-Track - *At Secretary's Office for 51 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Amending definition of "cold" [Action 5210] Fast-Track - *At Governor's Office for 24 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 350 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Final – *Effective: 6/2619*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling chemicals in Schedule I [Action 5261] Final – *Effective: 6/26/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 15 and 21 [Action 4538] Final - *At Secretary's office for 3 days*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *At DPB for 6 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Proposed - *Register Date: 3/18/19* Comment from: 3/18/19 to 5/17/19 Board to adopt final regulations – 6/5/19

Board of Pharmacy
Regulatory/Policy Actions – 2019 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB2559	Waiver for electronic prescribing	Medicine Nursing Dentistry Optometry	6/13/19 or 8/2/19 7/16/19 6/21/19 6/28/19 (signed 3/21)	**12/24/19**
SB1719	Registration of agents/wholesale distribution of oils	Pharmacy	Amend final once effective (signed 3/21)	**12/24/19**

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1803	Chemicals/drugs in CI & CII	Pharmacy	6/5/19	8/7/19
SB1557	Registration of NP and PA; dosage limitations	Pharmacy	Amend final once effective	

NON-REGULATORY ACTIONS

Legislative source	Affected agency	Action needed	Due date
HB2158	Pharmacy	Revision of protocol – guidance document	6/5/19
HB2557	Department – PMP	Change in reporting requirements; publication on websites	7/1/19
SB1289	Department/Enforcement	Procedures for putting drugs under seal or seizure	7/1/19
SB1516	PMP	Revision of procedures on disclosure; registration of DOC investigators	7/1/19
SB1557	Medicine/Pharmacy/Department	Inclusion of NPs and PAs for registration to issue certifications Participation in workgroup to study oversight organization	7/1/19
SB1557	Pharmacy/Department	Participation in workgroup to study oversight organization	11/1/19
SB1632	Pharmacy	Development of standardized form for certification with DOE	7/1/19
SB1452 (not passed)	Pharmacy (Department)	Study of limited permit for non-profit to dispense certain drugs	11/1/19
Budget bill	Pharmacy (Department)	Report to JCHC on efforts to promote drug disposal	11/1/19
Letter from Del. Hodges	Pharmacy	Outsourcing/compounding for hospital systems	11/1/19

HJ662: Directs the Joint Commission on Health Care to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements, standing orders, and statewide protocols in the Commonwealth, including a review of the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in accordance with laws and regulations.

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

MEMORANDUM

TO: Members, Board of Pharmacy

FROM: David E. Brown, D.C.

DATE: May 13, 2019

SUBJECT: Revenue and Expenditure Analysis

Virginia law requires that an analysis of revenues and expenditures of each regulatory board be conducted at least biennially. If revenues and expenditures for a given board are more than 10% apart, the Board is required by law to adjust fees so that the fees are sufficient, but not excessive, to cover expenses. The adjustment can be either an increase or decrease.

The Board of Pharmacy ended the 2016 - 2018 biennium (July 1, 2016, through June 30, 2018) with a cash balance of $2,191,669. Current projections indicate that expenditures for the 2016 - 2018 biennium (July 1, 2016, through June 30, 2018) will exceed revenue by approximately $2,232,813. When combined with the Board's $2,191,669 cash balance as of June 30, 2018, the Board of Pharmacy projected cash balance on June 30, 2020, is ($133,144).

As you are aware, the board has pending regulations to increase fees therefore we recommend no additional action to change license fees be taken at this time. Please note that these projections are based on internal agency assumptions and are, subject to change based on actions by the Governor, the General Assembly and other state agencies.

We are grateful for continued support and cooperation as we work together managing the fiscal affairs of the Board and the Department.

Please do not hesitate to call me if you have questions.

cc: Caroline Juran, Executive Director
Lisa R. Hahn, Chief Operating Officer
Charles E. Giles, Budget Manager
Elaine Yeatts, Senior Policy Analyst

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

Enclosed:

Copy of NOIRA announcement resulting from petition submitted by Mr. Lavino from CVS Health

Copy of comment on NOIRA

Proposed amendment to section 275

Board action:

1) Adopt proposed amendment as recommended by the Regulation Committee or
2) Revise proposed amendment.

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Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action: Delivery of dispensed prescriptions; labeling

Notice of Intended Regulatory Action (NOIRA)

Action 5093 / Stage 8346

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Preliminary Draft Text	None submitted	Sync Text with RIS
Agency Statement	7/17/2018	Upload / Replace
Governor's Review Memo	10/4/2018	
Registrar Transmittal	10/4/2018	

Status	
Public Hearing	Will be held at the **proposed** stage
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
DPB Review	Submitted on 7/17/2018 Policy Analyst: Cari Corr Review Completed: 7/27/2018 *DPB's policy memo is "Governor's Confidential Working Papers"*
Governor's Review	Review Completed: 10/4/2018 Result: Approved
Virginia Registrar	Submitted on 10/4/2018 **The Virginia Register of Regulations** Publication Date: 10/29/2018 **Volume: 35 Issue: 5**
Comment Period	**Ended 11/28/2018** **1 comments**

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, VA 23233-1463

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Agency Department of Health Professions

Board Board of Pharmacy

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

Action	**Delivery of dispensed prescriptions; labeling**
Stage	**NOIRA**
Comment Period	Ends 11/28/2018

Back to List of Comments

Commenter: Otto Wachsmann 11/28/18 7:39 pm

Label requirements for pharmacy address and phone number on the label.

Personally and professionally, I believe the label should clearly indicate both Pharmacy's names and phone numbers so patients and their healthcare providers may access appropriate information when necessary. At least one major mail order provider (not CVS) lists the phone number for the patient call center on their label and not the address of the pharmacy. When calling for information about the prescription using the number on the bottle one calls the number, they can spend several minutes providing the prescription and patient information to an automated system. Then a customer service agent gets on the line where the same information is verified, then it is transferred to the pharmacy and a pharmacy technician even in another state re-verifies the prescription and then it is forwarded to a pharmacist where it is verified again. This can take 15 minutes which is an awful lot of time when a healthcare provider needs to tend to other patients. It is also very confusing to the patient. Shouldn't they have control over who fills their prescriptions and be able to address them directly? Shouldn't both pharmacies be listed so there is no question to the patient what is going on here? What does a patient do when they have two prescriptions picked up at their local pharmacy and for whatever reason those prescriptions were filled remotely at two different central fill pharmacies for that local pharmacy? Yes, having both names on the label can be confusing to the patient but the patient didn't create this confusion. Many of these regulations were initially created for the patient's benefit. It needs to be clear to the patient who and where their prescription is being filled and how to contact their pharmacist directly for questions.

Project 5715 - NOIRA

BOARD OF PHARMACY

Delivery of dispensed prescriptions; labeling

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

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

B. Delivery to another pharmacy.

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

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

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

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

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

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription. 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 for assuring confidentiality of patient information; and

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

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device 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.

Agenda Item: **Final Action – Regulations for Pharmaceutical Processors**

Enclosed:

Copy of Townhall notice

Copy of minutes of public hearing on proposed regulations – 3/26/19

Copies of comments on proposed regulations

Changes recommended by the Regulation Committee

Staff note:

Emergency regulations expire on August 8, 2019. In order to prevent a gap in regulation, the final action must be submitted to the Registrar by noon on June 19, 2019.

Committee action:

1) Adopt final amendments as recommended by the Regulation Committee; or

2) Revise amendments with additional changes.

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Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing Pharmaceutical Processors [18 VAC 110 - 60]**

Action: New regulations

Proposed Stage

Action 4695 / Stage 8484

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	3/8/2019 9:48 am	Sync Text with RIS
Agency Statement	12/3/2018 (modified 3/4/2019)	Upload / Replace
Attorney General Certification	1/17/2019	
DPB Economic Impact Analysis	2/20/2019	
Agency Response to EIA	2/21/2019	Upload / Replace
Governor's Review Memo	2/27/2019	
Registrar Transmittal	2/27/2019	

Status	
Changes to Text	The proposed text has changed from that of the **emergency stage**.
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 12/3/2018 Review Completed: 1/17/2019 Result: Certified
DPB Review	Submitted on 1/17/2019 Economist: Oscar Ozfidan Policy Analyst: Melanie West Review Completed: 2/20/2019 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 2/22/2019
Governor's Review	Review Completed: 2/27/2019 Result: Approved
Virginia Registrar	Submitted on 2/27/2019 **The Virginia Register of Regulations**

	Publication Date: 3/18/2019 **Volume: 35 Issue: 15**
Public Hearings	**03/26/2019 9:10 AM**
Comment Period	**In Progress!** **Ends 5/17/2019** **Currently 0 comments**

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This person is the primary contact for this board.
This stage was created by Elaine J. Yeatts on 12/03/2018
12

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARINGS FOR PHARMACEUTICAL PROCESSOR REGULATIONS AND TO SCHEDULE CERTAIN CHEMICALS IN SCHEDULE I

March 26, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The public hearings were called to order at 9:10 a.m.

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT: James L. Jenkins, Jr.

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

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

A powerful synthetic opioid:

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

Research chemicals:

- alpha-pyrrolidinoisohexiophenone (other name: alpha-

PiHP)
- 1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP)

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

PULIC COMMENT:

Scott May, Chemistry Program Manager with the Department of Forensic Science provided information on the 3 chemicals the department has identified for the Board's consideration to place into Schedule I.

No other comment on this subject was provided.

CALL FOR PUBLIC COMMENT:

Mr. Saenz then call for public comment on the proposed regulations for pharmaceutical processors. Copies of the proposed regulations were provided to the board members and on the back table for the public.

PUBLIC COMMENT:

Caley Crawford, with Virginia Medical Cannabis Coalition which represents the five pharmaceutical processors, offered comment that their mission is to ensure all laws and regulations are aligned with the goal of patient safety. Ms. Crawford commended the board and added that she is pleased with the passage of SB 1557 and SB 1719 that increases access, formulations, and labeling, and offered to serve as a resource to the board.

Aaron Lopez, representing Dalitso, made comment asking the board to remain vigilant in the unregulated sales of over-the-counter CBD products. He offered that the unregulated sale of CBD is confusing to the public and that the CBD suppliers are not being held accountable to the same standards as the pharmaceutical processors.

Jean Michelle Pedini, Executive Director of Virginia NORML thanked the board for allowing Virginians to access CBD. She expressed concern over unregulated products, patient safety, access, and affordability.

Dylan Bishop, Virginia Cannabis Association, offered support to the board.

ADJOURN:

The public hearing adjourned at 9:25am.

Rafael Saenz, Chairman

Caroline D. Juran, Executive Director

Date

Date

Board of Pharmacy

Summary of Public Comment on Regulations

18VAC110-60-10 et seq. Regulations Governing Pharmaceutical Processors

Proposed regulations to replace emergency regulations were published on March 18, 2019 with comment requested until May 17, 2019. A public hearing was conducted on March 26, 2019.

The following comment was received at the public hearing:

Commenters	Comment
Caley Crawford Va. Medical Cannabis Coalition	Pleased with the passage of legislation in 2019 and offered to be a resource for the Board.
Aaron Lopez Dalitso	Asked the Board to remain vigilant in the unregulated sales of over-the-counter CBD products; not accountable to same standards as the pharmaceutical processors.
Jean Michell Pedini, Virginia NORML	Thanked the Board for allowing Virginians access to CBD and expressed concern about unregulated products, patient safety, access, and affordability.
Dylan Bishop Va. Cannabis Association	Offered support of his organization to the Board

The following comments were received by hard copy, email or posted on the Virginia Regulatory Townhall:

Commenters	Comment
Regina Whitsett SAFE Executive Director	Expressed position of SAFE in opposition to growing marijuana and setting up dispensaries for cannabidiol oil and THC-A oil. Concern that Board's regulations will further open the door to marijuana legalization in Virginia.
Mary Crozier Community Coalitions of Virginia	Same comments as those of SAFE.
Virginia Medical Cannabis Coalition Katie Hellebush	Requested that changes enacted by the 2019 General Assembly (SB1556 and SB1719) be included in adoption of final regulations, including allowing patients to designate one or more registered agents, allowing pharmaceutical processors more flexibility in hiring employees, allowing transfer and wholesale distribution of CBD or THC-A products between processors, and allowing cannabis to grown earlier than two weeks from opening the facility. The comment also requested an amendment to clarify that the concentration of THC in any THC-A oil may be up to 10 percent greater or less than the level of THC measured for labeling.
Virginia NORML Jean Michelle Pedini	Recommended testing regulations as outlined in Colorado for medical Cannabis products

	Recommended elimination of prohibition of telemedicine for first year after certification. Requested reduction of the $50 fee for patient registration; recommended eliminating or reducing cost for patient, caregiver and registered agent registration. Recommended the Board allow a patient to have at least two registered agents and that agents be allowed to serve a maximum of four individual patients with a higher number for patients in health care/residential facilities.
Cannabis Business Association of Virginia, Stephen Baril	Asked the Board to consider expansion of the supply channels and an increase in the number of growers, processors and retailers in Virginia. Requested that the Board remove the prohibition of using telemedicine for the first year of certifying a patient for the use of cannabidiol or THC-A oil Recommended post-production testing of the cannabidiol or THC-A oil rather than testing of the cannabis plant before it is processed into a product for human consumption. Made specific recommendations for accreditation and registration of laboratories and for the standards used in testing samples of the product.
Political Capital Aaron Lopez, Representative for Dalitso	Requested that 2019 legislative changes be incorporated into the final regulations. Additionally, comments were made in the following sections: 10 – Definitions: Amend "ninety-day supply" to clarify that solid dosage forms are allowed. Definition of resident should allow individuals who live out-of-state but have responsibility for a patient in Virginia to be registered as an agent. 20 – Fees: Practitioner fee should be a one-time fee or a nominal renewal fee. Patient fee should be reduced for renewal. Asked that registration of a product be confined to a listing of products produced every six months, rather than a registration of each one. 40 – Prohibition on financial benefit by practitioner: would like allowance for recommendation of a particular product. 50 – Registration: allow registration of persons out-of-state. Would like clarification of board's authority to deny registration and whether there is an exception for a person who needs the product. 130 – Granting of processor permit: Need to further define word "agent" to be clear the criminal background check refers to the delivery agent of the processor. 170 – Processor employee license and registration: Recommended only allowing the dispensing area to handle the labeling of patient information; allow only for handling of finished products in the dispensing portion of the facility. 190 – Pharmacy technician: Remove "production" as a job function to avoid confusion. Allow technician to contact prescriber for clarification.

	220 – Processor prohibitions: Further define the term "facility." Allow for sale of products relating to the oils. 280 – Cultivation and production: Requirements for testing should apply to all processing in-state and also to out-of-state products sold in Virginia. Asked by registration of individual products and turn around time for approval. 290 – Labeling: Regulations should apply to all consumable CBD and THC-A products. 295 – Labeling: Asked whether each product has to have a separate batch label and patient label; asked what a practitioner is able to recommend in terms of dosing, active amounts, number of doses, etc. 300 – Laboratory testing: Requirements should apply to all producers, in-state or out-of-state 330 – Disposal of CBD and THC-A: Asked clarification of who in the processing facility is allowed to disposal
Virginia Cannabis Industry Association Rebecca Gwilt	Requested testing regulations similar to Colorado with specific lists of prohibited substances, guidelines for batching and testing, and a framework for certifying laboratories. Requested a reduction or elimination of registration fees for patients Requested allowing telemedicine by practitioner for certification Requested an enhancement of the role of a registered agent, such as allowing a licensed healthcare or residential facility to serve as registered agent for its residents/patients.

The Board will consider the comments and staff recommendations prior to adoption of final regulations on June 5, 2019.

VIRGINIA MEDICAL CANNABIS COALITION

Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463
Via email: pharmbd@dhp.virginia.gov

April 30, 2019

Dear Mr. Chair and Members of the Board,

The Virginia Medical Cannabis Coalition (VMCC) wants to thank you again for all your hard work as the Commonwealth moves forward with its medical cannabis program in 2019. VMCC is a nonprofit consortium of the five processors awarded the right to manufacture medical CBD and THC-A oil exclusively for medical use across the Commonwealth.

VMCC offers these public comments requesting that changes enacted by the Governor and General Assembly during the 2019 General Assembly Session be included in the final regulations governing pharmaceutical processors. Delaying any of these regulatory changes will be challenging for patients, providers, caregivers and processors and will likely result in higher costs and less access for patients.

As enacted, SB1719 made changes to Virginia's pharmaceutical processor program, which establishes registered patient agents, creates more opportunities in hiring practices, allows for wholesale distribution between processors, allows for more accurate start-up production time, and clarifies labeling standards.

Below please find VMCC's comments on each of these changes made under SB1719.

1. Allow patients to designate one or more registered agents that may receive, in place of the patient, their CBD or THC-A products from a facility or by a facility's delivery agent.

· 18VAC110-60-310 allows only the patient, parent, or legal guardian to pick-up or receive the product. This is an issue for someone that utilizes a caregiver or helper that is not necessarily a legal guardian. Currently regulations do not even allow a spouse or relative to pick-up or receive the product, a significant departure from current pharmacy allowances.

· VMCC believes that registered agents will provide better access to patients that otherwise may have difficulties physically picking up or receiving the product. Creating the registered agent will allow those unable to pick up or receive the product in person to still obtain their CBD-THC-A oil initially at a facility or subsequently through a delivery agent.

· Additionally, we believe that patients should be able to designate more than one registered agent should they choose. For example, an older patient may want to designate their caregiver(s) and their

two children as registered agents. Severely limiting the patient's ability to designate caregivers is limiting their access to this product.

· VMCC supports regulating the number of patients per registered agent and does not envision registered agents taking the place of pharmaceutical processor delivery drivers.

2. Allow pharmaceutical processors more flexibility in the hiring of employees

· 18VAC110-60-170 requires at a minimum two years of experience as a pharmacy technician, a degree in horticulture, chemistry or pharmacology, or two years of prior experience in cultivation or extraction in order to work certain functions and does not allow for on-the-job training to gain this experience. VMCC believes that such requirements would make it nearly impossible for processors to hire local people to do jobs that certainly do not require degrees or expertise and supports the changes made via SB1719.

· In addition to other employees authorized by the Board, SB1719 allows a pharmaceutical processor to 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.

· VMCC Members look forward to hiring local employees in their facilities. The changes made by SB1719 to provide greater flexibility will ensure that pharmaceutical processors are staffed with highly qualified professionals while allowing other employees new to the field to gain on-the-job training and experience in a new industry in the Commonwealth.

· VMCC believes updating the regulations now to reflect these changes is imperative to pharmaceutical processors as they look to begin staffing their facilities in 2019. Should the Board wait to change the regulations until next year, the pharmaceutical processors will be forced to change their hiring practices after-the-fact instead of allowing them to be proactive in finding local talent as they prepare to open their doors.

3. Allow for the wholesale distribution and transfer of CBD or THC-A products between pharmaceutical processors.

· 18VAC110-60-220 prohibits the sale, delivery, transportation or distribution of products between facilities. Conceptually, this was designed as a security and compliance measure, but when viewed as a business model, the restriction against wholesale commerce makes no sense for patients and regulators alike. It's challenging to envision a pharmacy delivering a particular products hours and hours across the state to a single patient. Allowing the processors to buy and sell products helps spread a variety of medications and dosage forms to the patients of Virginia.

This change is necessary in order to provide patients a better range of product formulations while keeping costs affordable.

- VMCC has the following comments on wholesaling of product:

  - Wholesaling should be an option for each of the pharmaceutical processors but should not be required.

  - Transfer and wholesale should be of finished product—not plants.

  - "Processors should not be required to maintain a certain percent of processor stock products vs. wholesale or transfer products from the other licensed facilities. Stock percentage requirements would limit a processor's ability to provide a full array of products to patients thus limiting their access to specifically beneficial formulations."

  - Any pharmaceutical processor can enter into agreement with any of the other pharmaceutical processors for wholesaling and transfer of products. No limitations should be placed on the number of processors one can transfer with.

  - The system should operate like a normal business where if a pharmaceutical processor wants to work with another processor, they generate purchase orders and invoices as is standard practice in wholesaling businesses.

  - Product must be moved between facilities by the processor companies themselves and cannot be moved by a third-party contractor—the same as currently required for delivery.

4. Allow cultivation of Cannabis to begin upon an issued permit by the Board.

- 18-VAC110-60-30(G) does not adequately account for the time it takes to cultivate a plant prior to initially opening the facility.

- This change is imperative to make to the regulations now rather than later. Currently only 2 weeks are permitted to go from seed to shelf, an impossible feat for processors. VMCC asks the Board to please include this change in the regulation changes underway at this time. Delaying this change will make cultivation deadlines unwieldy as start-up begins in 2019.

5. Clarify that the concentration of THC in any THC-A oil may be up to 10 percent greater than or less than the level of THC measured for labeling.

- 18VAC110-60-285 requires all active ingredients fall within a range of 97% to 103% for identical labeling, whereas it should read 90% to 110%.

- This change is already allowed in the law and, as a result, this is a technical change to ensure the Code is applied correctly in the regulations.

- VMCC supports this clarification as processors were concerned with the nearly impossible standard (far stricter than any in the pharmaceutical field) being set in current labeling requirements.

VMCC appreciates the work the Board of Pharmacy is doing to ensure a successful pharmaceutical processor program. We hope that you will consider our comments in your evaluation of the regulations.

If you have any questions, please feel free to reach to Katie Hellebush, Executive Director of the Virginia Medical Cannabis Coalition.

Thank you for your time and consideration.

Sincerely,

Katie Hellebush

Katie Hellebush
Executive Director

Cannabis Business Association of Virginia

Public Comment to Board of Pharmacy RE: Pharmaceutical Processors

May 1, 2019

The following comments are offered on behalf of the Cannabis Business Association of Virginia (CBAV), a 501(c)(6) industry/trade association formed to advocate for the expansion and protection of existing pharmaceutical, retail, and agricultural cannabis markets to ensure the highest quality, safest and compliant products and services are readily accessible to consumers in Virginia.

Telemedicine

The proposed regulations under 18VAC110-60-30 requires that a "practitioner issuing a certification shall... 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"* (18VAC110-60-30(B), emphasis added). And, 18VAC110-60-30(C) states that "Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation." Hence, under these proposed regulations, a practitioner not only has to conduct an in-person physical examination of a patient prior to issuing a certification, but has to continue to see that patient in-person for at least a year before that practitioner can treat that patient via telemedicine, even if that practitioner's professional judgment would allow him to do so earlier otherwise.

CBAV asserts that there is no justifiable reason to support a prolonged delay in a practitioner's ability to use his professional judgment to determine the manner and frequency of patient care and evaluation, including the use of telemedicine. As such, the **CBAV respectfully requests that the Board of Pharmacy (BoP) remove the provision prohibiting a practitioner from using telemedicine for both the initial consultation prior to issuing a certification and "for at least the first year after certification."**

If, however, the BoP is insistent that an in-person visit must be required before a certification is issued, the **CBAV would ask that the BoP still consider removing the moratorium on the practitioner's use of "telemedicine for at least the first year of certification"** as stated in the proposed 18VAC110-60-30(C), as the initial in-person consultation ought to be enough to alleviate the BoP's concerns.

Laboratory Requirements; Testing

With regards to the laboratory testing requirements for pharmaceutical processors proposed by the BoP, CBAV would like to point out that the proposed regulations require the cannabis plant material to be tested *before* it is processed into a product for human consumption, but there is no requirement to test the product once it is processed and ready for human consumption. **CBAV recommends that the regulations require post-production laboratory testing of the products** to ensure that patients are indeed receiving precise dosages.

The proposed regulations under 18VAC110-60-30 also contain to requirement that a pharmaceutical processor utilize a laboratory to handle, test, or analyze cannabidiol oil or THC-A oil that is accredited or registered with the BoP or Virginia's Division of Consolidated Laboratory Services (DCLS), which is responsible for certifying and accrediting laboratories to ensure compliance with federal and state regulations meant to protect public health and the environment. **CBAV suggests requiring that all such labs used by pharmaceutical processors be accredited and so registered.**

As such, CBAV recommends the following changes with regard to 18VAC110-60-300:

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

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

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has registered with the Board of Pharmacy or Virginia's Division of Consolidated Laboratory Services (DCLA), which is responsible for certifying and accrediting laboratories to ensure compliance with federal and state regulations meant to protect the public's health and the environment.

A. To register, an independent laboratory shall:

(1) Submit a completed independent laboratory registration form;

(2) Submit a copy of the certificate of accreditation accompanied by the scope of accreditation

B. A provisional registration may be issued to an independent testing laboratory that has not yet been issued a certificate of accreditation in Virginia if the independent testing laboratory:

(1) Submits a completed independent laboratory registration form;

(2) Submits a copy of the contract with the accreditation body applying to become accredited accompanied by a copy of the proposed scope of the accreditation;

Terms Defined:

(1) "Accreditation body" means a nonprofit, impartial organization that requires conformance to 17025 ISO/IEC requirements and is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement for Testing.

(2) "Certificate of accreditation" means a certificate issued by an accrediting body for the independent testing laboratory facility, entity or site to be registered in Maryland.

(3) "Scope of accreditation" means a document issued by the accreditation body which describes the methodologies, range, and parameters for testing medical cannabis or products containing medical cannabis for which the accreditation has been granted.

~~B. Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches. A pharmaceutical processor shall make a sample available from each batch for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue and (ii) conduct an active ingredient analysis.~~

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

~~D. Under no circumstances shall a pharmaceutical processor include Cannabis in a cannabidiol oil or THC-A oil product or sell it prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.~~

~~F. If a sample of Cannabis does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.~~

B. After processing and before dispensing the cannabidiol oil or THC-A oil product to patients, a pharmaceutical processor shall take a representative sample from each batch for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue and residual solvents and (ii) conduct an active ingredients analysis.

Terms Defined:

(1) A batch is defined as a quantity of cannabidiol oil or THC-A oil from a production lot that is identified by a batch number or other unique identifier.
(2) A representative sample is one that is stable, homogeneous, and representative of the batch from which it is taken where steps were taken to minimize sampling error.

C. Under no circumstances shall a pharmaceutical processor dispense or sell cannabidiol oil or THC-A oil 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.

D. The processor shall require the laboratory to immediately return or properly dispose of any Cannabis products and materials upon the completion of any testing, use, or research.

E. If a sample of the cannabidiol oil or THC-A oil product does not pass microbiological contaminants, mycotoxins, heavy metals, and/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.

F. If a sample of the cannabidiol oil or THC-A oil product does not pass the residual solvents test based on the standards set forth in this subsection, the batch can be remediated with further processing. After further processing, the batch must be retested (i) for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue and residual solvents and (ii) to conduct an active ingredients analysis.

1. For purposes of the microbiological test, a ~~Cannabis~~ sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a ~~Cannabis~~ sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance

Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a ~~Cannabis~~ sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Note: The standards and limits are based on the limits recommended in the American Herbal Pharmacopia for Cannabis Inflorescence.

Metal	~~Natural Health Products Acceptable Limits ug/kg body weight/Day~~ Limit, ug/daily dose
Arsenic	~~<0.14~~ 10
Cadmium	~~<0.09~~ 4.1
Lead	~~<0.29~~ 6.0
Mercury	~~<0.29~~ 2.0

4. For purposes of the pesticide chemical residue test, a ~~Cannabis~~ sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if ~~it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.~~

*The list of pesticide chemical residue that may be found 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 has over 400 pesticides, some of which are not relevant to the cannabis industry or Virginia. As well, the tolerance level for those pesticides depends on the food product that is being tested, where cannabis and products that contain cannabis are not include on the list. It is recommended that the State of Virginia follow the method outlined in the "Technical Report: Oregon Health Authority's Process to Determine Which Types of Contaminants To Test For in Cannabis Products and Levels for Action". https://www.oregon.gov/oha/PH/PreventionWellness/marijuana/Documents/oha-8964-technical-report-marijuana-contaminant-testing.pdf

This method looks at pesticides commonly used in cannabis production as well as pesticides commonly used in their region and ranks a comprehensive list by general toxicity, analytical capabilities, detection frequency, and availability of the pesticide to determine a list of 60 pesticide analytes that should be tested and their detection limits. In the interim, the list of 18 pesticides found in the American Herbal Pharmacopia for Cannabis Inflorescence that are commonly used in cannabis cultivation can be used:

Pesticides Commonly Used in Cannabis Cultivation
Abamectin (Avermectins B1a and B1b)
Acequinocyl
Bifenazate
Bifenthrin (synthetic pyrethroid)
Chlormequat chloride
Cyfluthrin (synthetic pyrethroid)
Daminozide (Alar)

Etoxazole
Fenoxycarb
Imazalil
Imidacloprid
Myclobutanil
Paclobutrazol
Pyrethrins
Spinosad
Spiromesifen
Spirotetramat
Trifloxystrobin

5. For purposes of the residual solvents test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Note: The standards and limits are based on the limits recommended in the American Herbal Pharmacopia for Cannabis Inflorescence.

Solvent	ppm
Acetone	5000
Benzene	2
Butanes	5000
Cyclohexanes	3880
Cloroform	2
Dichloromethane	600
Ethyl Acetate	5000
Heptanes	5000
Hexanes	290
Isopropanol	5000
Methanol	3000
Pentanes	5000
Propane	5000
Toluene	890
Xylene	2170

6. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for THC, THC-A, CBD, CBD-A and reported on a dry weight basis.

G. If a sample of Cannabis passes the microbiological contaminants, mycotoxins, heavy metals, pesticide chemical residue and residual solvents tests, the entire batch may be utilized by the processor for immediate ~~manufacturing,~~ packaging, and labeling for sale.

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, ~~or~~ pesticide chemical residue, or residual solvent test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians and registered practitioners who have certified qualifying patients.

Resources used for developing recommendations:

- Upton, Roy, et al. *Cannabis Inflorescence: Cannabis SPP.: Standards of Identity, Analysis, and Quality Control.* American Herbal Phamacopia, 2014
- Section 1111 of the United States Pharmacopeia. Microbiological Examination of Non-Sterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use General Chapter
- Farrer, DG. *Technical report: Oregon Health Authority's process to decide which types of contaminants to test for in cannabis.* Oregon Health Authority. 2015 December.
- The regulations and laboratory testing requirements for the states or Oregon, Washington, Illinois, and Maryland were heavily referenced.

POLITICAL CAPITAL
Policy Advocates and Government Affairs

To: Caroline Juran, Executive Director
Cindy Warriner, Committee Chairman
Perimeter Center
9960 Mayland Dr
Second Floor
Henrico, VA 23233

May 2, 2019

Re: Current Emergency Regulations for Pharmaceutical Processors

We would like to thank the Virginia Board of Pharmacy (the Board) for the opportunity to comment on the "Current Emergency Regulations pertaining to Pharmaceutical Processors." We appreciate the time and effort the Board put into these regulations and hope to add to it with the following comments.

We recognize that these regulations do not take into consideration the recent changes made to the statute which have a direct impact on a several sections. Therefore, we strongly recommend making those revisions before finalizing these regulations as they would have an impact on the processors starting day one of operations and will affect patient access before doors are opened. We try to point out some of those areas that need to reflect statute changes. We might not have highlighted all the changes and would like to be able to have an open dialog with the Board in the future to discuss those changes.

Comments:

1. **Definitions (110-60-10)**

Ninety-day Supply
The current definition allows for liquid and semi-liquid dosages, however what is not clear are the allowable amounts for solid dosage forms. We would like to see this definition reflect solid dosage forms and the expectation from the Board on what the dosage amounts might look like. Or make it clear in the regulations that Ninety-day supply for solid dosage forms are allowed.

Production/Produce
The application of the production/produce definition will be problematic moving forward. The current definition applies to just about every employee who will work for a processor. The three departments of a Virginia processor should be defined separately (Dispensing, Processing, Cultivation). Further into the regulations there is a discussion around supervision, every employee is considered a pharmacy technician and will require a pharmacist's supervision. Recent changes to the statute allow for "authorized personnel" which will impact this definition and the later discussion. For example, a horticulturalist may supervise the cultivation employees, a chemical engineer may supervise the processing employees, and a pharmacist will supervise the dispensing. See section 110-60-190.

Resident
We would request the Board allow for those individuals who have a responsibility to a citizen of the Commonwealth but who live outside the state. Such as those individuals who have ailing/elderly parents within the Commonwealth that are unable to procure our services for themselves. Those individuals, even though they live outside the state should have access to register as an Agent for their ailing/elderly parents, at least under special circumstances and after a review by the Board.

2. **Fees (110-60-20)**

Practitioner
The fees for a practitioner should be either a one-time fee or at a nominal renewal fee if the practitioner remains in good standing with the Board and has no changes to their certification. The fees would only serve as a deterrent to the practitioner since there is no financial gain from their recommendation of the use of CBD or THC-A.

Patient
The fees a patient must pay should be reduced for renewal as to only reflect the actual cost for the processing of their renewal or change of information.

Processor
The Board has asked that each CBD/THC-A product that is developed be registered with the Board. We are concerned with this request as it can lead to a delay in access for a patient and could be overly burdensome for the processor. In addition, the fees for registration for each product while minimal, should be part of the yearly registration already being asked for by the Board.

A simple requirement twice a year for each processor to file a complete list of products produced over the previous six months would be better suited for the Board to review what has been produced and dispensed. This is already being done in the reporting of Outsourcing Facilities to the Food and Drug Administration. The files will reflect each product and the ingredients used as well as quantity and dispensing amounts.

3. **Prohibition (110-60-40)**

Subsection (B)
We encourage the Board to clearly define what a practitioner may or may not do in the recommendation of the use of either CBD or THC-A. We respect the Board's clear view of no financial relationships between the practitioner and a processor, however we would like the practitioner to be able to recommend to a patient not only that they are a candidate for use of CBD/THC-A oil, but that their might be a specific product that would benefit the patient. If the practitioner has a product, that they know to be beneficial to their patients, we suggest the practitioner be able to recommend that specific product. The recent changes to the statute now allow for sale between processors, which will allow for all patients within the commonwealth access to each any recommended product.

The allowance for a specific product recommendation does not prejudice a practitioner and allows for them to have a greater impact on their patient's wellbeing.

4. Registration (110-60-50)

Recent laws passed allowed for a "registered agent" to act on behalf of a patient. We would like to see the regulation reflect that change before passage.
We also see the requirement for proof of residency again. We encourage the Board to allow for exceptions and consider those potential agents who live outside the commonwealth yet care for the need of patients within the commonwealth.

Subsection A(6)
Currently the emergency regulations state the board may deny a registration for any violation pertaining to controlled substances. We would like further clarification of this and if there is any exception for patients who desperately need access to the products from the processors.

5. Granting of Processor Permit (110-60-130)

Subsection A(2)
We understand the need for the requirement for criminal background checks for all employees, but we are unsure of the Board's term "agent" in this section. This term needs to be defined or changed. Further into the emergency regulations the board uses a term "delivery agent" and this might be what the Board is referencing here. If so the term "agent" needs to be replaced with the more specific term.

Subsection G
The time in which a processor may start growing has been changed by the legislature to 60 days prior to opening date. The regulations should reflect this change in the law.

6. Processor Employee License and Registration (110-60-170)

Subsection C(2-8)
In review of the regulations listed here it would appear that these guidelines are like those currently used in pharmacy. However, the opening and repackaging of products containing CBD, THC-A, and THC should be reviewed more strictly. We recommend only allowing the dispensing area to handle the labeling of patient information, and if different dosage amounts are needed to have those requirements met during the processing stage. This allows only for the handling of finished products in the dispensing portion of the facility.

Subsection E
Recent laws have passed that would allow for those individuals that do not have at least two years of experience in the growing, cultivation, or extraction to work for a processor under an individual who does have the experience and has been authorized by the Board. The new regulations should reflect this.

Subsection G
Recent laws have passed that would allow for the PIC to authorize certain personnel access to secured areas without the direct supervision of a pharmacist. These regulations need to reflect the new changes in the law.

7. Pharmacy Technician (110-60-190)

Subsection B(1)
This section would be better served, and less confusion would remain by removing the term "production" as a job function.

Subsection C(4)
The phrase "recommended by the practitioner" references the practitioner's ability to do more than just allow a patient to use CBD/THC-A. We feel this is a reasonable step in allowing a practitioner greater ability in management of the health of the patient.

Subsection C(5)
While current law stipulates that a pharmacy technician is not to call a practitioner's office to discuss a prescription, under these regulations the pharmacy technician should be allowed to call for clarification. Since the practitioner is not prescribing, the tech will only be confirming patient information. The pharmacists will be in consultation with the patient on the actual prescription.

8. Processor Prohibitions (110-60-220)

Subsection A(2)
The term "facility" is not clearly defined. Newly passed legislation allows for the sale between processors, but this term might be used for an associated business facility separate from a processors main processing location. We would like to see the Board further define.

Subsection B
Once again, the phrase "direct supervision" by a pharmacist is being used. Newly passed laws state that the PIC may authorize individuals to operate without direct supervision. Please review and change the stated regulation to reflect current law.

Subsection C
Current regulations state that processors are only allowed to sell CBD and THC-A oil. We would like the Board to consider allowing the processors to sell ancillary products such as:

- Pill cutter
- Extra droppers
- Gloves
- Pill dispensers
- Etc.

Subsection H
Current regulations state that a processor shall not sell, distribute or dispense CBD or THC-A oil via a delivery service. However, section 54.1-3442.7 allows for a processor to utilize a delivery service. We request the emergency regulations be changed to reflect this allowance per statute.

9. Security Requirements (110-60-240)

Subsection A(8)
Under newly passed laws, an authorized employee can access secured areas without the direct supervision of a pharmacist. Will this allow for a "Horticulturalist" or "Authorized Employee" to also have keys to areas they are assigned if they are the designated personnel?

10. Cultivation and Production (110-60-280)

Subsections A-C
These requirements for testing before processing should apply to all processing in the state and also applied to all out of state products being sold in the Commonwealth of Virginia. This is a patient safety issue and should apply across the board regardless of the origin of the product.

11. Registration of Products (110-60-285)

Subsection A
As stated before in these comments we would like to better understand the need for the individual registration of products. We also would like to know the turnaround time for approval of the products? We are concerned about patient access in a timely manner.

Subsection B
Recently passed legislation allows for products that are within a plus or minus of 10%, regarding the amount of active ingredient, to be allowed to be labeled with the same name. We request the Board reflect this change in the regulations.

12. Labeling (Batch) (110-60-290)

The labeling and record keeping of all CBD and THC-A products entering and produced in the state should carry the same responsibilities. If this is about patient safety, then the regulations should apply to all consumable CBD and THC-A products.

13. Labeling (Individual Product) (110-60-295)

Does each product need to have a separate batch label and patient label, or can they be integrated?

Subsection A(10)
The regulations are stating that a processor will need to follow the direction of a practitioner for a patient. We would like to know what a practitioner is able to recommend in terms of dosing, active amounts, number of doses a day.

14. Laboratory Testing (110-60-300)

Subsection B
The laboratory requirements should be applied to all producers in the state as well as those importing from outside of the state.

15. Dispensing CBD (110-60-310)

Subsection A(1)
Recently passed legislation includes the allowance of a "registered agent." This section should reflect current law and allow for the registration and the ability for dispensing to a registered agent.

16. Disposal of CBD and THC-A (110-60-330)

The regulations state that the disposal of these products must be done in the presence of an agent of the Board. We would like further clarification of who in the processing facility is allowed to perform this as well as does it have to be in the presence of an agent of the Board or can it be done by authorized personnel as long as there are witnesses to its disposal?

Once again, we are appreciative of the Boards wiliness to allow us to comment and for their hard work during this process. We remain available for comments and questions regarding our above comments and are willing to participate in the process to ensure a safe product for the patients and citizens of Virginia's Commonwealth.

Sincerely,

Aaron R. Lopez, JD, FCLS
Representative of Dalitso (Pharmaceutical Processor in Northern Virginia)
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POLITICAL CAPITAL
Policy Advocates and Government Affairs

To: Caroline Juran, Executive Director
Cindy Warriner, Committee Chairman
Perimeter Center
9960 Mayland Dr
Second Floor
Henrico, VA 23233

May 16, 2019

Re: Current Emergency Regulations for Pharmaceutical Processors

We would like to thank the Virginia Board of Pharmacy (the Board) for the opportunity to file follow-up comments to the "Current Emergency Regulations pertaining to Pharmaceutical Processors." We appreciate the time and effort the Board put into these regulations and hope to add to it with the following comments.

Toward the end of the Board Sub-Committee meeting we had discussed testing and would like to recommend following the regulations followed by the State of Colorado for their Medical Cannabis products.

Here is a link to Colorado regulations:
https://www.colorado.gov/pacific/sites/default/files/ColoradoRegister.pdf1%20CCR%20212%20-1%20Medical%20Effective%2002022018.pdf (also attached)

Contaminant Levels

Section (M 712) covers the Sampling and Testing Program that are very close to what was being discussed during the meeting. We recommend following their model as we feel they have found much success in providing safe guardrails for patients and processors.

Contaminant Testing Requirements and Processes

Section (M 1501 – 1507) covers Contaminant Testing requirements. Virginia law will deviate a bit from what Colorado law will allow due to the fact Virginia Processors will have to conform to Dietary Supplement cGMP (DS cGMP) levels of processing (21 CFR 111). Those areas covered by DS cGMP will supersede any area not covered by the Colorado law.

Conclusion

Our recommendation is to follow Colorado laws on sampling and testing contaminant levels and then allowing for DS cGMP to guide the processors on processes and procedures to ensure product safety.

Please let us know if you have any questions,

Aaron Lopez, JD, FCLS
Political Capital LLC
Representative for Dalitso

May 17, 2019

VIA EMAIL
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
pharmbd@dhp.virginia.gov

Dear Mr. Chair and Members of the Board of Pharmacy:

The Cannabis Business Association of Virginia (CannaBizVA) is a non-profit, trade association formed to advance legislation, regulation and implementation to support and grow Virginia's regulated cannabis industries. Accordingly, CannaBizVA offers the following comment, which prioritizes patient access to care and free enterprise.

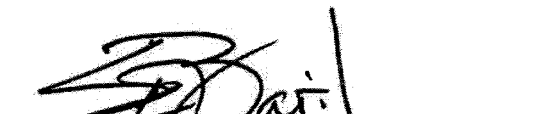
CannaBizVA respectfully requests the Board of Pharmacy consider expanding, if not outright dissolving, the government-sanctioned oligopoly currently governing Virginia's medical cannabis industry. Allowing for only one vertically integrated, seed-to-sale pharmaceutical processor in each of the Commonwealth's five geographically bound Health Service Areas functions to the detriment of Virginia's small business economy and, most importantly, patient access to care.

The regulatory framework currently in place, and again proposed through the present Notice of Proposed Rule Making, is outdated and not adequately scaled to meet anticipated patient demand. This framework and supply chain model was enacted during the 2017 General Assembly session when CBD and THC-A oil was approved only for patients with intractable epilepsy. It is estimated that around 25,000 Virginians are plagued with this ailment. CannaBizVA contends that one vertically integrated, seed-to-sale pharmaceutical processor in each of the Commonwealth's five geographically bound Health Service Areas was likely sufficient to meet the demands of 25,000 potential patients.

However, in 2018, the General Assembly passed legislation providing practitioners latitude to treat with CBD or THC-A oil *any* diagnosed condition or disease determined by the practitioner to benefit from such use, which exponentially expanded the anticipated demand for CBD & THC-A oil treatments to potentially each of Virginia's 8.5 million citizens without a coinciding expansion of supply channels. As such, the Commonwealth could very well be tasked with treating upwards of a few million patients through a system designed to serve less than 1% of that demand. The current proposal simply does not have the capacity to suit the demands soon to be placed on the system.

Further complicating patient access are the geographic limitations on the current and proposed regulatory framework. With only one pharmaceutical processor in each of the Commonwealth's vast and sprawling Health Service Areas, a qualifying medical cannabis patient living in Danville would have to drive no less than two and a half hours to the closest pharmaceutical processor in order to receive his/her medicine. This is particularly troubling when you consider that these patients are dealing with any number of ailments, spanning from chronic pain, anxiety, autism, PTSD, or intractable epilepsy, which can cause multiple seizures an hour.

An easy fix to the patient access issues of supply chain capacity and geographic barriers would be to simply open up Virginia's medical cannabis market. Allowing more growers, processors, and retailers to operate in Virginia would increase production capacity, decrease travel time, and stimulate small, local farms and businesses. CannaBizVA encourages the Board of Pharmacy to maintain current quality and security standards, but expand the number of CBD and THC-A oil suppliers, processors, and retailers operating in the Commonwealth.



Stephen E. Baril, Esq., Managing Director
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cc: Caroline Juran, RPh, Executive Director, VA Board of Pharmacy (via email)
CannaBizVA Board of Directors (via email)

Caroline Juran, Executive Director
Cindy Warriner, Committee Chairman
Perimeter Center Drive
9960 Mayland Dr.
Second Floor
Henrico, VA 23233

May 17, 2019

RE: Pharmaceutical Processor Regulations

Virginia NORML would like to thank the Virginia Board of Pharmacy (the Board) for the opportunity to submit comments for the regulations pertaining to Pharmaceutical Processors. We appreciate the time and effort the Board has put into these regulations and submit the following comments in the interest of our members and Virginia patients.

Contaminant Testing

Regarding the Board's request for contaminant testing regulations recommendations, Virginia NORML suggests those outlined by the State of Colorado for medical cannabis products. (Attached)

Telemedicine

In the interest of expanded patient access, Virginia NORML recommends eliminating the current prohibition of telemedicine "for at least the first year after certification." Because requiring practitioner registration historically decreases practitioner participation in state-regulated medical cannabis programs, allowing telemedicine for medical cannabis certifications will greatly expand program access and participation for patients while decreasing patient and practitioner costs.

Should the Board elect to continue the requirement for the initial consult to occur in-person, then Virginia NORML recommends allowing telemedicine subsequent to the initial evaluation.

Patient Registration

Virginia NORML receives dozens of calls and emails each week from registered patients and Virginians attempting to navigate the registration process. What we have repeatedly heard is that the $50 annual patient registration is particularly burdensome for some, and especially so when there are multiple registrants per household. Virginia NORML recommends eliminating or significantly reducing the cost for patient, caregiver, and registered agent registrations.

Registered Agents

Virginia NORML recommends that the Board allow a patient to appoint at minimum (2) two registered agents, and that registered agents be allowed to serve a maximum of (4) four individuals in a personal capacity. Virginia NORML recommends registered agents serving patients in assisted living, rehabilitation, hospice, and residential treatment facilities, hospitals, or other residential facilities administering healthcare services be allowed to serve a higher number of patients as deemed appropriate by the Board.

Virginia NORML thanks the Board for their continued dedication to ensuring patients safe and convenient access to affordable, pharmaceutical-grade medical cannabis products. I am available for questions regarding the above comments, and remain committed to providing insights, data, and best practices for establishing patient-focused cannabis regulation.

Respectfully,

Jenn Michelle Pedini
Executive DIrector
Virginia NORML

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May 17, 2019
Department of Health Professionals

Virginia Board of Pharmacy
9960 Mayland Drive, suite 300
Henrico, VA 23233
ATT: Ms. Caroline D. Juran, RPh, DPh
Executive Director, Virginia Board of Pharmacy
Email: Pharmbd@dhp.virginia.gov
Phone: (804) 367-4456

Re: Current Emergency Regulations pertaining to Pharmaceutical Processors

Dear Ms. Juran,

The Virginia Cannabis Industry Association (VCIA) is grateful to the Board of Pharmacy for the opportunity to share comments from Virginia's new cannabis industry participants, including ancillary service providers, physicians, and laboratory services providers, all of whom will need to work together with the Board and the current conditional permittees to ensure the success of Virginia's regulated cannabis program ("the Program"). VCIA thanks the Board for its ongoing and tireless work in developing the infrastructure upon which the Program will thrive, and we look forward to working alongside the Board in pursuit of making the Program successful, safe, and sustainable.

VCIA submits public comment regarding four specific topics covered in the final regulations and 2019 legislation taking effect July 1, each of which is addressed in detail below. These include:

- **Testing Methods for CBD and THC-A Oils to Maximize Public Safety and Minimize Cost Burden**
- **Enabling Access to Certification Through Telemedicine Consults**
- **Reducing Barriers to Access by Eliminating or Reducing Registration Fees for Patients**
- **Enhancing the Role of Registered Agent to Reduce Burden on Patients and Providers**

Testing Methods for Medical Cannabis Products to Maximize Public Safety and Minimize Cost Burden

It is VCIA's position that Virginians will be best served by leveraging the time-tested methods and standards of states that have already developed comprehensive, patient-centered testing regulations. Rigorous testing is vital to ensuring patient safety, but that rigor must be balanced against the cost of such testing. These costs are first borne by the producers, and then are passed on to consumers.

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Several states have comprehensive cannabis testing regulations, but we believe the best balance has been struck in Colorado.

Colorado's regulations[1] include: (1) a comprehensive list of prohibited adulterants, including microbials, mycotoxins, solvents, pesticides, and other chemicals, and heavy metals, (2) guidelines for batching and testing for potency and adulteration, and (3) a framework for certifying laboratories. The regulations put patient safety first and provide clarity to the industry regarding their obligations and the enforcement framework.

Reducing Barriers to Access by Eliminating or Reducing Registration Fees for Patients
(18VAC110-60-20)

Any barriers to access will affect both the ability for Virginians to obtain needed therapeutic options and the sustainability of the Program as a whole. There are significant existing barriers to patients' ability to access and afford these medications. These include stigma, transportation barriers, cost, and inability to locate a registered provider. Imposing registration fees are unnecessary additional barriers that will prevent provider and patient adoption, which could impact the sustainability of the program in its early years in particular. It is VCIA's position that physician and patient fees are burdensome and that costs should be limited to those charged to the revenue-generating industry participants. VCIA recommends that fees for annual renewal be eliminated, and that initial registration fees should be reduced significantly.

Enabling Access to Certification Through Telemedicine Consults
(18VAC110-60-30)

It is VCIA's position that excluding telemedicine consults as a means of establishing whether a patient can be certified is another barrier to access that hurts patients and threatens the sustainability of the Program. VCIA recommends the elimination of Section 18VAC110-60-30(C), which states "C. Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation."

Virginia has been a leader in the embrace of telemedicine by our hospitals, insurers, and physicians. The Virginia Board of Medicine Guidance Document 85-12,[2] which was revised in October 2018, states:

[1] https://www.colorado.gov/pacific/sites/default/files/ColoradoRegister.pdf1%20CCR%20212%20-1%20Medical%20Effective%2002022018.pdf. See §§ M1501 – 1507.

[2] https://www.dhp.virginia.gov/medicine/guidelines/85-12.pdf.

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*The Virginia Board of Medicine ("Board") recognizes that using **telemedicine services** in the delivery of medical services offers potential benefits in the provision of medical care. The appropriate application of these services **can enhance medical care by facilitating communication between practitioners, other health care providers, and their patients, prescribing medication, medication management, obtaining laboratory results, scheduling appointments, monitoring chronic conditions, providing health care information, and clarifying medical advice.***

The Board of Medicine's guidelines[3] now even allow physicians to prescribed controlled substances without having an in-person meeting with their patient. That does not mean that there is no framework in place to protect patients. Practitioners are permitted to prescribe controlled substances as long as they take appropriate steps to establish a "bona fide practitioner-patient relationship." It provides practitioners with the autonomy to decide whether a telemedicine consult is appropriate or warranted as an alternative to an in-person examination, but it also contains specific requirements, including: (1) fully verifying and authenticating the location and, to the extent possible, confirming the identity of the requesting patient; (2) disclosing and validating the practitioner's identity and applicable credential(s); (3) obtaining a medical and drug history; (4) performing or causing to be performed an appropriate examination of the patient (which can be done remotely); (5) initiating additional interventions and follow-up care, and (6) obtaining appropriate consents from requesting patients after disclosures regarding the delivery models and treatment methods or limitations, including any special informed consents regarding the use of telemedicine services.

If the Board wishes to balance patient safety and the prevention of fraud or abuse in the program, VCIA encourages the Board to adopt regulations that reflect the standards similar to those contained in Virginia Code § 54.1-3303. These requirements allow practitioners to decide whether a telemedicine consult is an appropriate method to evaluate a patient via a virtual, face-to-face, interactive, two-way, real-time communication. There is less risk to the patient in a physician certification interaction than there would be if the practitioner was actually prescribing a substance. The Program requires a second layer of protection—that is, the interaction between the patient and the pharmacist or pharmacy tech at the Pharmaceutical Process. We ask that you consider, in addition, the likely access problems for patients with mobility problems, those who are located in rural areas unlikely to have many available providers, and those with transportation challenges. For these patients, the availability of a low risk telemedicine consultation would significantly improve their access to certification.

Enhancing the Role of Registered Agent to Reduce Burden on Patients and Providers

Senate Bill 1719 "authorizes a patient or, if such patient is a minor or an incapacitated adult, such patient's parent or legal guardian to designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification." The Board is permitted to set a limit on the number of patients for whom any individual is authorized to act as a

[3] *See also* Virginia Code § 54.1-3303 (eff. 2020).

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registered agent. VCIA understands these regulations have not yet been drafted, but as these changes are in the process of being drafted, we encourage the Board to consider allowing a single person to have multiple registered agents. For instance, a patient may want his or her daughter and her spouse to be able to possess her medicine. VCIA also encourages the Board to consider the concerns of healthcare facilities and senior living organizations and facilities, who manage medications for the elderly, frail, and disabled Virginians who may not have the mental or physical ability to manage their own medications. For instance, if an assisted living facility has a resident who is a registered patient, that facility is not currently permitted to possess that resident's medication. VCIA suggests that the Board allow licensed healthcare and residential facilities to serve as registered agent for its residents/patients. VCIA recommends the Board also consider allowing healthcare providers whose jobs entail administration of medication or assistance in the administration of medication to serve as registered agents.

Thank you for your time and attention!

Rebecca E. Gwilt
Executive Director
Virginia Cannabis Industry Association
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757.846.4936

The Virginia Cannabis Industry Association's mission is to represent members' best interests to advance legislation, regulations, and implementation in support of Virginia's regulated cannabis industry. The mission includes bringing the highest quality, safest, and compliant medical cannabis products and services to consumers in Virginia to improve their quality of life, comfort, and well-being.

The Virginia Cannabis Industry Association's vision is to provide a single voice for the membership, conveying the collective interests of pharmaceutical processors, ancillary businesses, and other stakeholders in Virginia's regulated cannabis industry. The vision includes collaboration with State and Local Governments and the community to assist in education, and to build the industry in a sustainable manner in a competitive, well-regulated market which will compel our members to cultivate, manufacture, and sell the finest products available.

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing Pharmaceutical Processors [18 VAC 110 - 60]**

Action	**New regulations**
Stage	**Proposed**
Comment Period	Ends 5/17/2019

All comments for this forum

Back to List of Comments

Commenter: Regina Whitsett, SAFE Executive Director 5/17/19 2:38 pm

SAFE's Public Comment re Regulations Governing Pharmaceutical Processors

Substance Abuse Free Environment, Inc. (SAFE), is a non-profit substance abuse prevention coalition serving Chesterfield County since 1999. Our mission is to engage key community stakeholders in working together to prevent and reduce substance abuse. www.chesterfieldsafe.org

SAFE provides this public comment in response to 18VAC110-60. Regulations Governing Pharmaceutical Processors **and states:**

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.
2. The Virginia Board of Pharmacy is violating federal law by setting up marijuana growers and dispensaries. Virginia law nor the board's regulations preempt federal law.
3. CBD-THC-A-THC oils are not FDA approved medicines.
4. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
5. **Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.**
6. **FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.**
7. It is medical malpractice for physicians, physicians' assistants and nurses to provide written certification for the promotion and use of marijuana as a medicine in the form of CBD-THC-A-THC oils without FDA approval because there is not sufficient scientific evidence of the benefits and effects on patient safety.
8. It is ethically inappropriate for pharmacists to grow and dispense CBD-THC-A-THC oil without sufficient research on dosage and interactions.
9. A registered agent model for pickup and delivery of CBD-THC-A-THC oils will increase the risk of diversion and access to non-registered patients.
10. Increased access to marijuana oils may contribute to increased usage in 12-17 year olds. (The National Survey on Drug Use and Health reports, SAMHSA 2016)

11. Marijuana usage, including oils, is linked to mental illness and opioid use.
12. If the Virginia Board of Pharmacy adopts these new emergency regulations as permanent regulations, it will further open the door to marijuana legalization in Virginia. All states that have legalized marijuana began with medical marijuana.
13. Revenues collected from marijuana do not outweigh the negative impacts on public safety, public health, the workplace, academics, health, black market and natural resources.

Regina Whitsett, SAFE Executive Director, 804-694-7794, whitsett@chesterfieldsafe.org

Commenter: Mary Crozier, Community Coaliltions of Virginia 5/17/19 4:31 pm

restrict marijuana

Community Coalitions of Virginia (CCoVA) is a non-profit organization that consists of representation from substance abuse prevention coalitions (#41), organizations (#5) and individuals (#4) across the state. CCoVA works collaboratively to prevent and reduce substance abuse and related risk factors in Virginia communities in ways that are measurable and improve quality of life. For more information please see our website, www.communitycoalitionsofva.com

Community Coalitions of Virginia provides this public comment in response to the Virginia Board of Pharmacy New Regulations Governing Pharmaceutical Processors; May 17, 2019.

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.

2. The Virginia Board of Pharmacy is violating federal law by setting up marijuana grows and dispensaries. Virginia law nor the board's regulations preempt federal law.

3. CBD-THC-A-THC oils are not FDA approved medicines.

4. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.

5. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illness covered in these regulations.

6. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.

7. It is medical malpractice for physicians to provide written certification for the promotion and use of marijuana as a medicine in the form of CBD-THC-A-THC oil without FDA approval because there is insufficient scientific evidence of the benefits and effects on patient safety are unknown.

8. It is ethically inappropriate for pharmacists to grow and dispense CBD-THC-A-THC oil without sufficient research on dosage and interactions.

9. Attorney General Jeff Session has reversed the Cole Memo, now instructing federal law enforcement to enforce federal law with regard to marijuana manufacturing and possession.

10. Increased access to marijuana oils increases usage in 12-17 year olds. (The National Survey on Drug Use and Health reports, SAMHSA)

11. Marijuana usage, including oils, is linked to mental illness and opioid use.

12. If the Virginia Board of Pharmacy adopts these new permanent regulations, it will further open the door to marijuana legalization in Virginia. All states that have legalized marijuana began with medical marijuana.

13. Revenues collected from marijuana do not outweigh the negative impacts on public safety, public health, the workplace, academics, health, black market and natural resources.

Contact Information:

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Commenter: Cannabis Business Association of Virginia 5/17/19 4:53 pm

Patient Access and Free Enterprise

Dear Mr. Chair and Members of the Board of Pharmacy,

The Cannabis Business Association of Virginia (CannaBizVA) is a non-profit, trade association formed to advance legislation, regulation and implementation to support and grow Virginia's regulated cannabis industries. Accordingly, CannaBizVA offers the following comment, which prioritizes patient access to care and free enterprise.

CannaBizVA respectfully requests the Board of Pharmacy consider expanding, if not outright dissolving, the government-sanctioned oligopoly currently governing Virginia's medical cannabis industry. Allowing for only one vertically integrated, seed-to-sale pharmaceutical processor in each of the Commonwealth's five geographically bound Health Service Areas functions to the detriment of Virginia's small business economy and, most importantly, patient access to care.

The regulatory framework currently in place, and again proposed through the present Notice of Proposed Rule Making, is outdated and not adequately scaled to meet anticipated patient demand. This framework and supply chain model was enacted during the 2017 General Assembly session when CBD and THC-A oil was approved only for patients with intractable epilepsy. It is estimated that around 25,000 Virginians are plagued with this ailment. CannaBizVA contends that one vertically integrated, seed-to-sale pharmaceutical processor in each of the Commonwealth's five geographically bound Health Service Areas was likely sufficient to meet the demands of 25,000 potential patients.

However, in 2018, the General Assembly passed legislation providing practitioners latitude to treat with CBD or THC-A oil *any* diagnosed condition or disease determined by the practitioner to benefit from such use, which exponentially expanded the anticipated demand for CBD & THC-A oil treatments to potentially each of Virginia's 8.5 million citizens without a coinciding expansion of supply channels. As such, the Commonwealth could very well be tasked with treating upwards of a few million patients through a system designed to serve less than 1% of that demand. The current proposal simply does not have the capacity to suit the demands soon to be placed on the system.

Further complicating patient access are the geographic limitations on the current and proposed regulatory framework. With only one pharmaceutical processor in each of the Commonwealth's vast and sprawling Health Service Areas, a qualifying medical cannabis patient living in Danville would have to drive no less than two and a half hours to the closest pharmaceutical processor in order to receive his/her medicine. This is particularly troubling when you consider that these patients are dealing with any number of ailments, spanning from chronic pain, anxiety, autism, PTSD, or intractable epilepsy, which can cause multiple seizures an hour.

An easy fix to the patient access issues of supply chain capacity and geographic barriers would be to simply open up Virginia's medical cannabis market. Allowing more growers, processors, and retailers to operate in Virginia would increase production capacity, decrease travel time, and stimulate small, local farms and businesses. CannaBizVA encourages the Board of Pharmacy to

maintain current quality and security standards, but expand the number of CBD and THC-A oil suppliers, processors, and retailers operating in the Commonwealth.

Respectfully,

CannaBizVA

DRAFT Final Regulations

BOARD OF PHARMACY

New regulations

CHAPTER 60

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I

General Provisions

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"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 [~~, which cannot exceed 60 fluid ounces~~] .

["Batch means a quantity of cannabidiol oil or THC-A 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 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 cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

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

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

"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 cannabidiol oil or THC-A 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 cannabidiol oil or THC-A 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, or legal guardian.

"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, or legal guardian.

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. Replacement of registration for a qualifying patient, parent, or legal guardian 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
~~6.~~ 8.] Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
[~~7.~~9.] Reinspection fee.	$1,000
[~~8.~~ 10.] Registration of each cannabidiol oil or THC-A 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 cannabidiol oil or THC-A 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 cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

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

5. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabidiol oil or THC-A oil for treating the 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 cannabidiol oil or THC-A 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 practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation.

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

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

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

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

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

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabidiol oil or THC-A oil;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. If the board denies an application or renewal of a qualifying patient, parent, or legal guardian applicant, the board shall provide the applicant with notice of the grounds for the denial

and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

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

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

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

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

D. If a patient, parent, or legal guardian becomes aware of the loss, theft, or destruction of the registration of such patient, parent, or legal guardian, the patient, parent, or legal guardian shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial

registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

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

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

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

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

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

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

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

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's

withdrawal of the written certification the patient has not obtained a valid written certification from a different practitioner;

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

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

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

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

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

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

8. The registration of the patient, parent, or legal guardian was lost, stolen, or destroyed, and the patient, parent, or legal guardian failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

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

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

Part III

Application and Approval Process for Pharmaceutical Processors

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

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

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

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

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

A. The application process for permits shall occur in three stages: submission of initial application, 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 oil pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

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

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

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

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

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

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

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

k. A blueprint of the proposed pharmaceutical processor 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, cannabidiol oil, or THC-A 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 cannabidiol oil or THC-A oil and to safely dispense such products; and

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

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

3. The board shall conduct criminal background checks on 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 oil;

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

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

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

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

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

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

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

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor, change the location of an existing pharmaceutical processor, make structural changes to an

existing pharmaceutical processor, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

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

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

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

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

1. Notify the board;

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

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

B. The proposed disposition of all Cannabis, dispensing records, patient information records, and other required records shall be reported to the board. If the Cannabis and records are to be transferred to another processor located in Virginia, the owner shall inform the board and the patients and include on the public notice the name and address of the processor to whom the Cannabis and records are being transferred and the date of transfer.

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

as soon as he knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

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

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

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

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

[3. If a new owner's share constitutes 5% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required by subsection E of § 54.1-3442.6.]

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 oil that is authorized under state law and regulations;

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

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

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

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

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

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

Part IV

Requirements for Pharmaceutical Processor Personnel

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

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

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

C. 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 cannabidiol oil and THC-A oil as authorized by the PIC.

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

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

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

J. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor 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, cannabidiol oil, and THC-A oil;

2. Procedures and instructions for responding to an emergency;

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

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

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

C. The PIC shall assure the continued competency of all employees through continuing in-service training 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 pharmacy technicians to one pharmacist.

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

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

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

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding (i) cannabidiol oil, THC-A oil, or other drugs either before or after cannabidiol oil or THC-A 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 oil or any other drug the patient may be taking;

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

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

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

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

A. No person shall be PIC for more than one pharmaceutical processor 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 oil are met;

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

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

a. Pharmaceutical processor permit;

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

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

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

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

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, cannabidiol oil, or THC-A oil on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC 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 sell cannabidiol oil or THC-A oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

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

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

1. 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, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil is stored.

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

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

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

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

H. A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil 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 cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

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

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

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

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

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

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

1. Name and location of the processor;

2. Contact information for the processor;

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

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

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

F. No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions:

laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

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

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

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

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

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

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

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

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor prior to commencing business shall:

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

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

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

C. The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and address of the registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold; the kind and quantity of cannabidiol oil or THC-A oil sold or disposed of; and the method of disposal.

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

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

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

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

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the first 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 cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation;

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

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

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

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

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

8. Not allow keys to be left in the locks or accessible to 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 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 oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

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

2. The video system shall have:

a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an

alert to the processor within five minutes of the failure, either by telephone, email, or text message;

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

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

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

3. All video 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 oil has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

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

A. A pharmaceutical processor shall:

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

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

breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil 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 cannabidiol oil or THC-A oil. These shall include policies and procedures that:

1. Restrict movement between compartments;

2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility;

3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.

C. The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all

errors and inaccuracies in inventories. Pharmaceutical processors shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. 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 cannabidiol oil or THC-A oil from the market or (ii) promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;

2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and

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

D. The processor shall store all Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil accessible only to the minimum number of specifically

authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, inside an area or building that affords adequate security.

18VAC110-60-260. Recordkeeping requirements.

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

1. Guarantees the confidentiality of the information contained 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 cannabidiol oil or THC-A oil; or (iii) any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law-enforcement authorities and the board.

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

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

1. An alarm activation or other event that requires a response by public safety personnel;

2. A breach of security;

3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours; and

4. Corrective measures taken if any.

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 Oil

18VAC110-60-280. Cultivation and production of cannabidiol oil or THC-A oil.

A. No cannabidiol oil or THC-A oil shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops.

B. Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

C. Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.

18VAC110-60-285. Registration of products.

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

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD); [and]

4. Cannabidiolic acid (CBDA) [~~; and~~

~~5. Any other active ingredient that constitutes at least 1.0% of the batch used in the product~~] .

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of [~~97% to 103%~~ 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 oil product brand name;

4. Is obscene or indecent;

5. May encourage the use of marijuana, cannabidiol oil, or THC-A oil for recreational purposes;

6. May encourage the use of cannabidiol oil or THC-A oil for a disease or condition other than the disease or condition 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 oil product unless supported by substantial evidence or substantial clinical data.

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

A. Cannabidiol oil or THC-A oil produced as a batch shall not be adulterated.

B. Cannabidiol oil or THC-A oil produced as a batch shall be:

1. Processed, packaged, and labeled according to the U.S. Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, 21 CFR Part 111; and

2. Labeled with:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285;

c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number so as to facilitatc any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of testing and packaging;

e. The expiration date [based on stability testing] ;

f. The quantity of cannabidiol oil or THC-A oil contained in the batch;

g. A terpenes profile and a list of all active ingredients, including:

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD);

(4) Cannabidiolic acid (CBDA); and

[~~(5) Any other active ingredient that constitutes at least 1.0% of the batch used in the product; and~~]

h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, [~~and~~] heavy metals [, residual solvents,] and pesticide chemical residue analysis.

[~~18VAC110-60-295. Labeling of dispensed cannabidiol oil or THC-A oil.~~

~~A. A pharmaceutical processor shall label each cannabidiol oil or THC-A oil product prior to dispensing by a pharmacist and shall securely affix to the package a label that states in legible English:~~

~~1. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285;~~

~~2. A serial number as assigned by the pharmaceutical processor;~~

3. The date of dispensing the cannabidiol oil or THC-A oil;

4. An appropriate expiration date, not to exceed six months;

5. The quantity of cannabidiol oil or THC-A oil contained in the package;

6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis;

8. The name and registration number of the qualifying patient;

9. The name of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. Name and address of the pharmaceutical processor; and

12. Any cautionary statement required by statute or regulation.

B. No person except a pharmacist or pharmacist technician under the direct supervision of a pharmacist at the pharmaceutical processor shall alter, deface, or remove any label so affixed.

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

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

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

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (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. [~~Immediately prior to producing any~~ After processing and before dispensing the] cannabidiol oil or THC-A oil product, a pharmaceutical processor shall [~~segregate all harvested Cannabis into homogenized batches. A pharmaceutical processor shall~~] make a sample available from each batch [of product] for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, [residual solvents,] and pesticide chemical residue and (ii) conduct an active ingredient analysis [and terpenes profile] . [The sample size shall be a statistically valid sample as determined by the board.]

C. From the time that a batch of [~~Cannabis~~ cannabidiol or THC-A oil product] has been homogenized for sample testing [~~and eventual packaging.~~] until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold

from use the entire batch [~~of Cannabis~~] , except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the [~~Cannabis~~ batch of oil product] in a secure, cool, and dry location so as to prevent the [~~Cannabis~~ batch] from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor [~~include Cannabis in a cannabidiol oil or THC-A oil product or sell it~~ sell a cannabidiol oil or THC-A oil product] prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any [~~Cannabis~~ cannabidiol or THC-A oil] products and materials upon the completion of any testing, use, or research.

F. If a sample of [~~Cannabis~~ cannabidiol or THC-A oil product] does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a [~~Cannabis~~] sample of [cannabidiol oil or THC-A oil product] shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance

Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a [~~Cannabis~~] sample [of cannabidiol oil or THC-A oil product] shall be deemed to have passed if it meets the following standards:

Metal	[~~Natural Health Products Acceptable Limits ug/kg body weight/Day~~ Limits - parts per million (ppm)]
Arsenic	[~~<0.14~~ <10 ppm
Cadmium	~~<0.09~~ <4.1 ppm
Lead	~~<0.29~~ <10 ppm
Mercury	~~<0.29~~ <2 ppm]

4. For purposes of the pesticide chemical residue test, a [~~Cannabis~~] sample [of cannabidiol oil or THC-A oil product] shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

[5. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD); and

4. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological,

mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.]

G. If a sample of [~~Cannabis~~ cannabidiol oil or THC-A oil product] passes the microbiological, mycotoxin, heavy metal, [residual solvent,] and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate [~~manufacturing,~~] 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 and registered practitioners who have certified qualifying patients.

18VAC110-60-310. Dispensing of cannabidiol oil or THC-A oil.

A. A pharmacist in good faith may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification.

1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian. The pharmacist or pharmacy technician shall verify in the 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 [~~two~~ 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, or legal guardian and shall maintain record of such viewing in accordance with policies and procedures of the processor.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian shall receive more than a 90-day supply of cannabidiol oil or THC-A oil 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 name [~~or kind~~] of cannabidiol oil or THC-A oil [that was registered with the board pursuant to 18VAC110-60-285] and its strength;

3. The serial number assigned to the oil during production;

4. The date of dispensing the cannabidiol oil or THC-A oil;

5. The quantity of cannabidiol oil or THC-A oil dispensed [~~, which cannot exceed 60 fluid ounces~~] ;

[6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

d. Cannabidiolic acid (CBDA);

7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;

~~6.~~ 8.] The name and registration number of the registered patient;

[~~7.~~ 9.] The name and registration number of the certifying practitioner;

[~~8.~~ 10.] Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

[~~9.~~ 11.] The name or initials of the dispensing pharmacist;

[~~10.~~ 12.] Name, address, and telephone number of the pharmaceutical processor;

[~~11.~~ 13.] Any necessary cautionary statement; and

[~~12.~~ 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.

[C. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-

A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.]

D. The cannabidiol oil or THC-A oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

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

F. A pharmacist shall be responsible for verifying the accuracy of the dispensed oil in all respects prior to dispensing and shall document that each verification has been performed.

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

H. A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, or legal guardian if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor shall distribute the written policies and procedures to all

pharmaccutical proccssor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

a. The date of the quality assurance review and the names and titles of the persons performing the review;

b. The pertinent data and other information relating to the dispensing error reviewed;

c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient;

d. The findings and determinations generated by the quality assurance review; and

e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes if any.

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

18VAC110-60-330. Disposal of cannabidiol oil or THC-A oil.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by disposal in accordance with a plan approved by the board and in a manner as to render the cannabidiol oil or THC-A 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 cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:

1. The date and time of disposal;

2. The manner of disposal;

3. The name and quantity of cannabidiol oil or THC-A oil disposed of; and

4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil.

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

FORMS (18VAC110-60)

Application for registration of a patient, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a parent or legal guardian, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a practitioner to issue certifications, online form available at https://www.license.dhp.virginia.gov/apply

Application for a pharmaceutical processor

Board of Pharmacy

2020 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3300 and 54.1-3321, relating to registration as a pharmacy technician.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303, and 54.1-3321 of the *Code of Virginia* are amended and reenacted as follows:

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

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

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

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

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

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

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

"Pharmacy technician trainee" means a person registered with the board for the purpose of performing duties restricted to a pharmacy technician for completing a pharmacy technician training program in accordance with § 54.1-3321(E) of the Code of Virginia.

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

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

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

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

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

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

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

B. To be registered as a pharmacy technician trainee, a person shall submit application to the Board and fee as established in regulation.

C. To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education or other Board-approved accrediting body with substantially similar standards or federal services pharmacy technician training program and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~. The Board shall also promulgate regulations for issuing a registration through credentialing to persons previously practicing as a pharmacy technician based on minimum standards set forth in regulation.

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

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

~~E.~~F. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

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

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the amendments to subsection C of this section shall not become effective until July 1, 2021.

Draft 2020 Legislative Proposal

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § **54.1-3303** relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § **54.1-3420.2**.

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, ~~or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;~~ or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ **54.1-3301**, **54.1-3304**, and **54.1-3304.1** shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ **54.1-3300** et seq.) or Chapter 34 (§ **54.1-3400** et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

Issues to be Addressed by Regulation Committee

(From comments on Periodic Review)

In section 10, amend definition of "faxed prescription" to allow an electronic image.

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

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

In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy."

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

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

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

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

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

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

VIRGINIA BOARD OF PHARMACY
CATEGORIES OF FACILITY LICENSURE

PHARMACY: This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. Federal law allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

NONRESIDENT PHARMACY: This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

MEDICAL EQUIPMENT SUPPLIER: This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

NONRESIDENT MEDICAL EQUIPMENT SUPPLIER: This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. ~~This license does not authorize distribution of prescription drugs or devices to the ultimate user.~~

NONRESIDENT WHOLESALE DISTRIBUTOR: This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors.

WAREHOUSER: ~~This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements.~~ This permit ~~may be preferable to the wholesale distributor license~~ is for those entities which distribute

prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. ~~This permit does not authorize distribution of prescription drugs or devices to the ultimate user.~~

NONRESIDENT WAREHOUSER: This registration is for those entities located in another state which distribute prescription drugs into Virginia, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This registration may also be preferable for those entities which only distribute prescription devices, and no prescription drugs.

NON-RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs.

RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use.

NONRESIDENT MANUFACTURER:
This registration authorizes any manufacturer located outside the Commonwealth to ship prescription drugs into the Commonwealth.

CONTROLLED SUBSTANCES REGISTRATION (CSR): This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouser, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration to dispense naloxone without charge or compensation. An entity at which a patient is being treated 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 and is being prescribed Schedule II through VI controlled substances may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

OUTSOURCING FACILITY: This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite,

the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

NONRESIDENT OUTSOURCING FACILITY: This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

Practitioner of the Healing Arts to Sell Controlled Substance Facility Permit: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

THIRD-PARTY LOGISTICS PROVIDER: This permit authorizes the permit holder, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device.

NONRESIDENT THIRD-PARTY LOGISTICS PROVIDER: This registration authorizes the registrant located in another state, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device.

* **§ 54.1-3455. Schedule VI.**

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 of the Code of Virginia and Regulation 18VAC110-20-321 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection. USP Chapter 800 describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. USP first published Chapter 800 in 2014. It was first published as an official standard in February 2016 with a delayed implementation date of July 1, 2018. On September 27, 2017, USP published a notification of intent to revise the effective date of chapter <800> to December 1, 2019. While full compliance with Chapter 800 is encouraged, only those requirements related to compounding are legally required.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***Are there specific educational and training requirements regarding personnel?***

Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***What BUD must be assigned to a single dose vial used in preparing a compounded sterile product?***

- If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;
- If the single dose vial is puntured within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;
- A puntured single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center For Disease Control (CDC) and USP Appendix);
- A closed system transfer device (CSTD) should not be used to extend the BUD of a single-dose vial to exceed the 1 hour BUD when punctured outside of an ISO Class 5 environment or the 6 hour BUD when punctured within and not removed from an ISO Class 5 environment.

5. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***

No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

6. ***How may stability information be taken into consideration when assigning a BUD?***

Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

7. ***What concepts, at a minimum, should be taken into consideration when determining drug stability?***

Pharmacists should use professional judgment to determine appropriate references of chemical stability information and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:

- Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
- Stability of the drug is not concentration-dependent; and,
- The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

8. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

9. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

10. ***Do batches less than 25 require sterility testing to be performed?***

No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:

- high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
- in multiple-dose vials (MDVs) for administration to multiple patients or
- CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

11. How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?

Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.
*****Note-** this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

13. How often must media-fill testing be performed?

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. *****Note** - the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively. Annual media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

14. If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. *****Note-** this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

15. Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?

Per USP, sterility testing is not required for autoclaved CSP prepared in batches less than 25 and if the storage times for high-risk CSPs are not exceeded. If the storage times of high-risk CSPs

are exceeded, sterility testing is required. Once sterility testing is successfully completed, a longer BUD may be assigned based on the criteria described in the chapter (e.g., based on stability studies).

16. Does USP-NF address how long a CSP may hang for infusion?

No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

17. May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

18. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

19. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method

suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.

- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

20. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

21. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

22. How should a dilution or stock bag for pediatrics be treated?

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.

23. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality

processes into their sterile compounding to minimize the risk and the introduction of contamination.

24. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

25. How often must air and surface sampling be performed?

USP requires air sampling to be performed at least every 6 months. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). USP requires surface sampling to be performed "periodically". The Board advises that surface sampling should be performed at least quarterly. It may be performed by pharmacy personnel or outsourced.

26. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be 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. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions.

Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

27. What minimally should be taken into consideration when compounding multidose vials?

Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.

28. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

29. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

30. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- Not more than 3520 particles (0.5 μm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

31. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

32. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

33. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

34. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes.

35. In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?

USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile

when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

36. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

37. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

38. What risk-level is associated with repackaging an undiluted multi-dose vial?

The repackaging of an undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.

39. May a microbiological method alternative to compendial methods be used?

Regarding sterility testing, USP Chapter <797> states, "The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible." Additionally, USP General Chapter <1223> "provides guidance on the selection, evaluation, and use of microbiological methods as alternatives to compendial methods. To properly implement alternative methods, one must consider a number of important issues before

selecting the analytical technology and qualifying that method with the actual product. These issues include, but are not limited to, identification of suitable alternative methodology, development of user specifications for equipment selection, demonstration of the applicability of the method as a replacement for a standard compendial method, and qualification of the method in the laboratory.....*General Notices and Requirements* in the *USP* states, "Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances." General Chapter <1223> also makes reference to 21 CFR Part 211.194 stating, "This subsection of the regulations also recognizes the legal basis of *USP* and the *National Formulary (NF)* standards and makes it clear that it is the responsibility of the user to validate methods or procedures that differ from those standardized in the compendia." Refer to *USP* for additional guidance.

40. What is the status of the General Chapter <800> and when will General Chapter <800> become official?

USP announced the **intent to postpone** the official date of General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*. Per USP, the intent of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding — Sterile Preparations*, to provide a unified approach to quality compounding. The next revision to General Chapter <797> is anticipated to be published in the *Pharmacopeial Forum* 44(5) September/October 2018 for a second round of public comment. Both USP General Chapter <797> and USP General Chapter <800> are anticipated to become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

41. What does 'official date' mean?

Per USP, the USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, and other government authorities. USP has no role in enforcement.

42. Other than the change to the official date, are there other expected substantive changes to USP General Chapter?

Per USP, no. The only part of USP General Chapter <800> that is expected to change is the official date, which is expected to be changed to December 1, 2019.

43. Is <800> ~~currently~~ enforceable in ~~the United States~~Virginia?

~~Per USP, from a compendial standpoint, a USP general chapter numbered below <1000> becomes enforceable through reference in the General Notices, a monograph, or another applicable general chapter numbered below <1000>. At this time, <800> is not specifically referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>.~~ Section §54.1-3410.2 (E) of the Drug Control Act requires compliance with USP-NF standards for compounding. When the chapters become official in December 2019, the

law will require compliance with the requirements in Chapter 800 that relate to compounding. Standards within Chapter 800 that do not relate to compounding will not be required under current law.

~~However, states may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. USP has no role in enforcement. As a result, the specific enforceability of <800> depends on the legal framework that you are analyzing.~~

44. Does the December 1, 2019 official date of <800> impact my current or early adoption of the general chapter?

Per USP, no. USP encourages adoption and implementation of General Chapter <800> to help ensure a quality environment and protection of healthcare workers and patients when hazardous drugs are handled.

45. How do I adopt USP General Chapter <800> if sections are not harmonized with USP General Chapter <797>?

Per USP, two sections that are not harmonized between the two chapters are: Segregated Compounding Area and 'Low volume' hazardous drug compounding. Below please find guidance on how to adopt USP <800> until the revised USP <797> is published.

Segregated Compounding Area (SCA)

- USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area (SCA).
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 30 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in USP <797> and C-SCA in <800>.
  - For early adoption of <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in the chapter and the CSP is assigned a BUD of 12 hours or less.
  - For facilities that have not yet adopted <800>, the standards in USP <797> would apply. Only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA.

"Low volume" hazardous drug compounding

- USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.

- For early adoption of <800>, HDs must be prepared in a C-SEC meeting the requirements in the chapter.
- For facilities that have not yet adopted <800>, the standards in <797> would apply. Facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.

46. What are the hazardous drugs (HD) that USP Chapter <800> oversees?

Refer to the most current National Institute for Occupational Safety and Health (NIOSH) list at www.cdc.gov. Note: Chapter <800> defines HDs are those on the NIOSH list, not the EPA hazardous materials list. Some drugs on the Environmental Protection Agency (EPA) list may not be on the NIOSH list, e.g., epinephrine.

47. In general, how are drugs grouped within the NIOSH list?

Hazardous drugs are categorized into three tables:

- Antineoplastic drugs, e.g., cisplatin, methotrexate
- Non-antineoplastic drugs, e.g., carbamazepine, estrogen/progesterone combinations
- Non-antineoplastic drugs that have adverse reproductive effects, e.g., temazepam, warfarin

48. What drugs MUST comply with all USP Chapter <800> containment requirements?

Drugs on the NIOSH list that will be involved in compounding must follow the requirements in this chapter include:

- Any HD active pharmaceutical ingredient (API) on any of the three tables, and
- Any antineoplastic requiring manipulation other than counting or repackaging.

49. What drugs do NOT have to comply with all the USP Chapter <800> containment requirements?

Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:

- Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms, that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)

50. How should a pharmacist determine how to comply with 800?

Pharmacists should ask themselves the following questions, at a minimum:

- What drugs do I receive, store, dispense that are deemed hazardous pursuant to the NIOSH list and are used in compounding products?
- Must those drugs comply with all containment requirements or do some qualify for performing an assessment of risk?
- What changes will I need to make to my facility in order to comply with Chapter <800>?

- What personnel training is needed to meet compliance?
- What cleaning processes must be implemented or changed to meet compliance?
- What activities do I perform with these hazardous drugs, e.g., compounding, administration, etc.?

51. If it is determined that the pharmacy stocks HDs, what options exist for the pharmacy?

The pharmacy may treat all dosage forms of all HDs that are used in compounding products the same and follow all containment requirements in Chapter <800> or it may perform an assessment of risk to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API.

52. What hazardous drugs may be considered during an assessment of risk?

- Antineoplastics that only need to be counted or packaged
- Non-antineoplastics
- Reproductive-only hazards

53. What should be considered, at a minimum, during an assessment of risk?

- Type of HD, dosage form, risk of exposure, packaging, manipulation to be performed
- Alternative containment strategies and/or work practices should be documented
- The assessment of risk shall be reviewed every 12 months and documented.

54. What minimal questions and/or information will an inspector for the Board of Pharmacy be asking during an inspection? Note: Refer to page 1 regarding enforcement of Chapter <800>.

- Does the pharmacy perform sterile or non-sterile compounding?
- Does the pharmacy stock HDs that are used in compounding products? The list of HDs that are used in compounding products that the pharmacy stocks must be provided for inspector review.
- Are all HDs that are used in compounding products contained in a manner consistent with USP Chapter <800> or was an assessment of risk performed to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API. The assessment of risk must be provided for inspector review.
- Who is the 'designated person' for the pharmacy who is responsible for the continuing to evaluate the fundamental practices and precautions for handling HDs?
- Documentation of required training.
- Appropriate personnel equipment.
- Appropriate engineering controls.
- Standard operating procedures for safe handling of HDs that are used in compounding products for all situations in which the HDs are used throughout the facility.

55. What does USP Chapter <800> list as the general engineering control requirements for performing non-sterile HD compounding?

Table 2. Engineering Controls for Nonsterile HD Compounding

Containment Primary Engineering Control (C-PEC)	Containment Secondary Engineering Control (C-SEC)
• Externally vented (preferred) or redundant-HEPA filtered in series • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 air changes per hour (ACPH) • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas • Fixed walls

56. What does USP Chapter <800> list as the general engineering control requirements for performing sterile HD compounding?

Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 buffer room with an ISO Class 7 ante-room	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 30 air changes per hour-ACPH • Negative pressure between 0.01 and 0.03 inches of water colum relative to adjacent areas	As described in (797
Unclassified C-SCA	• Externally vented • Examples: Class II BSC or CACI	• Externally vented • 12 ACPH • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas	As described in (797) for CSPs prepared in a segregated compounding area

57. Where may a list of recommended personal protective equipment by type of drug formulation and engineering controls for working with HDs in a healthcare setting be found?

Table 5 of the NIOSH list.

58. Regarding the Segregated Compounding Area (SCA) definition, Chapter <797> states an SCA may be a designated space, room or demarcated area. Chapter <800> states SCA requires fixed walls and removes the "space or demarcated area". Please clarify the Board's expectations on this issue.

Per USP, please note the differences in terminology in <797> and <800>. General Chapter <800> specifies that this is a containment segregated compounding area (C-SCA). For hazardous drug compounding, the C-SCA must have fixed walls. For nonhazardous drug sterile compounding,

the SCA may be in an unclassified area (and not necessarily have fixed walls). For the C-SCA, fixed are also necessary to maintain negative pressure.

59. ***Regarding low-risk level compounding with 12 hour or less beyond use dating (hood within a non-ISO Class 7 area), Chapter <797> states that this configuration does not allow hazardous compounding. Chapter <800> states that it is allowed, but only low and medium risk HDs may be prepared and beyond use dating (BUD) that cannot exceed <797> for being prepared in a SCA. Please clarify the Board's understanding on this issue.***

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a containment segregated compounding area (C-SCA). USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

60. ***Chapter <797> also allows for placement of an isolator outside of an ISO Class 7 buffer room with meeting of specification requirements and allowance of full BUD. Chapter <800> states if the containment primary engineering control (C-PEC) is placed in a containment segregated compounding area (C-SCA), then the BUD of all compounded sterile products must be limited as described in <797>. Again, Chapter <797> states that this configuration does not allow hazardous compounding. Please clarify the Board's understanding on this issue.***

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a C-SCA. USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

61. ***With the implementation of Chapter <800>, will USP continue to allow compounding aseptic isolators (CAI) placed outside of a classified area to be used to compound sterile products and assigned a full BUD as authorized in <797>?***

Yes, Chapter <797> still allows for a compounding aseptic isolator (CAI) placed outside of a classified area to be used to compound sterile products and assigned the full storage period BUD provided the conditions specified in the chapter are met. Note, for compounding sterile hazardous drugs, the compounding aseptic containment isolator (CACI) must be placed in a negative pressure containment secondary engineering control (C-SEC) with adequate air changes per hour (ACPH).

62. ***Does Chapter <800> recommend wipe sampling and medical surveillance?***

Yes, Chapter <800> states that "environmental wipe sampling for HD surface residue should be performed routinely." Medical surveillance is also a recommendation of the chapter. The chapter states that "healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program." Note, both of these issues are recommendations of Chapter <800> and not a requirement.

63. USP Chapter <800> states that antineoplastic hazardous drugs (HD) that require manipulation other than counting or repackaging should be stored separately. Does this include any dosage formulation, or is that left to the risk assessment?

Per USP, this is intended to include any dosage form that does NOT require any further manipulation (i.e. counting tablets, pouring liquids). This is a recommendation and is not required under Virginia law.

64. USP <797> and USP <800> recommend the use of closed-system drug-transfer devices (CSTD). Is there guidance on the proper evaluation of the available technologies?

USP currently recommends the use of CSTDs for compounding HDs. Per USP, it is not a requirement as there is no published universal performance standard for evaluation of CSTD containment. NIOSH is currently working on developing such a protocol.

65. Is a line of demarcation for doffing personal protective equipment (PPE) required for all hazardous containment secondary engineering controls?

USP <800> *requires* a doffing area if the negative-pressure hazardous drug (HD) buffer room is entered through the positive-pressure non-hazardous drug buffer room. Additionally, it states a designated doffing area *should* be indicated within all containment secondary engineering controls (C-SEC). Other than the line of demarcation mentioned in section 5.3.2, General Chapter <800> does not specify where doffing should occur. However, this is entity dependent and should additionally follow garbing requirements in <797>.

66. USP <800>, within Section 5.3, indicates that an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Are there applicable laws and regulations in Virginia regarding eyewash stations and/or other emergency or safety precautions?

The Board is not currently aware of laws and regulations in Virginia related to use of eyewash stations or other safety precautions related to this issue.

67. May a laminar airflow workbench (LAFW) or a compounding aseptic isolator (CAI) be used for compounding with an antineoplastic hazardous drug (HD)?

No.

68. Is it required to compound all sterile hazardous drugs within an externally vented containment primary engineering control (biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI))?

No, dosage forms of non-antineoplastic and reproductive risk hazardous drugs may be handled and compounded under an assessment of risk. If, however, bulk active pharmaceutical ingredients (API) of these drugs are used as starting ingredients, all of the containment requirements in <800> would apply. Refer to Box 1 within USP Chapter <800>.

69. What are the specifications required of a pass through chamber? Is it required be interlocking and HEPA filtered purged? Between what areas may these chambers be utilized?

General Chapter <800> defines a pass-through as "an enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors. The chapter does not require the pass-through to be HEPA filter purged and does not limit where these pass-throughs may be placed. General Chapter <800> additionally states that refrigerator pass-throughs must not be used.

70. Chapter <800> states sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. What is the intent of this statement?

The intent of prohibiting the storage of nonsterile compounding materials in sterile compounding areas is to minimize traffic flow into the sterile classified areas.

71. May bulk active pharmaceutical ingredients (API) used for sterile compounding be stored in the negative pressure C-SEC?

Yes. Refer also to USP's frequently asked question #16 found at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

72. Where must manipulation of non-sterile, non-antineoplastic and reproductive risk hazardous drugs (that are not bulk active pharmaceutical ingredients (API)) occur?

The location where manipulation occurs should follow an assessment of risk for non-antineoplastic and reproductive risk hazardous drugs (that are not bulk APIs). Facilities should determine their own strategies based on its assessment of risk.

73. Does Chapter <800> address whether scrubs that are worn within the hazardous compounding/storage area may be allowed to be taken home?

No. General Chapter <800> does not specify best practices for clothing under the gown. However, section 7.2 does require gowns to be disposable and shown to resist permeability by HDs.

74. What is the best practice for receiving hazardous drugs (HD)?

USP <800>, within Section 5.1, states antineoplastic HDs and all HD active pharmaceutical ingredients (API) must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas. Best practice is to unpack the hazardous drugs from the delivery tote, and leave packaged in a zip-locked plastic bag. From there, the unopened plastic bags should be moved to HD storage room, where the HDs can be removed from the bags and received into inventory.

HDs should never be withdrawn from the plastic transport bags in any room other than the HD storage room.

75. If the C-PEC vents externally and the room is able to maintain appropriate negative pressure and air exchanges, does the C-SEC need to be vented?

No.

For more information regarding USP Chapter <800>, an extensive list of frequently asked questions published by USP may be accessed at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.

Possible Meeting Dates for 2020

Full Board Meeting

March

Tuesday, March 3- BR2

Wednesday, March 4th – BR2

Tuesday, March 10th – BR 2

Wednesday, March 11th –BR 2

June

Tuesday, June 9th – BR 2

Thursday, June 11-BR 4

Tuesday, June 23-BR 4

Wednesday, June 24th – BR 2

Thursday, June 25-BR 2

September

Tuesday, September 1- BR 2

Wednesday, September 2- BR 4

Tuesday, September 8th – BR 2

Wednesday, September 9th – BR 4

December

Thursday, December 10th – BR 2

Tuesday, December 15th – BR 4

Thursday, December 17th – BR 2

Regulatory Meeting Dates

May (Formal Hearing also this month)

Friday, May 1- BR 2

Monday, May 4- BR4

Tuesday, May 5- BR 4

Monday, May 11- BR2

Thursday, May 21- BR 4

Thursday, May 28-BR 2

November (Formal Hearing also this month)

Monday, November 2 – BR 2

Tuesday, November 3- BR 2

Wednesday, November 4- BR 4

Monday, November 9- BR 2

Thursday, November 12- BR 2

Formal Hearings

January

Tuesday, January 7-BR 2

Wednesday, January 8- BR 2

Tuesday, January 14- BR 2

Wednesday, January 22- BR 2

February

Tuesday, February 4- BR 4

Wednesday, February 5- BR 2

Tuesday, February 11- BR 2

Wednesday, February 12-BR 4

April

Wednesday, April 1- BR 2

Tuesday, April 14-BR 2

Tuesday, April 21-BR 2

Wednesday, April 22- BR2

May (Regulatory Meeting also this month)

Friday, May 1- BR 2

Monday, May 4- BR4

Tuesday, May 5- BR 4

Monday, May 11- BR2

Thursday, May 21- BR 4

Thursday, May 28-BR 2

July

Wednesday, July 1- BR 2

Tuesday, July 7- BR 2

Wednesday, July 8- BR 2

Tuesday, July 14- BR 2

August

Tuesday, August 4- BR 4

Wednesday, August 5 BR 4

Wednesday, August 12- BR 2

Tuesday, August 18- BR 2

October

Tuesday, October 6- BR 2

Wednesday, October 7- BR 2

Wednesday, October 14- BR 4

Tuesday, October 20- BR 2

November (Regulatory Meeting also this month)

Monday, November 2 – BR 2

Tuesday, November 3- BR 2

Wednesday, November 4- BR 4

Monday, November 9- BR 2

Thursday, November 12- BR 2

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Licenses Issued

	12/1/17-2/28/18	3/1/18-5/31/18	6/1/18-8/31/18	9/1/18-11/30/18	12/1/18-2/28/19	3/1/19-4/20/19*	License Count 5/5/2019
Business CSR	81	86	50	59	41	19	1,333
CE Courses	0	1	0	2	0	0	9
Limited Use Pharmacy Technician	0	0	0	1	0	0	11
Medical Equipment Supplier	2	5	4	1	2	1	223
Nonresident Manufacturer	92	20	4	7	24	8	161
Nonresident Medical Equipment Supplier	12	12	12	9	10	5	305
Non-resident Outsourcing Facility	1	9	1	2	0	0	31
Non-resident Pharmacy	32	35	33	27	24	22	769
Non-resident Third Party Logistics Provider						8	10
Non-resident Warehouser						6	5
Non-resident Wholesale Distributor	13	22	16	12	13	3	631
Non-restricted Manufacturer	1	0	0	1	1	1	29
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	142	157	439	250	157	134	15,034
Pharmacist Volunteer Registration	0	0	2	0	0	0	0
Pharmacy	3	15	18	21	13	7	1,814
Pharmacy Intern	148	115	140	189	122	74	1,740
Pharmacy Technician	357	363	420	378	388	249	13,076
Pharmacy Technician Training Program	5	3	2	4	3	2	138
Physician Selling Controlled Substances	22	55	25	42	44	7	622
Physician Selling Drugs Location	1	10	10	4	8	3	170
Pilot Programs	2	0	1	0	0	2	18
Registered Physician For CBD/THC-A Oil			118	83	40	25	266
Repackaging Training Program	0	0	0	0	0	1	2
Restricted Manufacturer	0	0	0	0	1	0	48
Third Party Logistics Provider	3	1	0	1	0	0	5
Warehouser	39	3	10	7	9	0	106
Wholesale Distributor	1	0	3	0	0	0	65
Total	**957**	**912**	**1,308**	**1,100**	**900**	**577**	**36,621**

* Data for two months

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Inspections Completed

	12/1/17-2/28/18		3/1/18-5/31/18		6/1/18-8/31/18		9/1/18-11/30/18		12/1/18-2/28/19		3/1/19-4/30/19 *	
License Type												
Controlled Substances Registration	163		182		120		174		164		83	
Medical Equipment Supplier	22		22		25		19		10		11	
Non-restricted Manufacturer	1		0		0		3		3		1	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	23		22		31		38		30		11	
Restricted Manufacturer	0		2		0		0		1		0	
Third Party Logistics Provider	1		1		0		2		1		0	
Warehouse	11		11		14		12		10		7	
Wholesale Distributor	6		3		7		7		9		2	
Pharmacy	272		291		328		306		227		207	
Pilot	0		1		0		1		0		1	
Total	**499**		**535**		**525**		**562**		**455**		**323**	
Pharmacy (0201) Inspections												
Change of Location	4		5		9		7		0		0	
New	3		15		19		18		12		6	
Reinspection	2		8		6		13		14		4	
Remodel	31		43		31		42		40		38	
Routine	232		218		242		222		159		159	
Focus	0		2		1		4		0		0	
Federal Agency	0		0		18		0		0		0	
Compliance	0		0		2		0		2		0	
Pilot	0		0		0		0		0		0	
Total	**272**		**291**		**328**		**306**		**227**		**207**	
Pharmacy Routine Inspections												
No Deficiency	77	33%	66	30%	93	38%	109	49%	57	36%	53	33.0%
Deficiency	77	33%	80	37%	75	31%	64	29%	55	34%	47	30.0%
Deficiency & IPHCO	78	34%	72	33%	74	31%	49	22%	47	30%	59	37.0%
Total	**232**		**218**		**242**		**222**		**159**		**159**	

* Data for two months

Virginia Board of Pharmacy
June 5, 2019
Frequently Cited Deficiencies
December 2017 - April 2019

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is requirec	127
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)	53
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	47
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	42
12. Storage of prescription drugs not in the prescription department	30
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	28
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	28
7. Change of location or remodel of pharmacy without submitting application or Board approva	27
20. Pharmacist not checking and documenting repackaging or bulk packaging	23
20a. Pharmacist not documenting final verification of non-sterile compounding	23
Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)	**Cumulative Total**
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	176
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.	160
127. Repackaging records and labeling not kept as required or in compliance	115
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	79
108. Emergency access alarm code/key not maintained in compliance	75
124. Labels do not include all required information	70
122. Engaging in alternate delivery not in compliance	65
130a. Compounded products not properly labeled	64
123. Engaging in remote processing not in compliance	51
130. Required compounding/dispensing/distribution records not complete and properly maintained	38

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
Routine Inspections Completed	**232**	**218**	**242**	**222**	**159**	**159**	**1232**	**Repeat**	**Repeat**
Total Deficiencies	**127**	**115**	**123**	**83**	**60**	**101**	**609**	**14**	**222**
Average Deficiencies per Inspection	**0.5**	**0.5**	**0.5**	**0.4**	**0.4**	**0.6**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	2	2	0	1	2	9		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	5	3	9	12	6	12	47		2
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	4	2	2	7	2	5	22		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	1	2	0	0	0	1	4		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	2	1	1	1	0	0	5		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	1	0	0	1		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	4	6	7	3	2	5	27		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	1	0	1	1	1	1	5		1
9. Alarm not operational or not being set	0	1	1	0	0	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)	1	0	1	1	0	3	6		1

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	1	2	2	1	0	4	10		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	0	0	1	1	1	2	5		
12. Storage of prescription drugs not in the prescription department	12	8	5	1	1	3	30		9
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	0	1	5	0	0	4	10	1	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)	0	5	2	0	2	3	12	1	3
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)	6	5	16	9	8	9	53		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	31	17	24	20	16	19	127	5	102
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	6	7	6	2	3	4	28	1	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)	0	2	2	0	2	1	7		
18. Records of dispensing not maintained as required	7	3	4	2	3	2	21	1	1

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	2	0	1	0	1	0	4		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	5	7	4	4	0	3	23		15
20a. Pharmacist not documenting final verification of non-sterile compounding	6	5	3	3	1	5	23		3
20b. Pharmacist not documenting final verification of sterile compounding	6	2	5	3	1	3	20	1	11
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	1	0	0	0	0	1		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	0	1	1	0	2	0	4		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	2	1	0	0	0	0	3		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	1	0	0	0	1		2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	0	0	0	0	0		1

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	6	8	5	4	2	3	28	1	29
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	1	0	0	1	3	1	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	3	2	3	0	0	1	9	1	1
29. Unlawful compounding for further distribution by other entities	3	3	3	0	1	0	10		
30. Security of after-hours stock not in compliance	0	0	0	0	0	0	0		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	10	14	4	6	4	4	42	1	15
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	0	0	0	0		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	1	3	1	1	0	0	6		1

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
Routine Inspections Completed	232	218	242	222	159	159	1232	Repeat	Repeat
Total Deficiencies	302	259	228	160	160	150	1109	24	287
Average Deficiencies per Inspection	1.3	1.2	0.9	0.7	1.0	0.9	0.9		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	0	0	0	0	0	0		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	7	6	4	1	7	1	26	1	7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	4	5	3	1	1	0	14		7
106. Prescription department substantially not clean and sanitary and in good repair	1	0	0	1	2	0	4		2
107. Current dispensing reference not maintained	4	1	3	1	6	4	19		10
108. Emergency access alarm code/key not maintained in compliance	18	17	15	8	8	9	75	1	17
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	27	38	38	24	26	23	176	5	38
110. Storage of paraphernalia/Rx devices not in compliance	0	0	0	1	0	0	1		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	2	1	1	0	1	2	7	1	2
112. Biennial taken late but within 30 days	1	3	1	3	2	2	12		
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	40	28	32	26	20	14	160	1	52

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	10	4	7	2	0	0	23		
115. Other records of distributions not maintained as required	0	2	1	0	0	2	5		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	4	4	4	2	4	7	25	1	1
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	1	0	0	0	0	0	1		
119. Not properly documenting partial filling of prescriptions	10	8	4	4	5	3	34		24
120. Offer to counsel not made as required	2	0	0	0	0	0	2		
121. Prospective drug review not performed as required	0	0	0	1	2	0	3		
122. Engaging in alternate delivery not in compliance	14	15	16	9	6	5	65	1	7
123. Engaging in remote processing not in compliance	9	12	7	4	8	11	51	2	4
124. Labels do not include all required information	15	17	16	10	7	5	70		13
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	5	5	3	0	8	4	25	2	7
126. Special packaging not used or no documentation of request for non-special packaging	0	2	1	0	0	0	3		4
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	33	21	18	17	9	17	115	5	27
128. Unit dose procedures or records not in compliance	0	0	0	2	0	0	2		
129. Robotic pharmacy systems not in compliance	0	0	2	0	0	1	3		
130. Required compounding/dispensing/distribution records not complete and properly maintained	5	8	9	6	4	6	38		12
130a. Compounded products not properly labeled	18	9	10	9	9	9	64	2	11

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

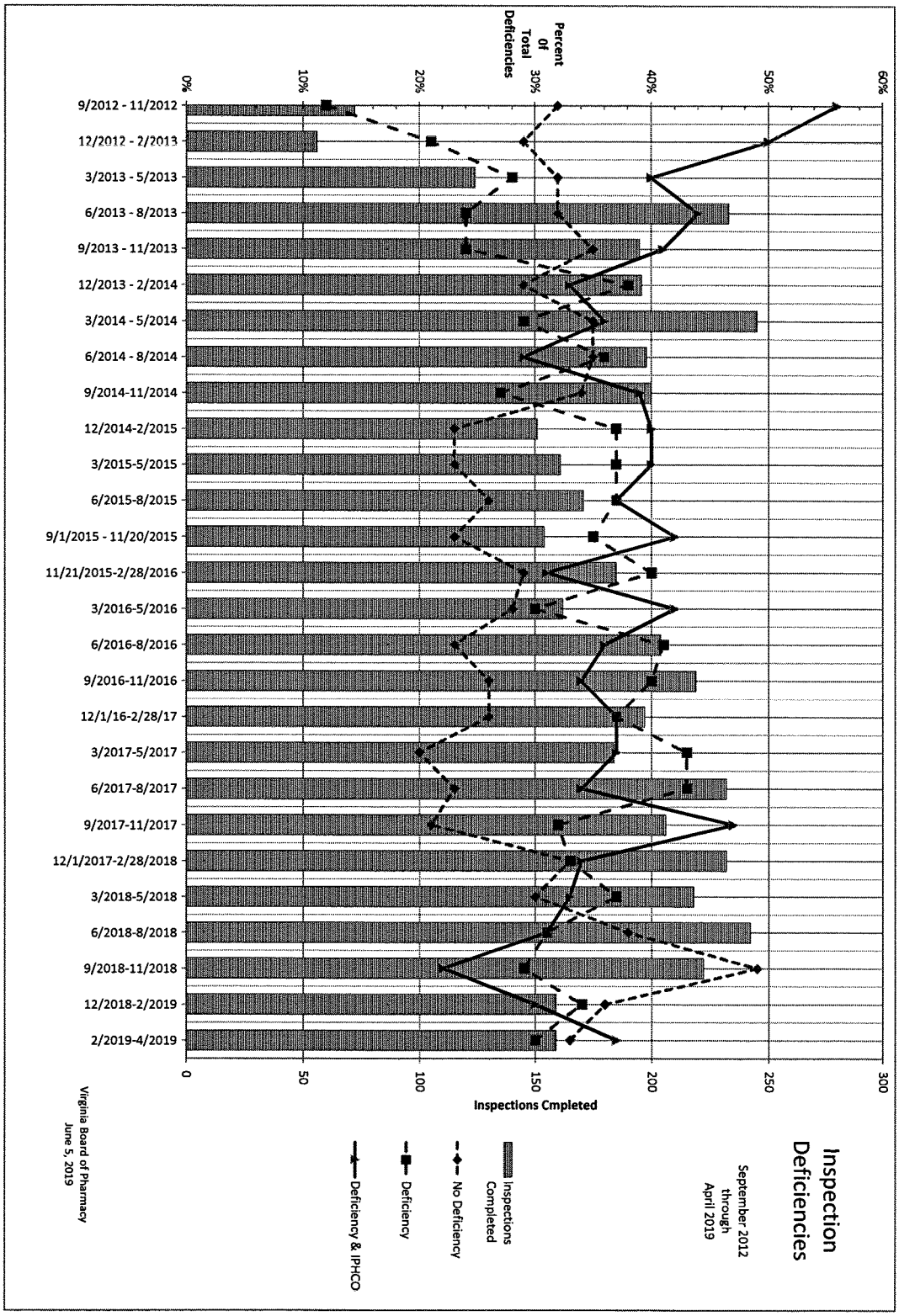
Deficiencies Above 100
(Formerly Minor Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	0	1	5	3	3	1	13		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	8	7	6	4	3	8	36	1	2
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	0	0	0	0		
Hospital specific or long-term care specific:							0		
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	0		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	1	2	1	1	0	0	5		1
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	1	0	1	4	1	3	10		
139. Emergency medical services procedures or records not in compliance	3	2	0	2	0	0	7		5
140. Emergency kit or stat-drug box procedures or records not in compliance	3	4	0	1	0	1	9		6
141. Maintaining floor stock in a long-term care facility when not authorized	0	0	0	0	0	0	0		
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	17	16	16	10	10	10	79	1	10
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	1	1	0	0	0	2		

Virginia Board of Pharmacy
Inspection Report
June 5, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19*	Total	3/19-4/19	Cumulative
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	9	9	1	0	0	0	19		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	5	0	0	0	0	5		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)	14	4	0	0	0	0	18		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	16	2	1	0	1	0	20		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)			1	3	7	2	13		3


Inspection Deficiencies
September 2012 through April 2019
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Inspections Cmpleted
Percent Of Total Deficiencies
0%
10%
20%
30%
40%
50%
60%
0
50
100
150
200
250
300
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019
2/2019-4/2019
Virginia Board of Pharmacy
June 5, 2019

Discipline Program Report

Staffing:
We will be conducting interviews for the Discipline Case Manager position later this week.

Open Cases as of 5/10/19:

Patient Care Cases	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	45	7	54	1	12	1	120
Non-Patient Care Cases	85	3	24	3	10	30	155
							275

Notes:

1) Patient care cases:
    - We have forty-five (45) patient care cases at Probable Cause as compared to thirty-two (32) that were reported in March 2019. Thirteen (13) of these cases are pending an IFC or FH.
    - Four (4) patient care cases at Probable Cause exceed 250 work days compared to three (3) reported in March 2019. (Note: This remains substantially below our 10% threshold for open cases).
    - We have twenty fewer cases at investigation compared to March 2019.
2) Non-patient care cases (inspection cases or compliance related cases)
    - We have recently started docketing cases for non-compliance as a result of the CE audit.

Upcoming Disciplinary Proceedings:

June 26, 2019	SCC-A	Rafael Saenz and Patricia Richards-Spruill
June 27, 2019	SCC-C	Cindy Warriner and Melvin Boone
July 18, 2019	SCC-B	TBD
July 25, 2019	SCC-A	TBD
July 31, 2019	Formal Hearings	All board members
August 14, 2019	Pilot SCC	TBD
August 22, 2019	Formal Hearings	All Board members
August 28, 2019	SCC-C	TBD
September 20, 2019	SCC-B	TBD
September 25, 2019	FBM/FH	All Board members

Executive Director's Report – June 5, 2019

Recent Presentations/Meetings:

- Monthly Planning Meeting for NABP/AACP Districts 1 & 2 Meeting
- March 29, 2019, RxPartnership Board Meeting
- April 11, 2019, Presentation to VCU School of Pharmacy First Year Students
- April 22-25, Rx Drug Abuse and Heroin Summit
- April 25, 2019, NABP Executive Committee Conference Call
- April 29, 2019, Presentation to VCU School of Pharmacy Law Students
- April 29, 2019, Pharmacist Inspector Training (Sammy Johnson)
- April 30, 2019, Presentation to School Nurse Coordinators
- May 1, 2019, Presentation to Students at Howard University (Beth O'Halloran)
- May 7-8, 2019, Enforcement Training, Agency Training
- May 14-18, 2019, NABP Annual Meeting
- May 21, 2019, Presentation to Board of Nursing
- May 23, 2019, Presentation to VASAP

Staffing:

- Annette Kelley started as Deputy Executive Director supervising pharmaceutical processor program
- Natasha Duncan started as Records Administrative Assistant
- Recruiting for Disciplinary Case Manager

FOR IMMEDIATE RELEASE
May 21, 2019
Media Contact: Larissa Doucette
847/391-4405; help@nabp.pharmacy

Delegates Approve Five Resolutions at the NABP 115th Annual Meeting

MOUNT PROSPECT, IL – Delegates from the member boards of pharmacy adopted five resolutions during the National Association of Boards of Pharmacy® (NABP®) 115th Annual Meeting, held May 16-18, 2019, in Minneapolis, MN. The resolutions addressed the following:

- Convening a task force of stakeholders to evaluate and make recommendations to NABP regarding the education requirements, practice responsibilities, and competence assessments for pharmacy technicians;
- Engaging stakeholders, including, but not limited to, the US Department of Health and Human Services, the National Council for Prescription Drug Programs, and the Tri-Regulator Collaborative, to encourage prescribers and pharmacists to use e-prescribing transactions, such as "RxChange" and "CancelRx," to avoid duplicative or inappropriate prescribing and medication therapy ("de-prescribing");
- Requesting Food and Drug Administration to clarify and standardize recall procedures for products prepared in 503B outsourcing facilities in accordance with the recall procedures for manufactured products; and
- Encouraging the Institute for Safe Medication Practices, the American Association of Colleges of Pharmacy, and other stakeholders to undertake efforts to obtain objective data analysis to determine the impact of workload, working conditions, and related topics on substantiated patient safety outcomes.

Additionally, a recognition resolution honoring members of the Association who have passed away was approved.

The complete text of the resolutions will be available in the Publications and Reports section of the NABP website, *www.nabp.pharmacy*, at the end of May 2019 and will also be published in the forthcoming Special Annual Meeting Issue of *Innovations®*.

NABP is the independent, international, and impartial Association that assists its state member boards and jurisdictions for the purpose of protecting the public health.