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
September 25, 2019
9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Scheduling Certain Substances: Cynthia Warriner, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
Public Hearing on Scheduling:	
• Possible Scheduling of Certain Chemicals in Schedule I of the Drug Control Act	1-2
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Cynthia Warriner, Chairman	
• Approval of Agenda	
• Approval of Previous Board Meeting Minutes:	
• June 5, 2019, Full Board Meeting	
• June 5, 2019, Public Hearing for Increase in Fees	3-10
• June 27, 2019, Special Conference Committee	11-12
• July 18, 2019, Special Conference Committee	13-15
• July 25, 2019, Special Conference Committee	16-18
• July 31, 2019, Formal Hearing	19-21
• August 14, 2019, Special Conference Committee- BOP Pilot Programs	22-24
• August 22, 2019, Formal Hearing	25-26
	27-29
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: David Brown, DC	
Update from VCU School of Pharmacy: Dean Joseph DiPiro, PharmD	
Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran	
• Update on Regulatory/Policy Actions	30
• Adoption of exempt regulation to schedule certain chemicals in Schedule I	31-43
• Adoption of emergency regulations for Pharmaceutical Processors	44-79
• Adoption of exempt regulations for Pharmaceutical Processors	80-87
• Adoption of Proposed Regulations for Labeling Dispensed Prescriptions	88-101
• Adoption of Final Regulations for Fee Increase	102-113

- Amend Guidance Document 110-7, *Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self,* and Guidance Document 110-8, *Information on Prescriptive Authority in Virginia* 114-122
- Amend Guidance Document 110-44, *Naloxone* and Guidance Document 110-1, *List of Categories of Facility Licenses,* and Repeal Guidance Document 110-45 123-141
- Consider allowances for hot and cold running water; Amend Guidance Document 110-28, Guidance for Free Clinic Pharmacy Applicants 142-143

New Business:

- Schedule Dates for 2020 Meetings 144-148

Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Inspection and Licensure Program – Caroline D. Juran 149-160
- Report on Pharmaceutical Processors – Annette Kelley 161
- Report on Disciplinary Program – Ellen B. Shinaberry 162
- Executive Director's Report – Caroline D. Juran 163

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

Adjourn

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

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

Notice of Public Hearing
Placement of Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:05 a.m. on September 25, 2019** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to September 11, 2019 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified nine (9) compounds for recommended inclusion into the Code of Virginia. We have provided a brief description, chemical name, and common name for each compound.

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

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

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

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

3. **5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. **1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

7. **3,4-methylenedioxy-N-benzylcathinone (other name: BMDP)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

June 5, 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 9:07 am.

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT:
James L. Jenkins, Jr.
Ryan Logan
Glen Bolyard
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Annette Kelley, 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 six members present, a quorum was established.

APPROVAL OF AGENDA: Mr. Saenz advised the board that the panel meeting at 1pm originally outlined in the agenda had been cancelled. He also recommended that a report from board counsel be added under the "Reports" section of the agenda. The agenda was unanimously adopted as amended.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

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

- **March 26, 2019, Full Board Meeting**

- **March 26, 2019, Public Hearing for Chemicals and Pharmaceutical Processor Regs**
- **March 28, 2019, Special Conference Committee**
- **April 16, 2019, Board Retreat**
- **April 17, 2019, Special Conference Committee**
- **May 3, 2019, Regulation Committee**
- **May 14, 2019, Special Conference Committee (motion by Ratliff, second by Boone)**

PUBLIC COMMENTS:

Christina Barrille, Executive Director, Virginia Pharmacist Association, began her comment by thanking the chairman for his leadership provided to the board over the past year. Ms. Barrille addressed the public comment offered by VPhA and VSHP to the board in a letter dated May 22, 2019 that was included in the agenda packet and asked for consideration of the suggested language for the legislative proposal addressing pharmacy technician educational standards.

Natalie Nguyen, Legislative Committee Chairman for Virginia Society of Health-System Pharmacists (VSHP) asked that the board consider the written comment provided by VSHP and VPhA regarding the pharmacy technician legislative proposal.

Monet Stanford with Kaiser Permanente offered comment on the recently passed legislation placing gabapentin into Schedule V. She inquired if dispensers would receive a grace period for coming into compliance.

DHP DIRECTOR'S REPORT:

Dr. Brown provided an update introducing the new DHP website. He shared that the new website was designed to be more user-friendly for the public. The new website functionality will also allow for board staff to amend the content directly, in lieu of coordinating with the agency IT department.

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Update on Regulatory/Policy Actions

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

Revenue and Expenditure Analysis

Ms. Yeatts provided an overview of the Revenue and Expenditure Analysis letter in the agenda packet. She stated the board has already taken action on this matter by proposing an amendment to regulations to increase licensure fees.

Report on Regulation Committee Meeting:

Recommendation on proposed regulations for labeling dispensed prescriptions

The Regulation Committee recommended adoption of the proposed regulatory language that would insert the following statement into 18VAC110-20-275(B)(2)(d): "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." However, there was discussion during the board meeting that listing only the dispensing pharmacy's name on the prescription label and not listing the name of the pharmacy where the patient picked up the prescription may create confusion for patients. It was requested that staff contact consumer groups such as Senior Connections and AARP to obtain consumer feedback on the proposed regulatory action.

ACTION ITEM:

Staff will contact consumer groups such as Senior Connections and AARP to obtain consumer feedback on the proposed regulatory action for labeling dispensed prescriptions.

MOTION:

The board voted unanimously to table the discussion until September when it could take the consumer groups' feedback into consideration. (motion by Saenz, second by Richards-Spruill)

Recommendation to adopt final regulations for Pharmaceutical processors

Staff reviewed with the board a summary of the public comments received found on pages 62-64 of the agenda packet, the Regulation Committee's recommendation, along with additional suggested amendments offered by staff for the board's consideration. Ms. Yeatts stated that it is recommended that no additional adjustment to fees be made until the program is fully operational and the board has a better idea of expenditures. She reminded the board that the pharmaceutical processor budget is separate from the Board of Pharmacy's main budget. There was discussion that a "delivery agent" could possibly be a contracted employee that otherwise complies with the laws and regulations, and that staff could consider adopting guidance or amending the regulations at a later time to provide clarification on this subject, if necessary. It was also stated that the board could potentially adopt guidance in September to recognize a valid sample size.

MOTION:

The board voted unanimously to adopt the final regulations for pharmaceutical processors as recommended by the Regulation Committee and subsequently amended as shown in [brackets] in the agenda packet. The amendments listed in the agenda packet include the following actions:

- **Amend the definition of "90-day supply" in 18VAC110-60-10 by striking "which cannot exceed 60 fluid ounces". The definition of "Batch" was added to mean "a quantity of cannabidiol oil or THC-A oil from a production lot that is identified by a batch number or other unique identifier";**
- **Insert in 18VAC110-60-20 fees for "change of ownership not requiring a criminal background $100.00" and "change of ownership requiring a criminal background check $250";**
- **Amend 18VAC110-60-150 by adding a subsection E(3) that reads: "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";**

- **Amend 18VAC110-60-220 (H) by inserting "or an agent of the processor";**
- **Amend 18VAC110-60-285 (A)(5) by striking "Any other active ingredient that constitutes at least 1.0% of the batch used in the product";**
- **Amend 18VAC110-60-285 (B) by replacing "97% to 103%" with "90 to 110%";**
- **Amend 18VAC110-60-290 (B)(2)(e) by inserting "based on stability testing";**
- **Amend 18VAC110-60-290 (B)(2)(g)((5)) by striking "Any other active in gradient that constitutes at least 1.0% of the batch used in the product, and;" and inserting "residual solvents" to subsection B(2)(h);**
- **Strike 18VAC110-60-295 in its entirety;**
- **Amend 18VAC110-60-300 (B) to read "After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board";**
- **Amend 18VAC110-60-300 (C) by striking the word "cannabis", "and eventual packaging", and "of Cannabis" in the first sentence.**
- **Amend 18VAC110-60-300 (D) by striking "include Cannabis in a cannabidiol oil or THC-A oil product or sell it" and replace with "sell a cannabidiol oil or THC-A oil product";**
- **Amend 18VAC110-60-300 (E) by replacing the term "Cannabis" with "cannabidiol oil or THC-A oil";**
- **Amend 18VAC110-60-300 (F) by replacing the term "Cannabis" with "cannabidiol oil or THC-A oil product";**
- **Amend 18VAC110-60-300 (F)(2) by striking "Cannabis" and inserting "cannabidiol oil or THC-A oil product" after "sample of";**
- **Amend 18VAC110-60-300 (F)(3) by replacing "Natural Health Products Acceptable Limits ug/kg body weight/Day" with "Limits – parts per million (ppm)";**
- **Amend 18VAC110-60-300 (F)(4) by striking "Cannabis" and inserting "of cannabidiol oil or THC-A oil product" after "sample";**
- **Amend 18VAC110-60-300(F)(5), (F)(6), (G) and (H) and 18VAC110-60-310 as presented in the agenda packet. (Warriner, second by Nelson)**

Recommendation on number of patients associated with registered agent

It was reported that the Regulation Committee did not deliberate on this topic since no action could be taken until the law becomes effective on July 1, 2019. The board agreed to table this topic until the September board meeting.

Consideration of possible 2020 legislative proposals

Pharmacy Technician Education Standards

The Regulation Committee recommended adoption of the legislative proposal included in the agenda packet. The board considered comment received and recognized that the legislative proposal did not include language to grandfather current pharmacy technician trainees.

MOTION:

The Board voted unanimously to not adopt the legislative proposal included in the agenda packet as recommended by the Regulation Committee.

The Board then focused its discussion on amending the draft legislative proposal to include language as jointly recommended by VPhA and VSHP and to address grandfathering pharmacy technician trainees. Ms. Yeatts stated that there is no need to grandfather current pharmacy technician registrants since they have already satisfied compliance with current standards for obtaining a pharmacy technician registration. It was determined that the delayed effective date should be established in regulation, not in the legislative proposal.

MOTION:

The board voted unanimously to direct staff to draft a legislative proposal on pharmacy technician education standards that requires (i) completion of a training program that meets accreditation standards approved by the Board or operated through a federal services, (ii) passing a national examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association, (iii) grandfathers pharmacy technician trainees enrolled in a board-approved training program prior to the effective date of the requirements, and (iv) requires the board to promulgate emergency regulations for implementation. (motion by Ratliff, Second by Richards-Spruill)

Compounding of Essentially Copies

The Regulation Committee recommended the board to adopt the legislative proposal to amend §54.1-3410.2 as presented on page 152 of the agenda packet.

MOTION:

The Board voted unanimously to adopt the legislative proposal as presented that would amend §54.1-3410.2 by striking from (H)(2), "or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;".

Telepharmacy

The Regulation Committee recommended that the board take no action on a legislative proposal to address telepharmacy at this time. No action was taken by the Board.

White/Brown Bagging

The board has already adopted proposed regulation on this subject. The Regulation Committee recommended that the board take no additional action on this subject at this time. No action was taken by

the Board.

CONSIDERATION OF COMMENTS RECEIVED DURING PERIODIC RRGULATORY REVIEW THAT EXCEED THE SCOPE OF NOIRA

Ms. Yeatts recommended to the board that it take no action at this time since the board has numerous regulatory actions in place. The board determined that the Regulation Committee should consider these comments at a future meeting.

GUIDANCE DOCUMENT 110-1, CATEGORIES OF FACILITY LICENSURE

Staff recommended language as found on page 156 of the agenda packet to amend Guidance Document 110-1 to include additional licensure categories that were recently implemented.

MOTION:

The board voted unanimously to adopt Guidance Document 110-1, *Categories of Facility Licensure*, as presented. (motion by Warriner, second by Boone)

GUIDANCE DOCUMENT 110-36, COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Based on comments offered by USP at the recent NABP annual meeting, staff is recommending the board amend Guidance Document 110-36 to clarify that enforcement of USP Chapter 800 standards will primarily apply to compounding. Enforcement of Chapter 800 may also apply to repackaging if the proposed regulation requiring repackaging to comply with USP standards becomes final. There was discussion that question #63 should be deleted as it may not be written clearly.

MOTION:

The board voted unanimously to adopt Guidance Document 110-36 as presented and amended by striking question #63. (motion by Nelson, second by Ratliff)

NEW BUSINESS

Election of Chairman and Vice-Chairman

MOTION:

The board voted unanimously to elect Ms. Warriner as Chairman. (motion by Boone, second by Richards-Spruill)

The board voted unanimously to elect Mr. Ratliff as Vice-Chairman. (motion by Nelson, second by Boone)

Schedule dates for 2020 Meetings

Tentative dates were provided on pages 178-181 of the agenda packet for the board to review and confirm eligibility. Because four members were not in attendance, it was decided to email the dates to the full board for determining availability.

REPORTS

Chairman's Report	Mr. Saenz shared his experience attending the NABP Annual meeting, noting Ms. Juran's recent election as Treasurer of NABP. He also shared that the June board meeting was his last board meeting as his term expires June 30, 2019.
Report on Board of Health Professions	Ms. Juran provided an update on behalf of Mr. Logan.
Report on Inspection and Licensure Program	Ms. O' Halloran provided an overview of the update included in the agenda packet.
Report on Disciplinary Program	Ms. Shinaberry provided an overview of the update included in the agenda packet. She noted that the Disciplinary Case Manager position interviews were conducted on June 7, 2019. Ms. Shinaberry also stated that the CE audits were in process which may cause an increase in case load moving forward.
Executive Director's Report	Ms. Juran provided an overview of the update included in the agenda packet. She shared information regarding the upcoming NABP District 1 & 2 Meeting in Vermont and encouraged attendance. Ms. Juran also shared her experiences at the Rx Drug Summit in Atlanta, GA.
Board Counsel's Report	Mr. Rutkowski provided the board with an update on the appeal for pharmaceutical processors, alerting the board of the upcoming court date scheduled for June 7, 2019.
Motion:	**The board voted unanimously to enter into closed session pursuant to §2.2-3711(A)(11) to consult with counsel regarding actual or probable litigation. Additionally, it was moved that Caroline Juran, Sammy Johnson, Beth O'Halloran, Ellen Shinaberry, Annette Kelley, and Kiara Christian attend the closed meeting because their presence was deemed necessary and would aid the Board. (motion by Nelson, second by Richards-Spruill)**
Motion:	**The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Nelson, second by Warriner)**
Jane P. Wright Registration No. 0202-010363	A Possible Summary Suspension was held in the matter of Jane P. Wright to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacist in Virginia.

DECISION: Upon a motion by Ms. Warriner, and duly seconded by Ms. Nelson, the panel voted unanimously that, with the evidence presented, the practice as a pharmacist by Jane Wright, poses a substantial threat to the public; and therefore the license of Ms. Wright shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Wright for the revocation of her pharmacist license.

James Misenko

License No.

0202-010856

Consideration of consent order

DECISION: Upon a motion by Ms. Warriner, and duly seconded by Mr. Ratliff, the panel voted unanimously to accept the consent order for revocation of his pharmacist license.

Taylors Pharmacy dba Florida Discount Drug

Permit No. 0214-001420

Consideration of consent order

DECISION: Upon a motion by Mr. Ratliff, and duly second by Ms. Nelson, the panel voted unanimously to accept the consent order to reinstate the non-resident pharmacy registration.

ADJOURN: With all business concluded, the meeting adjourned at 12:52 pm.

Rafael Saenz, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR INCREASE IN FEES

June 5, 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 hearing was called to order at 9:03 a.m.

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT:
James L. Jenkins, Jr.
Glenn L. Bolyard, Jr.
Ryan K. Logan
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, 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 the proposed regulations to increase fees.

The Board of Pharmacy proposes to increase their fees to cover expenses for essential functions of review of applications, licensing, inspections, investigation of complaints against licensees, and adjudication and monitoring of disciplinary cases

required for public health and safety in the commonwealth. Copies of the proposed fee increases were provided in the agenda packet. Mr. Saenz shared that the public comment period for this topic closes as of July 6, 2019.

PUBLIC COMMENT: No public comment was offered.

ADJOURN: The public hearing adjourned at 9:07 am.

Rafael Saenz, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, June 27, 2019
Commonwealth Conference Center
Second Floor
Hearing Room 5

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 10:05 am.
PRESIDING:	Kris Ratliff, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Mykl Egan, DHP Adjudication Specialist Ileita Redd, Discipline Program Specialist
JENNIFER RUNK JIMMERSON License No. 0202-012177	Jennifer R. Jimmerson, pharmacist, appeared on her own behalf to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 19, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, 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 Jennifer R. Jimmerson. Additionally, she moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order for completion of continuing education requirements.
AMBER CLUTTER Registration No. 0230-032069	Amber Clutter, pharmacy technician, did not appear and was not represented at the informal conference to discuss allegations that she 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 Mr. Boone, 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 Amber Clutter. 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 Mr. Boone and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order to issue a Reprimand.
JAMES RIVERS License No. 0202-005001	James Rivers, pharmacist, appeared on his own behalf to consider his application for reinstatement of his pharmacist license and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 13, 2019 Notice.
Closed Meeting:	Upon a motion Mr. Boone, 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 James Rivers. Additionally, she moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Boone and duly seconded Mr. Ratliff, the Committee voted unanimously enter an Order for reinstatement pending certain terms and conditions.

ADJOURNED: 1:37 pm

_____
Kris Ratliff, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday July 18, 2019
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:45 a.m.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	Glenn L. Bolyard, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Claire Foley, DHP Adjudication Specialist
PRINCE WILLIAM RX, INC. d/b/a/ PROSPERITY PHARMACY Permit No. 0201-004275	Vinod Patel, Pharmacist-in-Charge of Prosperity Pharmacy, did not appear to discuss allegations that Prosperity Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 29, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Prosperity Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code §2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to issue a monetary penalty with certain terms and conditions.
FERESHTEH EJTEMAI License No.: 0202-010147	Fereshteh Ejtemai, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 15, 2019 Notice. She was represented by Michael Goodman, Esq. and Nora Ciancio, Esq.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Fereshteh Ejtemai. Additionally, he moved that J. Samuel Johnson, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to issue a reprimand, a monetary penalty, and additional continuing education for Ms. Ejtemai.

ADJOURNED: 12:15 PM

Patricia Richards-Spruill, Chair

J. Samuel Johnson
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday July 25, 2019
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:04 a.m.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	Glenn L. Bolyard, Committee Member
STAFF PRESENT:	Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Claire Foley, DHP Adjudication Specialist
GIHAN W. SERAKA License No.: 0202-204419	Gihan W. Seraka, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy, and to review her compliance with the Order of the Board of Pharmacy entered June 12, 2018, as stated in the June 14, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Gihan W. Seraka. Additionally, he moved that Ellen Shinaberry, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code §2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing.
HUDGINS PHARMACY Permit No. 0201-002220	Chiquita Loving, Pharmacist-in-Charge of Hudgins Pharmacy, did not appear to discuss allegations that Hudgins Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 11, 2019 Notice. The pharmacy was represented by Gerald C. Canaan, II, Esq.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Hudgins Pharmacy. Additionally, he moved that Ellen Shinaberry, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to issue a monetary penalty.

ADJOURNED: 11:38 AM

Patricia Richards-Spruill, Chair

Date

Ellen Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

July 31, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:15 a.m.

PRESIDING: Kris Ratliff, Chair

MEMBERS PRESENT:
Glenn Bolyard
Cheryl Nelson
Rafael Saenz
Rebecca Thornbury

STAFF PRESENT:
Caroline Juran, Executive Director, Board of Pharmacy
Kiara Christian, Admin Asst, Board of Pharmacy
Sean Murphy, Assistant Attorney General
James Rutkowski, Assistant Attorney General
Jessica Kelley, Adjudication Specialist, APD

QUORUM: With seven (5) members of the Board present, a panel was established.

FORMAL HEARING

QUORUM: With five (5) members of the Board present, a panel was established.

TERESSA A. ANTHONY
License #: 0202-011697

A formal hearing was held in the matter of Teressa A. Anthony, pharmacist, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia. Ms. Anthony did not appear on her own behalf and was not represented by counsel.

Jessica Kelley, DHP Adjudication Specialist, presented the case.

Kathy Ward, Substance Abuse Case Manager, HPMP, testified in person on behalf of the Commonwealth.

John Turner, Senior Investigator, DHP and Jody

Alperin, Clinical Psychologist, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Teressa Anthony. Additionally, she moved that Caroline Juran, Kiara Christian, and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Mr. Saenz and duly seconded by Ms. Nelson, the Board unanimously voted to suspend the pharmacist license of Teressa A. Anthony indefinitely for no less than 1 year.

POSSIBLE SUMMARY SUSPENSION

ADDITIONAL MEMBERS PRESENT:

Cynthia Warriner (joined via telephone at 11:55 AM). A quorum of the Board was established with six (6) members present.

JENNY E. GREEAR
Registration No. 0230- 031874

Sean Murphy, Assistant Attorney General, along with Jessica Kelley, Adjudication Specialist, presented a summary of the evidence in the case for the Board to consider a summary suspension.

DECISION:

Upon a motion by Ms. Warriner and duly seconded by Mr. Saenz, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Jenny E. Greear poses a substantial danger to the public; and therefore, the license of Ms. Greear shall be summarily suspended, and that a Consent Order shall be offered to Ms. Greear for the revocation of her registration to practice as a pharmacy technician, in lieu of a formal administrative hearing.

POSSIBLE SUMMARY SUSPENSION

LINDESHA A. CARNEY Registration No. 0230-029411	Sean Murphy, Assistant Attorney General, along with Jessica Kelley, Adjudication Specialist, presented a summary of the evidence in the case for the Board to consider a summary suspension.
DECISION:	Upon a motion by Ms. Warriner and duly seconded by Mr. Saenz, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Lindesha A. Carney poses a substantial danger to the public; and therefore, the license of Ms. Carney shall be summarily suspended, and that a Consent Order shall be offered to Ms. Carney for the revocation of her registration to practice as a pharmacy technician, in lieu of a formal administrative hearing.

CONSIDERATION OF CONSENT ORDER

MARK F. MORRELL License No. 0202207369	Ms. Shinaberry presented a Consent Order for in the matter of Mark F. Morell.
DECISION:	Upon a motion by Ms. Warriner and duly seconded by Mr. Bolyard the Board unanimously voted to accept the Consent Order.
ADJOURNED:	With all business concluded, the meeting adjourned at 12:20 PM.

Kris Ratliff, Chair	Caroline D. Juran Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

August 14, 2019

Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of an informal conference committee of the Board of Pharmacy was called to order at 11:23 AM.
PRESIDING:	Cynthia Warriner, Committee Chairman
MEMBER PRESENT:	Ryan Logan
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Anne Joseph, DHP Adjudication Specialist Kiara Christian, Executive Assistant
Kroger Pharmacy #523 Technician Product Verification (TPV)	Alexis Page, PharmD, Community-based Pharmacy Leadership and Management Fellow with Kroger; Michele Fountain, PharmD, Regional Clinical Manager for Kroger Pharmacy; David Flammia, Pharmacy Practice Coordinator for Kroger Pharmacy; Chris Koon, Pharmacy/Health & Wellness Merchandiser for Kroger Pharmacy; Anne Harrison, Pharmacy Manager for Kroger Pharmacy; Wylie Crane, PharmD Candidate, VCU School of Pharmacy class of 2020 were present to discuss the application, received April 18, 2019, for approval of an Innovative (Pilot) program from Kroger Pharmacy. Kroger Pharmacy is seeking permission to move forward with a Technician Product Verification pilot at six Kroger Pharmacies located in the state of Virginia. Kroger Pharmacy is seeking a waiver of 18VAC110-20-270 subsection C of the regulations governing the Practice of Pharmacy dealing with dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians, and § 54.1-3300 (A)(6) dealing with Acts Restricted to Pharmacist.
Discussion:	Representatives of Kroger Pharmacy presented information about the current Technician Product Verification pilot they are currently conducting in the state of Tennessee. The pilot began May 1, 2019.

Decision:	After consideration of the application and statements concerning the proposed Innovative (Pilot) program the board requested additional information prior to making a final decision. The board will reconvene on September 24, 2019 at 3:00 PM for further discussion.
ADJOURN:	With all business concluded, the meeting adjourned at 2:07 PM.

Cynthia Warriner
Committee Chairman

Date

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

August 22, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

Call to Order:	A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 10:05 a.m.
Presiding:	Cynthia Warriner, Chair
Members Present:	Kristopher Ratliff Glenn Bolyard Cheryl Nelson Patricia Richards-Spruill Melvin Boone
Staff Present:	Ellen Shinaberry, Deputy Executive Director Mykl Egan, Disciplinary Case Manager James Rutkowski, Assistant Attorney General Jessica Kelley, Adjudication Specialist, APD Kiara Christian, Executive Assistant
Quorum:	With six (6) members of the Board present, a quorum was established.

FORMAL HEARING

Lindesha A. Carney Registration #: 0230-029411	A formal hearing was held in the matter of Lindesha A. Carney, Pharmacy Technician, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Mr. Bolyard, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation in the matter of Ms. Carney. Additionally, he moved that Kiara Christian, Ellen Shinaberry, Mykl Egan and Jim

Rutkowski attend the closed meeting.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced that the board would move forward with the proceedings. (Motion by Ratliff, Second by Boone)

Jessica Kelley, DHP Adjudication Specialist, presented the case.

Ashley Hester, Senior Investigator, DHP, testified in person on behalf of the Commonwealth.

Lauren Lee Walker, Staff Pharmacist, CVS #5986, testified in person on behalf of the Commonwealth.

Lynwood Bird, Regional Loss Prevention Officer, CVS Pharmacy, testified in person on behalf of the Commonwealth.

Closed Meeting: Upon a motion by Mr. Ratliff, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Lindesha A. Carney. Additionally, he moved that Kiara Christian, Ellen Shinaberry, Mykl Egan and Jim Rutkowski attend the closed meeting.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Ratliff, Second by Boone)

Proposed Finding of Facts: Upon a motion by Ms. Richards-Spruill and duly seconded by Mr. Boone, the Board unanimously voted to accept the proposed findings of facts as amended by the board.

Decision:	Upon a motion by Ms., Nelson, duly seconded by Mr. Bolyard, the board unanimously voted to impose a revocation of the Pharmacy Technician registration issued 10/06/2016 to Lindesha A. Carney

CONSIDERATION OF CONSENT ORDERS

Marley Drug, Inc. Permit No.: 0214001534 Gwynn D. Parkinson Registration No.:	Ms. Shinaberry presented a Consent Order for reinstatement of the pharmacy permit for Marley Drug, Inc. and a Consent Order for Gywnn D. Parkinson, pharmacy technician
DECISION	Upon a motion by Ms. Nelson and duly seconded by Mr. Boone, the Board unanimously voted to accept the Consent Orders in the above referenced matters to reinstate the non-resident pharmacy permit for Marley Drug, Inc. and to accept the voluntary surrender for indefinite surrender of the right to renew the pharmacy technician registration for Gwynn D. Parkinson.
ADJOURNED	With all business concluded, the meeting adjourned at 11:37 am.

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

Board of Pharmacy
Chart of Regulatory Actions as of August 22, 2019

Board of Pharmacy		
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* *Board to adopt proposed regulations: 9/25/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *Register Date: 5/27/19* *Comment closed: 6/26/19* *Board to adopt final regulations: 9/25/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *At Secretary's Office for 69 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for pharmacy to be operational within 90 days [Action 5080] Fast-Track - *Register Date: 7/8/19* *Regulation effective: 8/22/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Amending definition of "cold" [Action 5210] Fast-Track - *Register Date: 6/10/19* *Regulation effective: 7/25/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 456 days*
[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 Governor's Office for 80 days*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *At Secretary's Office for 71 days* *Replacement of emergency regulation*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New Regulations Governing Pharmaceutical Processors [Action 4695] Final - *Register Date: 7/8/19* *Regulation effective: 8/7/19*

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

Staff Note:

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

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of regulation to schedule certain chemicals

Board action:

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

Notice of Public Hearing
Placement of Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:05 a.m. on September 25, 2019** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to September 11, 2019 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified nine (9) compounds for recommended inclusion into the Code of Virginia. We have provided a brief description, chemical name, and common name for each compound.

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

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

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

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

3. **5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. **1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

7. **3,4-methylenedioxy-N-benzylcathinone (other name: BMDP)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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

Project 6087 - none

BOARD OF PHARMACY

Chemicals in Schedule I

18VAC110-20-322. Placement of chemicals in Schedule I.

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

~~1. 2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

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

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

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

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

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

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

~~7. Synthetic opioids:~~

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

~~b. 3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~c. 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino) cyclohexyl]-N-methylacetamide (other name: U-48800), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~8. Central nervous system stimulants:~~

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

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

~~The placement of drugs listed in this subsection shall remain in effect until August 21, 2019, unless enacted into law in the Drug Control Act.~~

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

~~1. Research chemicals:~~

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

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

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

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

~~2. Synthetic opioids:~~

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

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

c. N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4piperidinyl]-propanamide (other name: 4phenylfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until December 12, 2019, unless enacted into law in the Drug Control Act.

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

1. 2,5-dimethoxy-4-chloroamphetamine (other name: DOC), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Synthetic opioids:

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

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

~~c. N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: Isobutyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~d. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

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

~~3. Cannabimimetic agent: 1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide (other name: 4-cyano CUMYL-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~4. Benzodiazepine: Flualprazolam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until March 4, 2020, unless enacted into law in the Drug Control Act.~~

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

~~1. Synthetic opioid: N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.~~

~~2. Cannabimimetic agent: N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

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

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

1. Synthetic opioid: N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Research chemicals:

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

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

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

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

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

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

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

1. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

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

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

The placement of drugs listed in this subsection shall remain in effect until December 25, 2020, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids.

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

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

2. Research chemicals.

a. 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence

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

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

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

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

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

3. Cannabimimetic agents.

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

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

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

Agenda Item: Emergency Action – Regulations for Pharmaceutical Processors

Enclosed:

Copy of SB1719 of the 2019 General Assembly

Copy of amendments relating to registration of agents and wholesale distribution

Staff note:

SB1719 requires the adoption of emergency regulations regarding the registration of agents for patients certified to receive cannabidiol or THC-A oil and provides for wholesale distribution of oils between processors.

Board action:

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

CHAPTER 690

An Act to amend and reenact §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; registered agent; pharmaceutical processors.

[S 1719]

Approved March 21, 2019

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

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

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

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

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

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

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

A. As used in this section:

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

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine.

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

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

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

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the

patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

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

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

G. *A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.*

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

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

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

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

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

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

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

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

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil

to a registered patient, *his registered agent,* or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; ~~and~~ (xi) a process for registering a cannabidiol oil and THC-A oil product*; and (xii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors.*

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

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

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

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

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

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3, *(ii) such patient's registered agent,* or ~~(ii)~~ *(iii)* if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, *registered agent,* parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, *registered agent,* parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, *registered agent,* parent, or legal guardian; and the current board registration issued to the patient, *registered agent,* parent, or legal guardian. No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

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

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

D. ~~A pharmaceutical processor shall ensure that the~~ *The* concentration of tetrahydrocannabinol in any THC-A oil on site ~~is within~~ *may be up to* 10 percent ~~of~~ *greater than or less than* the level of tetrahydrocannabinol measured for labeling ~~and~~. *A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and* shall establish a stability testing schedule of THC-A oil.

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.

Project 6129 - none

BOARD OF PHARMACY

Registered agent and wholesale distribution

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.

"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 registered agent 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, or registered agent.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

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

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

18VAC110-60-20. Fees.

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

B. Registration of practitioner.

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

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

1. Initial registration of a patient.	$50
2. Annual renewal of registration of a patient.	$50
3. Initial registration of a parent or legal guardian.	$25
4. Annual renewal of registration of a parent or guardian.	$25
5. Initial registration or annual renewal of a registered agent.	$25
~~5.~~ 6. Replacement of registration for a qualifying patient, parent, ~~or~~ legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed.	$25

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000

4. Change of name of processor.	$100
5. Change of PIC or any other information provided on the permit application.	$100
6. Change of ownership not requiring a criminal background check.	$100
7. Change of ownership requiring a criminal background check.	$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
9. Reinspection fee.	$1,000
10. Registration of each cannabidiol oil or THC-A oil product.	$25

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, or registered agent 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, or registered agent.

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

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

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

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

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

5. Payment of the appropriate fees; and

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

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

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

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

3. Payment of the applicable fee; and

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

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

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

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

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

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

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

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

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

5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabidiol oil or THC-A 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, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

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

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

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

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

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

A. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall exercise reasonable caution to transport and 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, or registered agent 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, or registered agent shall complete such disposal by one of the following methods:

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

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

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

The board may revoke or suspend the registration of a registrant (patient, parent, ~~or~~ legal guardian, or registered agent) under the following circumstances:

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

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

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

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

6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;

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

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

9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or notified the board of such change more than ~~14~~ 15 days after the change; or

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

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, or registered agent, except as required for a registered agent to act on behalf of a patient;

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

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

Part IV

Requirements for Pharmaceutical Processor Personnel

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

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

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

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

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

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

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

4. The measuring of the oil to be dispensed;

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

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

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

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

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils as authorized by the PIC or as otherwise authorized in law.

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

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

G. A 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.

18VAC110-60-190. 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, or registered agent 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, or registered agents:

a. Pharmaceutical processor permit;

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

c. The price of all cannabidiol oil or THC-A 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, or registered agent, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

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

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

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

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

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

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

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

H. A pharmacist shall counsel registered patients, parents, ~~and~~ legal guardians, and registered agents, if applicable, regarding the use of 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, except for the wholesale distribution of cannabidiol oil or THC-A oil products between pharmaceutical processors;

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

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

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

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

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

1. Name and location of the processor;

2. Contact information for the processor;

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

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

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

F. No person except a pharmaceutical processor employee or a registered patient, parent, ~~or~~ legal guardian, or registered agent shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting

laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

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

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

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

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

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

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

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

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor prior to commencing business shall:

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

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

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

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

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

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

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

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

18VAC110-60-251. Wholesale distribution of cannabidiol and THC-A oil products.

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

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

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

C. A pharmaceutical processor wholesale distributing cannabidiol oil or THC-A oil products shall store, handle, and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-20-250.

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

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

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

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

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

degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

B. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

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

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

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

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

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

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

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

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

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

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

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal 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 cannabidiol oil or THC-A oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

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

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

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

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

1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, ~~or~~ legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the processor.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, ~~or~~ legal guardian,

or registered agent shall receive more than a 90-day supply of cannabidiol oil or THC-A oil for a patient in a 90-day period from any pharmaceutical processor.

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:

1. A serial number assigned to the dispensing of the oil;

2. The brand name of cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;

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

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

5. The quantity of cannabidiol oil or THC-A oil dispensed;

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

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

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

9. The name and registration number of the certifying practitioner;

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

11. The name or initials of the dispensing pharmacist;

12. Name, address, and telephone number of the pharmaceutical processor;

13. Any necessary cautionary statement; and

14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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

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

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

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

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

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

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 pharmaceutical processor 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, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

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

B. A pharmaceutical processor 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, or registered agent where applicable, and the practitioner who certified the patient;

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

e. Recommended changes to pharmaceutical processor 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.

Agenda Item: Exempt Actions – Regulations for Pharmaceutical Processors

Enclosed:

Copy of SB1719 of the 2019 General Assembly

Copy of amendments to sections 130 and 170

Staff note:

SB1719 allows:

1) A processor to employ individuals with less than two years of experience to perform certain tasks under supervision.
2) A processor to begin cultivation as soon as a permit is issued.

Board action:

Adoption of amendments to conform regulations to changes in the Code of Virginia

CHAPTER 690

An Act to amend and reenact §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; registered agent; pharmaceutical processors.

[S 1719]

Approved March 21, 2019

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1, 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

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

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

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

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

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

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

A. As used in this section:

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

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine.

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

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

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

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the

patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

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

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

G. *A patient, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian, may designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.*

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

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

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

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

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

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

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

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

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil

to a registered patient, *his registered agent,* or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; ~~and~~ (xi) a process for registering a cannabidiol oil and THC-A oil product*; and (xii) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors*.

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

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

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

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

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

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3, *(ii) such patient's registered agent,* or ~~(ii)~~ *(iii)* if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, *registered agent,* parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, *registered agent,* parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, *registered agent,* parent, or legal guardian; and the current board registration issued to the patient, *registered agent,* parent, or legal guardian. No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

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

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

D. ~~A pharmaceutical processor shall ensure that the~~ *The* concentration of tetrahydrocannabinol in any THC-A oil on site ~~is within~~ *may be up to* 10 percent ~~of~~ *greater than or less than* the level of tetrahydrocannabinol measured for labeling ~~and~~. *A pharmaceutical processor shall ensure that such concentration in any THC-A onsite is within such range and* shall establish a stability testing schedule of THC-A oil.

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.

Project 6128 - none

BOARD OF PHARMACY

Exempt actions 2019

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~~ a processor may begin cultivation of Cannabis. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. 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.

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

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

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

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

~~J.~~ K. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor unless such license or registration has been reinstated and is current and unrestricted.

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

Staff Note:

As requested at the last Board meeting, a letter (copy included) requesting comment on the draft regulation was sent to:

1. Senior Connections
2. Virginia Citizens Consumer Council
3. Virginia Association of Area Agencies on Aging
4. Virginia Navigators
5. Virginia AARP

There were no comments in response.

Enclosed:

Copy of letter sent to senior/consumer groups

Proposed amendment to section 275

Board action:

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

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

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

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

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

Respond to the following questions:

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

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

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

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

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

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

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

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

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

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

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

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

Signature:	Date: 7/21/2017

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

September 28, 2017

Joseph Lavino
1 CVS Drive, Mail Code 2325
Woonsocket, RI 01887

Dear Mr. Lavino:

The Virginia Board of Pharmacy would like to thank you for submission of a petition for rule-making to amend regulations pertaining to the identification of a pharmacy or pharmacies on a prescription label.

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on October 30, 2017. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until November 22, 2017.

Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for December 11, 2017, and you will be informed of the Board's decision on your request after that meeting.

Again, the Board appreciates your interest in amending the regulations governing the practice of pharmacy.

Very truly yours,

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy

cc: Elaine J. Yeatts
Agency Regulatory Coordinator

Copy

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

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TEL (804) 367-4400
FAX (804) 527-4475

June 25, 2019

Virginia Citizens Consumer Council
Ms. Irene Leech, President
4220 Northfork Road
Elliston, VA 24087-3224

Dear Ms. Leech:

The Virginia Board of Pharmacy has voted to amend its regulations in response to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. All the required information about the **dispensing** pharmacy would be on the label. The petitioner noted that identification of multiple pharmacies on the label is confusing, and the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board is considering an amendment to its regulation to safeguard patient health and safety and wants to ensure that a prescription label contains pertinent information. Comment received thus far has been generally supportive of the petitioner's request.

A few board members expressed concern that patients, particularly senior citizens, might also want identifying information about the pharmacy holding the prescription for pick-up or delivery on the label, in addition to the identifying information for the pharmacy responsible for dispensing the medication. They asked that we contact certain groups to see if there were concerns. We would appreciate receiving any comment you may have by July 19, 2019.

You may send comment to me at: Department of Health Professions, 9960 Mayland Drive, Henrico, VA 23233 or by email to: Elaine.yeatts@dhp.virginia.gov. Please feel free to contact me at (804) 367-4688 if you have questions. Thanks.

Sincerely,

Elaine J. Yeatts

Elaine J. Yeatts
Senior Policy Analyst

cc: Caroline Juran
Executive Director, Board of Pharmacy

COPY

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

June 25, 2019

Virginia Association of Area Agencies on Aging
24 East Cary Street, Suite 100
Richmond, VA 23219

Dear Sir or Madame:

The Virginia Board of Pharmacy has voted to amend its regulations in response to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. All the required information about the **dispensing** pharmacy would be on the label. The petitioner noted that identification of multiple pharmacies on the label is confusing, and the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board is considering an amendment to its regulation to safeguard patient health and safety and wants to ensure that a prescription label contains pertinent information. Comment received thus far has been generally supportive of the petitioner's request.

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Sincerely,

Elaine J. Yeatts

Elaine J. Yeatts
Senior Policy Analyst

cc: Caroline Juran
Executive Director, Board of Pharmacy

Copy

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

June 25, 2019

Virginia Navigators
Adrienne Johnson, Executive Director
7501 Boulders View Drive, Suite 630
North Chesterfield, VA 23225

Dear Ms. Johnson:

The Virginia Board of Pharmacy has voted to amend its regulations in response to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. All the required information about the **dispensing** pharmacy would be on the label. The petitioner noted that identification of multiple pharmacies on the label is confusing, and the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board is considering an amendment to its regulation to safeguard patient health and safety and wants to ensure that a prescription label contains pertinent information. Comment received thus far has been generally supportive of the petitioner's request.

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Sincerely,

Elaine J. Yeatts

Elaine J. Yeatts
Senior Policy Analyst

cc: Caroline Juran
Executive Director, Board of Pharmacy

Copy

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

June 25, 2019

Senior Connections
Director: Thelma Watson
24 E. Cary Street
Richmond, VA 23219

Dear Ms. Watson:

The Virginia Board of Pharmacy has voted to amend its regulations in response to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. All the required information about the **dispensing** pharmacy would be on the label. The petitioner noted that identification of multiple pharmacies on the label is confusing, and the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board is considering an amendment to its regulation to safeguard patient health and safety and wants to ensure that a prescription label contains pertinent information. Comment received thus far has been generally supportive of the petitioner's request.

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Sincerely,

Elaine J. Yeatts

Elaine J. Yeatts
Senior Policy Analyst

✓

cc: Caroline Juran
Executive Director, Board of Pharmacy

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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

June 25, 2019

AARP - AARP Virginia State Office
707 East Main Street, Suite 910
Richmond, VA 23219

Attn: Ginger Thompson, Communications Director

Dear Ms. Thompson:

The Virginia Board of Pharmacy has voted to amend its regulations in response to a petition for rulemaking from CVS Health to eliminate a requirement for a pharmacy that is only holding a prescription for pick-up or delivery to a consumer to be identified on the prescription label. All the required information about the **dispensing** pharmacy would be on the label. The petitioner noted that identification of multiple pharmacies on the label is confusing, and the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board is considering an amendment to its regulation to safeguard patient health and safety and wants to ensure that a prescription label contains pertinent information. Comment received thus far has been generally supportive of the petitioner's request.

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Sincerely,

Elaine J. Yeatts

Elaine J. Yeatts
Senior Policy Analyst

cc: Caroline Juran
Executive Director, Board of Pharmacy

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: Adoption of final amendments for Fee increase:

Included in your agenda package is:

Copy of proposed action summary

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

Staff note:

A public hearing was conducted on 6/5/19; comments were accepted from 5/27/19 to 7/26/19. No comment was received.

Board action:

To adopt the proposed amendments to increase fees as a final action

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action: Increase in fees

Proposed Stage

Action 4938 / Stage 8270

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	5/8/2019 2:54 pm	Sync Text with RIS
Agency Statement	4/19/2018	Upload / Replace
Attorney General Certification	5/1/2018	
DPB Economic Impact Analysis	6/15/2018	
Agency Response to EIA	8/22/2018	Upload / Replace
Governor's Review Memo	5/8/2019	
Registrar Transmittal	5/8/2019	

Status	
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: 4/19/2018 Review Completed: 5/1/2018 Result: Certified
DPB Review	Submitted on 5/1/2018 Economist: Larry Getzler Policy Analyst: Jeannine Rose Review Completed: 6/15/2018 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 11/25/2018
Governor's Review	Review Completed: 5/8/2019 Result: Approved
Virginia Registrar	Submitted on 5/8/2019 The Virginia Register of Regulations Publication Date: 5/27/2019 Volume: 35 Issue: 20
Public Hearings	06/05/2019 9:05 AM

Comment Period	Ended 7/26/2019
	0 comments

Contact Information

Name / Title	Caroline Juran, RPh / *Executive Director*
Address: :	9960 Mayland Drive
	Suite 300 Richmond, VA 23233-1463
Email Address	caroline.juran@dhp.virginia.gov
Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

This person is the primary contact for this chapter.
This stage was created by Elaine J. Yeatts on 04/19/2018
16

Project 5322 - Proposed

BOARD OF PHARMACY

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.~~ 11. Innovative program continued approval based on board order not to exceed ~~$200~~ $260 per approval period.	
~~13.~~ 12. Approval of a pharmacy technician training program	~~$75~~ $100 every two years
~~14.~~ 13. 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
9. Nonresident warehouser registration	~~$270~~ $350
10. Nonresident third-party logistics provider 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
9. Nonresident warehouser registration	~~$270~~ $350
10. Nonresident third-party logistics provider 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
9. Nonresident warehouser registration	~~$90~~ $120
10. Nonresident third-party logistics provider 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
i. Nonresident warehouser registration	~~$240~~ $315
j. Nonresident third-party logistics provider 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.

Agenda item: Revision of guidance documents

Enclosed:

An amended draft of Guidance Documents 110-07 and 110-08

Staff note:

There are no substantive changes in these documents; text is revised for clarity and updated language. Text of the statute is also revised to be current.

Guidance documents have to be posted for a 30-day comment period, so the effective date will be at the conclusion of that period unless there are comments that object to the Board's action.

Board action:

Adoption of amendments to Guidance Documents 110-07 and 110-08.

VIRGINIA BOARD OF PHARMACY

PRACTITIONER/PATIENT RELATIONSHIP AND THE PRESCRIBING OF DRUGS FOR FAMILY OR SELF

~~In October 2005, the Board of Medicine promulgated regulations regarding a practitioner prescribing for self or family that replaced a previous guidance document on this subject. Section 18 VAC 85-20-25 applies to practitioners of medicine, osteopathic medicine, and podiatry. The same language was also included in the regulations for physician assistants and nurse practitioners. This issue has not been addressed in regulations of the Boards of Dentistry, however, in order to be a valid prescription, the requirements of §54.1-3303 would need to be met. The Board of Optometry addressed this issue in Regulation 18VAC105-20-40.~~

Several health regulatory boards that license prescribers have adopted regulations regarding a practitioner prescribing for self or family. Regulations for the Board of Medicine (18VAC85-20-25) apply to practitioners of medicine, osteopathic medicine, and podiatry. Identical language is included in regulations for physician assistants (18VAC85-50-176) and nurse practitioners (18VAC90-40-121). The Board of Optometry addressed this issue in 18VAC105-20-40.
While this issue has not been specifically addressed in regulations of the Board of Dentistry, the requirements of §54.1-3303 would need to be met by all prescribers in order for there to be a valid prescription.

18VAC85-20-25. Treating and prescribing for self or family

A. Treating or prescribing shall be based on a bona fide practitioner-patient relationship, and prescribing shall meet the criteria set forth in § 54.1-3303 of the Code of Virginia.

B. A practitioner shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.

C. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

18VAC105-20-40. Standards of conduct.

The board has the authority to deny, suspend, revoke, or otherwise discipline a licensee for a violation of the following standards of conduct. A licensed optometrist shall:

9. Treat or prescribe based on a bona fide practitioner-patient relationship consistent with criteria set forth in § 54.1-3303 of the Code of Virginia. A licensee shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.

Section of 54.1-3303 (B) from the Code of Virginia

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

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

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.

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

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

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the

instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

Virginia Board of Pharmacy

Prescriptive Authority in Virginia

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

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

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

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

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

Nurse practitioners or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For nurse practitioners, there is a 10-digit license number beginning with 0017, which should be on the prescription and can be verified through the web site www.dhp.virginia.gov under "on-line license lookup" and checking the occupation "Authorization to Prescribe." For physician assistants, there is a 10-digit license number beginning with 011, which can be verified through the web site www.dhp.virginia.gov under "on-line license lookup" and checking the occupation "Physician Assistant."

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

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

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV and VI narcotic and non-narcotic agents.

2. Topically administered Schedule VI agents:
    a. Alpha-adrenergic blocking agents;
    b. Anesthetic (including esters and amides);
    c. Anti-allergy (including antihistamines and mast cell stabilizers);
    d. Anti-fungal;
    e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
    f. Anti-infective (including antibiotics and antivirals);
    g. Anti-inflammatory;
    h. Cycloplegics and mydriatics;
    i. Decongestants; and
    j. Immunosuppressive agents.
3. Orally administered Schedule VI agents:
    a. Aminocaproic acids (including antifibrinolytic agents);
    b. Anti-allergy (including antihistamines and leukotriene inhibitors);
    c. Anti-fungal;
    d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
    e. Anti-infective (including antibiotics and antivirals);
    f. Anti-inflammatory (including steroidal and non-steroidal);
    g. Decongestants; and
    h. Immunosuppressive agents.

Schedule V drugs are excluded from the list of therapeutic pharmaceutical agents.

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

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

from the Code of Virginia:

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

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

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

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.

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

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

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

premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

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

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

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

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

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

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

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

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

I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450

and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

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

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

Agenda item: Revision of guidance documents

Enclosed:

An amended draft of Guidance Documents 110-44 and 110-1

Current version of Guidance Document 110-45 and 110-44

Staff note:

Because of substantial changes in the Code relating to the dispensing and distribution of naloxone, the protocols adopted by the Board for such activities need to be amended. The draft combines both 110-44 and 110-45 into one document in an effort to streamline the information and reduce any possible confusion with having two separate protocols. Additionally, minor edits are necessary in Guidance Document 110-1 as a result of the statutory requirements for obtaining a controlled substances registration when certain entities dispense naloxone.

Possible Board action:

Adopt amendments to Guidance Documents 110-44 and 110-1 as presented or as amended, and repeal Guidance Document 110-45

§ 54.1-3408. Professional use by practitioners. (Excerpt)

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Y. Notwithstanding any other law or regulation to the contrary, a person 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 dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Virginia Board of Pharmacy

Naloxone Protocols

54.1-3408 (X) and (Y) authorize certain persons to dispense naloxone pursuant to an order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements.

§54.1-3408

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Y. Notwithstanding any other law or regulation to the contrary, a person 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 dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may

occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 54.1-3408 (X)

a. Authorized Dispensers

The following individuals may dispense naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of §54.1-3408:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- School nurses,
- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services, and
- Firefighters.

b. Required Training

i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate

on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.

ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
   1. Name of entity or group of entities authorized to dispense naloxone pursuant to standing order;
   2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
   3. Prescriber's signature;
   4. Date of issuance; and
   5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

d. <u>Required Labeling and Recordkeeping</u>

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.

iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

e. <u>Required Instruction</u>

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

II. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in 54.1-3408 (Y)

a. Authorized Dispensers

The following individuals who are 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, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;
- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.

b. Training

- While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.
- Those persons acting on behalf of such organization and who intend to dispense injectable naloxone formulation with a hypodermic needle or syringe, must first complete training developed by and be authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:
   1. Name of organization authorized to dispense naloxone pursuant to standing order;
   2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
   3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
   4. Prescriber's signature;
   5. Date of issuance; and
   6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	Injection*
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. **Required Labeling, Recordkeeping, and Storage**

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The standing order must be maintained for two years from the last date of dispensing.

iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).

v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. **Required Instruction**

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

ii. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone to Entities Authorized to Possess, Administer, and Dispense Naloxone

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:

i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1;

ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services,

school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or

iii. Persons who are 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 and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials
e. Dispensers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

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.

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 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 that only distribute prescription devices, and no prescription drugs.

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 that 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 injectable naloxone ~~reversal~~ with a hypodermic needle and syringe 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

Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities

Pharmacists shall follow this protocol when dispensing naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose as authorized in subsection X of §54.1-3408.

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling unless the pharmacist is able to verify successful completion of the REVIVE! training program. If the naloxone is dispensed upon discharge from a hospital or delivered by a pharmacy to an alternate delivery site, e.g., a local health department, and the recipient has not completed the REVIVE! training program, the aforementioned counseling shall be provided by a pharmacist, physician, nurse practitioner, physician assistant, nurse, or an approved trainer of the REVIVE! training program within the hospital or at the alternate delivery site.
   b) The pharmacist shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

2) **Product Selection:** The pharmacist who dispenses naloxone pursuant to an oral, written or standing order shall dispense the drug and other items, if applicable, as prescribed and in accordance with this protocol.

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order issued to a specific individual, a pharmacist may dispense naloxone pursuant to a standing order. The standing order may be issued by an individual prescriber to a specific pharmacy or pharmacies, or the standing order may be issued by the Health Commissioner to all pharmacies located and permitted in Virginia. The standing order authorizes a pharmacist to dispense one or more of the specified naloxone formulations to any person seeking to obtain naloxone. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   a) Name of pharmacy authorized to dispense naloxone pursuant to standing order if the standing order is issued by a prescriber for a particular pharmacy or pharmacies;
   b) Contents to be dispensed, to include quantity of drug and directions for administration;
   c) Prescriber's signature; and
   d) Date of issuance.

4) Dispensing Requirements for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

Optional items include rescue breathing masks, and latex-free gloves.

5) Labeling and Records:

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation. A standing order issued by an individual prescriber or the Health Commissioner shall be maintained by the pharmacist for two years from the date of the last dispensing prior to expiration or discontinuation of the standing order.

Protocol for Distributing to Law-Enforcement Officers, Firefighters, and Employees of the Department of Forensic Science, Office of the Chief Medical Examiner, and Department of General Services Division of Consolidated Laboratory Services

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to:

1. Designated employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, and employees of the Department of General Services Division of Consolidated Laboratory Services who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services; or

2. Designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department.

Training shall be conducted in accordance with policies and procedures of the law enforcement agency, fire department, Department of Forensic Science, Office of the Chief Medical Examiner, or the Department of General Services Division of Consolidated Laboratory Services.

Resources:

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

Protocol for the Prescribing of Naloxone and Dispensing by Trainers

Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for opioid overdose reversal shall follow this protocol when dispensing naloxone, and the hypodermic needles and syringes required for injecting such naloxone, to a person, without charge or compensation, for administration to another person believed to be experiencing or about to experience a life-threatening opioid overdose as authorized in § 54.1-3408 (Y), §54.1-3466(F), and §54.1-3467(C). ***Note: Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol may dispense injectable naloxone with hypodermic needles and syringes.***

1) **Controlled Substances Registration:** An organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal on whose behalf an authorized trainer may dispense naloxone pursuant to a standing order shall apply for a controlled substances registration certificate from the Board of Pharmacy. The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration certificate.

2) **Standing Order:** An authorized trainer may dispense naloxone, and the hypodermic needles and syringes required for injecting such naloxone, pursuant to a standing order. The standing order must be issued by an individual prescriber to the organization on whose behalf the authorized trainer is acting. The standing order authorizes a trainer to dispense one or more of the specified naloxone formulations, and may authorize the dispensing of hypodermic needles and syringes for injecting such naloxone, to any person seeking to obtain naloxone following completion of a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services. A standing order is valid for no more than two years from the date of issuance and must contain the following information at a minimum:
   - **a.** Name of organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy on whose behalf the authorized trainer may dispense naloxone pursuant to the standing order;
   - **b.** Drug name, strength, quantity of naloxone to be dispensed, and directions for administration. If hypodermic needles and syringes are to be dispensed for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in part 3 of this protocol;
   - **c.** Prescriber's signature; and

d. Date of issuance.

3) Dispensing Requirements for Intranasal, Auto-Injector, or Injectable Administration:

Intranasal	Auto-Injector	Intranasal	Injection*
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.

**** Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of hypodermic needles and syringes, and who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol may dispense injectable naloxone with hypodermic needles and syringes.***

Optional items include rescue breathing masks, and latex-free gloves.

Trainers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

4) Storage, Labeling, Dispensing, and Recordkeeping:

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone, and hypodermic needles and syringes for injecting such naloxone, for opioid overdose reversal pursuant to §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) shall maintain the following records:

1. The prescriber's standing order issued in accordance with §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) authorizing the trained individual to dispense naloxone, and hypodermic needles and syringes for injecting such naloxone.
2. Invoices or other records showing receipts of naloxone, hypodermic needles, and syringes must be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone, description and quantity of hypodermic needles, and syringes transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer, name of trained individual approved by the Department of Behavioral Health and Developmental Services.
4. Record of dispensing indicating name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, description and quantity of hypodermic needles and syringes, if dispensed, and name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

B. The naloxone, hypodermic needles, and syringes shall be labeled with directions for use in accordance with prescriber's standing order, date of dispensing, name of person receiving drug, drug name, strength, name and telephone number for the entity associated with the controlled substances registration.

C. The trainer shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf Additionally, when dispensing injectable naloxone with hypodermic needles and syringes, the trainer shall provide the current REVIVE! brochure on proper disposal of hypodermic needles and syringes.

D. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

E. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate must ensure compliance with any recall procedures as issued by the manufacturer, United States Food and Drug Administration, or Board to

ensure affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

F. Except for a prescriber's standing order which must be maintained on-site for a period of not less than two years from the date of the last dispensing, records must be filed chronologically and maintained for a period of not less than two years from the date of transaction.

Resources:

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

Agenda item: Consider allowances for hot and cold running water; Amend Guidance Document 110-28, Guidance for Free Clinic Pharmacy Applicants

Enclosed:

An amended draft of Guidance Document 110-28

Staff note:

Staff is requesting guidance on the use of a bathroom sink by a physician selling controlled substances or a pharmacy when complying with the requirement for hot and cold running water.

Virginia Board of Pharmacy
Guidance for Free Clinic Pharmacy Applicants

Free clinics applying for a pharmacy permit which do not have a need for a full service pharmacy should apply for a special or limited-use permit as described in section 18 VAC 10-20-120 of the Virginia Board of Pharmacy Regulations and submit the required information with the application and fee. While waivers are granted by the Board on an individual case basis after considering the merit of each such request, the Board will normally waive certain provisions of the below regulation for free clinic pharmacies:

18 VAC 110-20-150-Physical Standards

- the size requirement of 240 square feet provided there is adequate room inside the enclosure for both storage of drug inventory, equipment, and records and for working space.

- the sink being inside the pharmacy provided there is a sink with hot and cold running water in close proximity ~~which is not a bathroom sink~~. A sink located in a bathroom may satisfy compliance if for handwashing purposes only, but shall not be approved if the pharmacy is performing compounding.

The Board typically requires that the provisions of 18 VAC 110-20-180 concerning the burglar alarm system and 18 VAC 110-20-190 concerning enclosures be met. A free clinic pharmacy may request a waiver of 18 VAC 110-20-190 (C) for the purpose of securing a drug order in the pharmacy if it is absolutely necessary that drugs be delivered in the absence of a pharmacist or for the purpose of repairing or upgrading essential pharmacy equipment when those repairs or upgrades cannot be reasonably performed while a pharmacist is present. A request for this waiver will be very closely scrutinized and granted at the discretion of the Board, if deemed necessary and appropriate, and only then under the specific conditions of 18 VAC 110-20-120 (B).

Full Board Meeting Dates 2020

Highlighted- There is a quorum

Dates in red not included on doodle survey

March 2020 **FBM**	**3** Rebecca Melvin Cindy Patricia Kristopher Glen	**4** Ryan Glen Rebecca Cheryl Cindy Kristopher	**10** Glen Melvin Cindy Patricia	**9** New possible Date	**11** Ryan Glenn Melvin Cindy Kristopher	**24** New possible Date	**25** New possible Date	
June 2020 **FBM**	**9** Glen Rebecca Melvin Cindy	**11** Glen Rebecca Melvin Cindy Kristopher	**15** New possible Date	**16** New possible Date	**23** Glen Melvin Cindy Patricia Kristopher	**24** Ryan Glen Melvin Cheryl Cindy Patricia Kristopher	**25** Glen Melvin Cindy Patricia Kristopher	**30** New possible Date
September 2020 **FBM**	**1** Glenn Cindy Kristopher	**2** Ryan Glen Rebecca Melvin Cheryl Cindy Kristopher	**8** Glen Melvin Cindy Patricia	**9** Ryan Glenn Rebecca Melvin Cheryl Cindy Patricia Kristopher	**15** New possible Date	**23** New possible Date	**29** New possible Date	

Full Board Meeting Dates 2020

Highlighted- There is a quorum

Dates in red not included on doodle survey

December 2020 FBM	7 New possible Date	9 New possible Date	10 Ryan Glen Rebecca Melvin Cheryl Cindy Patricia Kristopher	15 Glen Melvin Cindy Patricia Kristopher	17 Glenn Melvin Cindy Kristopher	18 New possible Date

Tentative 2020 Formal Hearing Dates

Highlighted- There is a quorum

Dates in red not included on doodle survey

January 2020 **FH**	**7** Glen Melvin Cindy Patricia	**8** Glen Ryan Melvin Cindy Cheryl	**14** Glen Melvin Cindy Patricia Kristopher	**21** New possible Date	**22** Glen Ryan Cindy Cheryl Kristopher		
February 2020 **FH**	**4** Glen Melvin Cindy Patricia Kristopher	**5** Ryan Glen Melvin Cindy Cheryl Kristopher	**11** Glen Melvin Cindy Patricia	**12** Ryan Melvin Cindy Glen	**18** New Possible Date		
April 2020 **FH**	**1** Glen Ryan Melvin Cindy Kris	**14** Glenn Cindy	**21** Glenn Cindy Patricia Kristopher	**22** Glen Ryan Melvin Cindy Cheryl Patricia Kristopher	**29** New possible Date		
May 2020 **FH** (Regulatory meeting this month)	**1** Glen Ryan Melvin Cindy Cheryl Kristopher	**4** Glen Melvin Cindy Patricia Kristopher	**5** Glen Melvin Cindy Patricia Kristopher	**11** Glen Melvin Cindy Patricia Kristopher	**13** New possible date	**21** Glen Melvin Cindy Kristopher	**22** Glen Ryan Melvin Cindy Cheryl Patricia Kristopher
May contd..	**28** Glen Melvin Cindy Kristopher	**29** Glen Ryan Melvin Cindy Kristopher					

July 2020 **FH**	**1** Glen Ryan Melvin Cindy Kristopher	**7** Glenn Cindy Patricia Kristopher	**8** Glen Ryan Cindy Kristopher	**14** Glen Cheryl Cindy Patricia	**21** New possible date	**24** New Possible Date
August 2020 **FH**	**4** Glen Melvin Cindy Patricia Kristopher	**5** Glen Ryan Melvin Cheryl Cindy Kristopher	**12** Glen Ryan Melvin Cindy	**18** Glen Melvin Cindy Patricia Kristopher	**26** New Possible Date	**27** New Possible Date
October 2020 **FH**	**6** Glenn Melvin Cheryl Cindy Patricia Kristopher	**7** Glenn Ryan Melvin Cheryl Kristopher	**14** Ryan Glenn Cindy	**20** Glenn Melvin Patricia Cindy Kristopher	**28** New Possible Date	**29** New possible date
November 2020 **FH** (Regulatory meeting this month)	**2** Glen Cindy Patricia Kristopher	**3** Glen Melvin Cindy Patricia Kristopher	**4** Ryan Glenn Melvin Cindy Kristopher	**9** Cheryl Nelson	**12** Glen Melvin Cindy Cheryl Patricia Kristopher	**20** New Possible Date

Regulatory Meeting Tentative 2020 Dates

(Formal hearings are also these months)

Highlighted- There is a quorum

May 2020 **Reg Meeting**	**1** Glenn Cheryl Kristopher	**4** Glenn Patricia Kristopher	**5** Glenn Patricia Kristopher	**11** Glenn Patricia Kristopher	**13** New possible date
May contd..	**21** Glenn Melvin Kristopher	**22** Glenn Cheryl Patricia Kristopher	**28** Glenn Kristopher	**29** Glen Kristopher	

November 2020 **Reg. Meeting**	**2** Glen Patricia Kristopher	**3** Glen Patricia Kristopher	**4** Glenn Kristopher	**9** Cheryl Nelson	**12** Glen Cheryl Patricia Kristopher	**20** New Possible Date

Kristopher, Glenn, Patricia, Cheryl, Rebecca

Virginia Board of Pharmacy
Inspection Report
September 25, 2019

Licenses Issued

	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	5/1/19-7/31/19	License Count 9/3/2019
Business CSR	86	50	59	41	19	36	1,398
CE Courses	1	0	2	0	0	0	9
Limited Use Pharmacy Technician	0	0	1	0	0	0	11
Medical Equipment Supplier	5	4	1	2	1	3	226
Nonresident Manufacturer	20	4	7	24	8	11	171
Nonresident Medical Equipment Supplier	12	12	9	10	5	30	346
Non-resident Outsourcing Facility	9	1	2	0	0	1	28
Non-resident Pharmacy	35	33	27	24	22	27	776
Non-resident Third Party Logistics Provider					8	58	84
Non-resident Warehouser					6	10	24
Non-resident Wholesale Distributor	22	16	12	13	3	22	658
Non-restricted Manufacturer	0	0	1	1	1	2	31
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	157	439	250	157	134	316	15,506
Pharmacist Volunteer Registration	0	2	0	0	0	2	0
Pharmacy	15	18	21	13	7	13	1,798
Pharmacy Intern	115	140	189	122	74	65	1,605
Pharmacy Technician	363	420	378	388	249	426	13,709
Pharmacy Technician Training Program	3	2	4	3	2	3	138
Physician Selling Controlled Substances	55	25	42	44	7	25	658
Physician Selling Drugs Location	10	10	4	8	3	7	173
Pilot Programs	0	1	0	0	2	1	23
Registered Physician For CBD/THC-A Oil		118	83	40	25	52	337
Repackaging Training Program	0	0	0	0	1	0	2
Restricted Manufacturer	0	0	0	1	0	1	48
Third Party Logistics Provider	1	0	1	0	0	1	5
Warehouser	3	10	7	9	0	0	109
Wholesale Distributor	0	3	0	0	0	1	68
Total	**912**	**1,308**	**1,100**	**900**	**577**	**1,113**	**37,941**

Virginia Board of Pharmacy
Inspection Report
September 25, 2019

Inspections Completed

	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		5/1/19-7/31/19	
License Type												
Controlled Substances Registration	182		120		174		164		83		145	
Medical Equipment Supplier	22		25		19		10		11		21	
Non-restricted Manufacturer	0		0		3		3		1		3	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	22		31		38		30		11		39	
Restricted Manufacturer	2		0		0		1		0		1	
Third Party Logistics Provider	1		0		2		1		0		1	
Warehouse	11		14		12		10		7		10	
Wholesale Distributor	3		7		7		9		2		11	
Pharmacy	291		328		306		227		207		348	
Pilot	1		0		1		0		1		0	
Total	**535**		**525**		**562**		**455**		**323**		**579**	
Pharmacy (0201) Inspections												
Change of Location	5		9		7		0		0		7	
New	15		19		18		12		6		13	
Reinspection	8		6		13		14		4		9	
Remodel	43		31		42		40		38		53	
Routine	218		242		222		159		159		253	
Focus	2		1		4		0		0		2	
Federal Agency	0		18		0		0		0		11	
Compliance	0		2		0		2		0		0	
Pilot	0		0		0		0		0		0	
Total	**291**		**328**		**306**		**227**		**207**		**348**	
Pharmacy Routine Inspections												
No Deficiency	66	30%	93	38%	109	49%	57	36%	53	33%	98	39%
Deficiency	80	37%	75	31%	64	29%	55	34%	47	34%	76	30%
Deficiency & IPHCO	72	33%	74	31%	49	22%	47	30%	59	37%	79	31%
Total	**218**		**242**		**222**		**159**		**159**		**253**	

Virginia Board of Pharmacy
September 25, 2019
Frequently Cited Deficiencies
March 2018 - July 2019

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	127
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	56
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
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	36
7. Change of location or remodel of pharmacy without submitting application or Board approval	34
20. Pharmacist not checking and documenting repackaging or bulk packaging	28
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	26
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	26
12. Storage of prescription drugs not in the prescription department	23
20a. Pharmacist not documenting final verification of non-sterile compounding	22
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)	180
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.	141
127. Repackaging records and labeling not kept as required or in compliance	102
108. Emergency access alarm code/key not maintained in compliance	77
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	76
123. Engaging in remote processing not in compliance	67
124. Labels do not include all required information	67
130a. Compounded products not properly labeled	60
122. Engaging in alternate delivery not in compliance	54
130. Required compounding/dispensing/distribution records not complete and properly maintained	42

Virginia Board of Pharmacy
Inspection Report
September 25, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
Routine Inspections Completed	**218**	**242**	**222**	**159**	**159**	**253**	**1253**	**Repeat**	**Repeat**
Total Deficiencies	**115**	**123**	**83**	**60**	**101**	**123**	**605**	**10**	**232**
Average Deficiencies per Inspection	**0.5**	**0.5**	**0.4**	**0.4**	**0.6**	**0.5**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	2	0	1	2	0	7		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	3	9	12	6	12	14	56		2
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	2	2	7	2	5	1	19		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	2	0	0	0	1	1	4		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	1	1	0	0	2	5		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	1	0	0	1	2		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	6	7	3	2	5	11	34		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	0	1	1	1	1	0	4		1
9. Alarm not operational or not being set	1	1	0	0	1	0	3		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	0	1	1	0	3	2	7		1

Virginia Board of Pharmacy
Inspection Report
September 25, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	2	2	1	0	4	2	11		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	0	1	1	1	2	3	8		
12. Storage of prescription drugs not in the prescription department	8	5	1	1	3	5	23	1	10
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	1	5	0	0	4	3	13		4
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	5	2	0	2	3	8	20		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)	5	16	9	8	9	6	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	17	24	20	16	19	31	127	5	107
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	7	6	2	3	4	4	26		4
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	2	2	0	2	1	0	7		
18. Records of dispensing not maintained as required	3	4	2	3	2	1	15		1

Virginia Board of Pharmacy
Inspection Report
September 25, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	0	1	0	1	0	2	4		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	7	4	4	0	3	10	28	2	17
20a. Pharmacist not documenting final verification of non-sterile compounding	5	3	3	1	5	5	22	1	4
20b. Pharmacist not documenting final verification of sterile compounding	2	5	3	1	3	1	15		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	1	0	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.	1	1	0	2	0	0	4		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	1	0	0	0	0	0	1		
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	1	0	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

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September 25, 2019

Deficiencies 1 - 100
(Formerly Major Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	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.	8	5	4	2	3	4	26		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	1	1	0	0	1	0	3		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	2	3	0	0	1	1	7		1
29. Unlawful compounding for further distribution by other entities	3	3	0	1	0	1	8		
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	14	4	6	4	4	4	36	1	16
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	3	1	1	0	0	0	5		1

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Deficiencies Above 100
(Formerly Minor Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
Routine Inspections Completed	**218**	**242**	**222**	**159**	**159**	**253**	**1253**	**Repeat**	**Repeat**
Total Deficiencies	**259**	**228**	**160**	**160**	**150**	**238**	**957**	**18**	**305**
Average Deficiencies per Inspection	**1.2**	**0.9**	**0.7**	**1.0**	**0.9**	**0.9**	**0.8**		
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.	6	4	1	7	1	3	22		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	5	3	1	1	0	1	11		7
106. Prescription department substantially not clean and sanitary and in good repair	0	0	1	2	0	2	5		2
107. Current dispensing reference not maintained	1	3	1	6	4	2	17		10
108. Emergency access alarm code/key not maintained in compliance	17	15	8	8	9	20	77	1	18
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	38	38	24	26	23	31	180	5	43
110. Storage of paraphernalia/Rx devices not in compliance	0	0	1	0	0	0	1		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	1	1	0	1	2	0	5		2
112. Biennial taken late but within 30 days	3	1	3	2	2	2	13		
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.	28	32	26	20	14	21	141	3	55

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Deficiencies Above 100
(Formerly Minor Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	4	7	2	0	0	1	14		
115. Other records of distributions not maintained as required	2	1	0	0	2	0	5		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	4	4	2	4	7	12	33		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	0	0	0	0	0	1	1		
119. Not properly documenting partial filling of prescriptions	8	4	4	5	3	13	37		24
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	0	0	1	2	0	0	3		
122. Engaging in alternate delivery not in compliance	15	16	9	6	5	3	54		7
123. Engaging in remote processing not in compliance	12	7	4	8	11	25	67	3	7
124. Labels do not include all required information	17	16	10	7	5	12	67		13
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	5	3	0	8	4	8	28	1	8
126. Special packaging not used or no documentation of request for non-special packaging	2	1	0	0	0	2	5	1	5
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	21	18	17	9	17	20	102		27
128. Unit dose procedures or records not in compliance	0	0	2	0	0	0	2		
129. Robotic pharmacy systems not in compliance	0	2	0	0	1	0	3		
130. Required compounding/dispensing/distribution records not complete and properly maintained	8	9	6	4	6	9	42	1	13
130a. Compounded products not properly labeled	9	10	9	9	9	14	60	2	13

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

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	1	5	3	3	1	1	14		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	7	6	4	3	8	7	35		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	2	1	1	0	0	0	4		1
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	0	1	4	1	3	2	11		
139. Emergency medical services procedures or records not in compliance	2	0	2	0	0	1	5		5
140. Emergency kit or stat-drug box procedures or records not in compliance	4	0	1	0	1	0	6		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	16	16	10	10	10	14	76	1	11
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	1	1	0	0	0	0	2		

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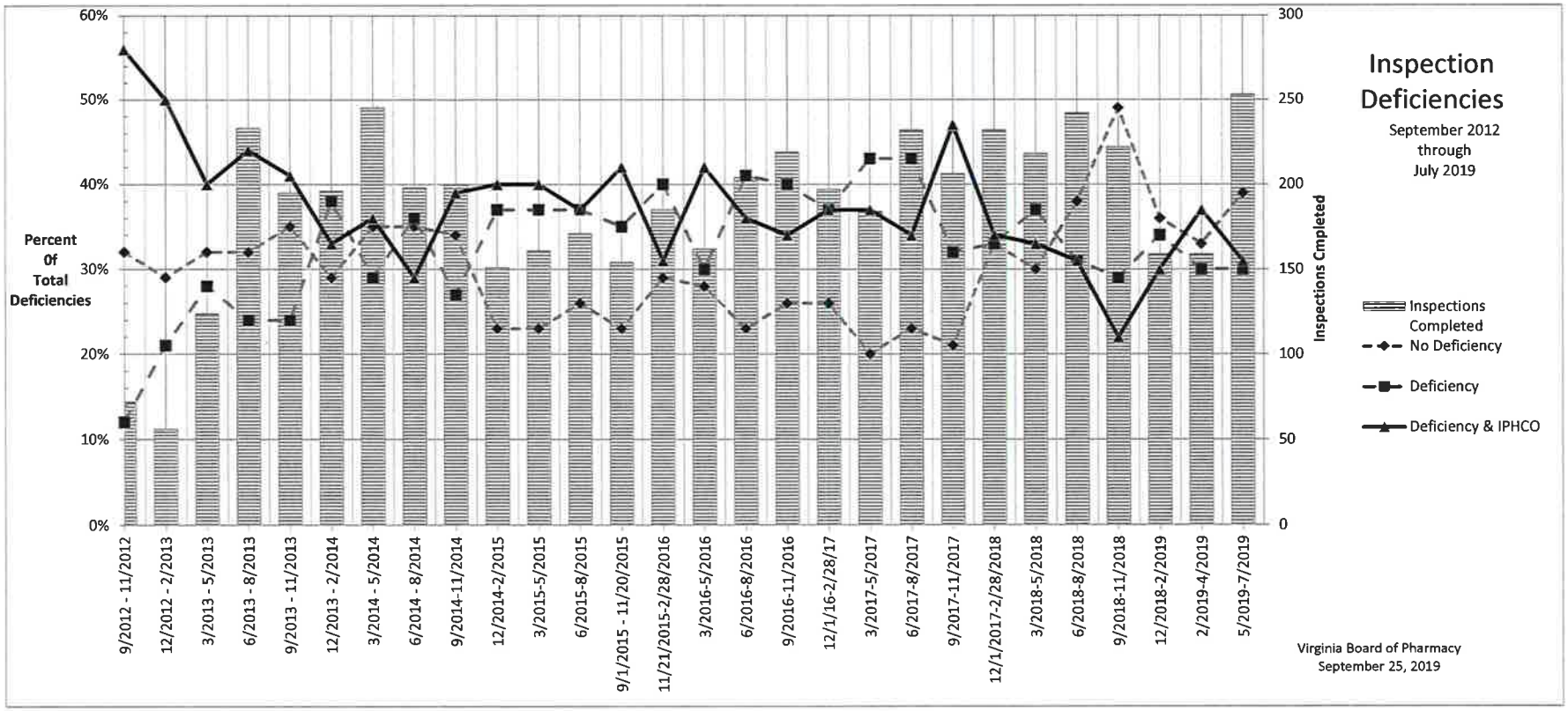
Deficiencies Above 100
(Formerly Minor Deficiency)

	3/18-5/18	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	Total	5/19-7/19	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	1	0	0	0	0	10		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	5	0	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)	4	0	0	0	0	0	4		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	2	1	0	1	0	0	4		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)		1	3	7	2	11	24		3


Inspection Deficiencies
September 2012 through July 2019
Percent Of Total Deficiencies
Inspections Cmpleted
60%
50%
40%
30%
20%
10%
0%
300
250
200
150
100
50
0
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
5/2019-7/2019
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Virginia Board of Pharmacy
September 25, 2019

Pharmaceutical Processors Report-September 25, 2019

- Continued participation on the Secretary of Health and Human Resources/Secretary of Agriculture and Forestry workgroup to review and recommend appropriate structure for oversight of industrial hemp products. Public meeting was held on 9/4/19. Report is due by 11/1/19 to the Chairmen of the Senate Committees on Agriculture, Conservation and Natural Resources and Education and Health and the House Committees on Agriculture, Chesapeake and Natural Resources and Health, Welfare and Institutions.
- Ongoing work to establish the CBD/THC-A patient and product registration verification process through the Prescription Monitoring Program.
- Coordination with the Department of Education to develop a standardized form to be available to each school board to use for students required to access CBD/THC-A oil products during the school day.
- Emergency and Exempt regulatory actions have been developed to address 2019 legislative requirements for the Regulations Governing Pharmaceutical Processors.
- Initial steps have been taken in the recruitment for a program admin specialist for the Pharmaceutical Processors program.
- Ongoing development of processor, patient, parent/guardian and registered agent related forms for use in the Pharmaceutical Processor program.
- Pharmaceutical Processor Inspection Report has been completed and sent to the Pharmaceutical Processors.

Pharmaceutical Processors Program-By the Numbers
As of 9/6/19

Registered Practitioners	341
Registered Patients	975
Registered Parents/Guardians	21
Pending applications for Patients	240
Pending applications for Parents/Guardians	15

Discipline Program Report

Staffing:
Mykl Egan has recently been hired as the Board's Discipline Case Manager.

Open Cases as of 8/30/19:

~~*APD – 1 case~~

Patient Care Cases	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	22	6	84	2	4	0	118
Non-Patient Care Cases	65	8	55	3	9	22	163*
							281

Notes:

1) Patient care cases:
   - We have twenty-two (22) patient care cases at Probable Cause as compared to forty-five (45) that were reported in June 2019. Six (6) of these cases are pending an IFC or FH.
   - We have a twice the number of cases at investigation as compared to June 2019.
2) Non-patient care cases (inspection cases or compliance related cases)
   - This number is slightly higher due to the CE audit.
3) Cases greater than 250 work days: We have twenty (20) cases exceeding 250 work days. Of this number, eight (8) cases are at a status of formal/informal hearing, seven (7) cases are at investigation, and four (4) cases are at probable cause.

Upcoming Disciplinary Proceedings:

October 9, 2019	Formal Hearing	
October 23, 2019	SCC-A	Patricia Richards-Spruill & Glenn Bolyard
November 13, 2019	Pilot Committee	Cindy Warriner & Ryan Logan
November 14, 2019	SCC-B	Kris Ratliff & Melvin Boone
November 21, 2019	Regulation Committee/Formal Hearings	
December 3, 2019	Full Board Meeting/Formal Hearings	

Executive Director's Report – September 25, 2019

Recent/Upcoming Presentations and Meetings:

- Monthly Planning Meetings for NABP/AACP Districts 1 & 2 Meeting
- June 17-18, 2019, NABP Orientation for New Executive Committee Members, IL
- June 20, 2019, BOP Staff Retreat, VA
- July 16-17, 2019, NABP PMPi Meeting, IL
- July 17-19, 2019, APhA Consensus Conference (Shinaberry), IL
- August 13, 2019, CBD Presentation to Board of Physical Therapy
- August 16-17, 2019, VPhA Annual Meeting, VA (O'Halloran, Shinaberry, Juran)
- August 23-25, 2019, NABP Executive Committee Retreat/Strategic Meeting, MN
- August 27, 2019, DHP Executive Directors' Retreat, VA
- September 12, 2019, CBD Presentation to ICF/IIDs
- September 19-21, 2019, NABP/AACP Districts 1 & 2 Meeting, VT
- September 26-27, 2019, Tri-Regulator Meeting, TX
- September 30-October 2, 2019, NABP Interactive Executive Director Forum, IL
- October 3, 2019, Joint Commission on Health Care Meeting, VA
- October 5, 2019, VCU Presentation on CBD, VA
- October 10-11, 2019, FDA Intergovernmental Meetings on DQSA (O'Halloran/Juran), MD
- October 21-24, 2019, National Association of State Controlled Substances Authorities, Richmond, VA

Staffing:

- Mykl Egan has started as Disciplinary Case Manager