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
December 18, 2018
9:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances: Rafael Saenz, 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

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Rafael Saenz, Chairman
- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - September 24, 2018, Special Conference Committee 2-5
  - September 25, 2018, Full Board Meeting 6-16
  - September 25, 2018, Public Hearing 17-18
  - October 9, 2018, Telephone Conference Call 19-20
  - October 17, 2018, Special Conference Committee 21-23
  - October 25, 2018, Formal Hearings 24-27
  - November 27, 2018, Special Conference Committee 28-30
  - November 28, 2018, Formal Hearings 31-32
  - November 28, 2018, Full Board Meeting Handout
  - November 28, 2018, Public Hearing Handout
  - December 7, 2018, Telephone Conference Call Handout

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran
- Regulatory update 33-34
- Adoption of exempt regulation to schedule certain chemicals in Schedule I 35-42
- Amend 18VAC110-20-10, Storage Temperature Definition reference to Freezer 43-45
- Adoption of final regulations for e-profile requirement 46-49
- Adoption of proposed regulations for labeling of dispensed medications 50-67
- Adoption of fast-track regulation for pharmacy permit rescission 68-70
- Review of guidance documents 71-95

Old Business:

- Finalize Pharmaceutical Processor Conditional Approvals
- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections

New Business:

- Presentation on Sanction Reference Points, Neal Kauder, Visual Research 96-115
- Review Pharmaceutical Processor Inspection Report 116-138

Reports:

- Chairman's Report – Rafael Saenz
- Report on Board of Health Professions – Ryan Logan
- Report on NABP Interactive Member Forum – Cindy Warriner
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Ellen B. Shinaberry 139-150
- Executive Director's Report – Caroline D. Juran 151
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Consideration of consent orders & summary suspension or summary restrictions, if any

Adjourn

****The Board will have a working lunch at approximately 12pm and present plaques to former board members. ****

*****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 **9:00 a.m. on December 18, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 7, 2018 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified seven (7) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description, chemical name, and common name for each compound.

The following compound is 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-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.

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.

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

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

6. **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.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Monday, September 24, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 09:01 a.m.
PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Patricia Richards-Spruill, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist Mykl Egan, DHP Adjudication Specialist
BRIAN W. LEWIS License No. 0202-221300	Brian W. Lewis, Pharmacist and Noah Wyer, Attorney, appeared on behalf of Mr. Lewis to discuss allegations that Mr. Lewis may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 18, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Brian W. Lewis. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Saenz, the Committee unanimously voted to refer the matter to the Board for a Formal Hearing and offer a Consent Order in lieu of the Formal Hearing.
MOHAMED ABDALLA License No. 0202-208298	Mohamed Abdalla, Pharmacist, and Barbara Queen, Attorney, appeared on behalf of Mr. Abdalla to discuss allegations that Mr. Abdalla may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 24, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Mohamed Abdalla. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
TIMBERLAKE FAMILY PHARMACY Permit No. 0201-004716	Vince Ettare, Pharmacist, appeared on behalf of Timberlake Family Pharmacy to discuss allegations that Timberlake Family Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 20, 2018 Notice.

Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Timberlake Family Pharmacy. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
VIENNA DRUG CENTER Permit No. 0201-000838	Robert Borgatti, Pharmacist and Lindsay Walton, Attorney, appeared on behalf of Vienna Drug Center to discuss allegations that Vienna Drug Center may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 1, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Virginia Supportive Housing. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in

	the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
AMANDA GORE Registration No. 0230-029035	Amanda Gore did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the Notice July 25, 2018 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Gore's legal address of record.
Decision:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Saenz, the Committee voted to refer the matter to the Board for a formal hearing, and offer a Consent Order in lieu of the formal hearing.
ADJOURNED:	4:35 PM

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 25, 2018
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 9:08 a.m.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:
Cynthia Warriner (arrived 9:17 a.m.)
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Ryan K. Logan (arrived 9:34 a.m.)
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
James S. Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Allyson K. Tysinger, Sr. Assistant Attorney General
David E. Brown, Director, DHP
Elaine Yeatts, Senior Policy Analyst, DHP
Sheralee Copeland, Executive Assistant

QUORUM: A quorum was established.

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

APPROVAL OF MINUTES: A handout of the draft minutes for the September 4, 2018 Ad Hoc Committee meeting was provided and considered for approval, in addition to the following minutes:

- June 20, 2018, Inspection Special Conference Committee
- June 20, 2018, Ad Hoc Committee for Routine Pharmacy Inspection Process
- June 21, 2018, Public Hearing to Schedule Certain Chemicals in Schedule I and to confirm to DEA scheduling
- June 21, 2018, Full Board Meeting
- July 19, 2018, Special Conference Committee

- August 14, 2018, Formal Hearings
- August 15, 2018, Special Conference Committee
- August 23, 2018, Public hearing to received comment on proposed regulations replacing emergency regulations for issuance of CSR's to community organizations to distribute naloxone and for tele-prescribing

MOTION:

The Board voted unanimously to adopt the minutes from June 20, 2018 through September 4, 2018, as presented. (motion by Nelson, second by Thornbury)

PUBLIC COMMENTS:

The board restricted public comments to two minutes each. A timer was projected on the screens in the room.

Randall Eads, a city manager for Bristol, Virginia, offered comment in support of the Dharma Pharmaceuticals pharmaceutical processor application.

Jeff Roden offered comment on the fees and proposed the idea of waiving the fee for children and spouses.

Peter Moore – Name appeared on the sign-up sheet to offer comment, but did not show when name was called.

Jim Layton offered support for Dalitso, LLC and Virginia-based research oriented facilities.

Nicole Miller commented on behalf of caregivers and expressed concern for the existing costs associated with taking care of a disabled child or incapacitated adult. Recommended the registration fees be valid for two years, similar to the Board of Medicine licensure requirements for physicians.

Michael Johnson, RPh, who owns Michael's Pharmacy in Abingdon, Virginia, offered support for the Dharma Pharmaceuticals pharmaceutical processor application.

Regina Whitsett, executive director of SAFE drug coalition in Chesterfield County and member of Coalitions of Virginia, offered comment in opposition of the laws authorizing pharmaceutical processors to dispense cannabidiol oil and THC-A oil, and offered support for FDA-approved products such as Epidiolex.

Christine Barrille, executive director of VPHA, expressed

support for the board's efforts in overseeing pharmaceutical processors and requested the pharmacist-in-charge language remain intact.

Michelle Peace, a Virginia Commonwealth University professor, commended the Board on including language that labs should be independent from all other persons. She recommended labs be located in Virginia since the DEA places the oils into Schedule I.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, welcomed the new Board members to the Board of Pharmacy. Dr. Brown commented on the importance of this being a "working" board and it will consist of active involvement from all members. Dr. Brown thanked the Board for its hard work and the work that is forthcoming. Dr. Brown reminded the board members to always put on your board "hat" and remember that we are here to serve the citizens of Virginia.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the Chart of Regulatory Actions included in the agenda packet. She stated the regulatory packet that includes a provision for a pharmacist to dispense a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration is scheduled to become effective October 31, 2018.

- ❖ Adoption of the Exempt Regulation to add certain chemicals to Schedule I

Ms. Yeatts reviewed the draft amendments to Regulation 18VAC110-20-322 to incorporate certain chemicals into Schedule I. The public hearing was conducted that morning prior to the full board meeting.

MOTION:

The board voted unanimously to adopt as final Regulation 18VAC110-20-322 by inserting subsection C which states:
"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 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 (18 months after the effective date of the regulation) unless enacted into law in the Drug Control Act." (motion by Warriner, second by Thornbury)

❖ Adoption of Proposed Regulations for Pharmaceutical Processors of CBD Oil and THC-A Oils

Ms. Yeatts reviewed the Emergency Regulations and advised that the underlined text in the agenda packet starting on page 82 reflects the amendments adopted by the board in June 2018 and that the highlighted text reflects recommended changes based on recent public comment.

Ms. Yeatts reviewed the Timeline for Promulgation of Emergency Regulations found on page 48 of the agenda packet. Once approved the OAG, DPB, SHHR, and Governor, the proposed regulations adopted on 9/25/18 will be open for a 60-day comment period and public hearing. Emergency regulations expire on 2/9/19 and the board will have to request a 6-month extension since it will not be possible for the permanent regulations to be in effect by that date.

In addition to staff's suggested amendments provided in the agenda packet based on public comment, the Board recommended additional amendments.

Following the review of 18VAC110-60-20, Mr. Ratliff expressed concern for the proposed fee for replacement of a patient/parent/guardian's registration whose information has changed such as with a change of address. It was recommended that this fee be stricken.

MOTION:

The Board unanimously voted to amend the language in 18VAC110-60-20 (C5) to read as follows: "Replacement of registration for a qualifying patient or parent or legal guardian whose original registration certificate has been lost, stolen, or destroyed." and to strike "shall submit the fee for a replacement registration" from 18VAC110-

60-70(C). (motion by Ratliff, second by Warriner).

In reviewing page 103, 18VAC110-60-170(D), Ms. Richards-Spruill recommended the provision for a pharmacy intern should be limited to after completing their first professional year of schooling.

MOTION: **The Board voted unanimously to amend 18VAC110-60-170(D) by inserting "who has completed the first professional year," after "...a registered pharmacy intern". (motion by Richards-Spruill, second by Warriner)**

After Ms. Yeatts reviewed 18VAC110-60-200(A), page 107, Ms. Thornbury questioned if the regulation should also prohibit the PIC of a pharmaceutical processor from being the PIC of a pharmacy.

MOTION: **The Board voted unanimously to amend 18VAC110-60-200(A) to read "No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy at any one time. (motion by Thornbury, second Nelson)**

Upon reviewing 18VAC110-60-210 (H), on page 110, Ms. Richards-Spruill recommended inserting language to require counseling on proper disposal.

MOTION: **The Board voted unanimously to amend the language in 18VAC110-60-210(H) by inserting at the end of the second sentence "and disposal of the oils in a manner that renders them non-recoverable." (motion by Warriner, second by Richards-Spruill)**

After reviewing 18VAC110-60-240 (D) on page 117, Mr. Boone recommended changing the requirement for testing security equipment from "no less than two times per year" to "at least every 6 months".

MOTION: **The Board voted unanimously to amend 18VAC110-60-240(D) to read as follows: "The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every 6 months." (motion by Boone, second by Warriner)**

Upon reviewing the Test Specification table 1 under 18VAC110-60-300 on page 128, Ms. Nelson noted the needed change from uppercase units to lowercase units, i.e., "uG/KG" to "ug/kg" and recommended "BW" be spelled out to read "By weight". No motion needed for this technical amendment.

Upon reviewing 18VAC110-60-330 (A) on page 133, Ms. Nelson expressed concern with regards to ensuring patient's ability to have an easy method of disposal. Mr. Logan commented that the patient needs a method to return the product to the pharmaceutical processor for destruction, if necessary. Mr. Ratliff commented that once a traditional drug has been dispensed, it cannot be returned to the pharmacy. Ms. Juran advised that staff will research the topic and the board can consider the matter at a future meeting.

Staff noted that the word "pharmacy" in 18VAC110-60-330(B) should be changed to "pharmaceutical processor". No motion needed for this technical amendment.

MOTION:

The Board voted unanimously to adopt the proposed regulations as presented and amended for Pharmaceutical Processors of CBD Oil and THC-A Oil. (motion by Thornbury, second by Bolyard)

Adoption of Final Regulations for Issuance of Controlled Substances Registration (CSR)

Ms. Yeatts announced that the Board needs a motion to adopt the Final Proposed Regulations.

MOTION:

The Board voted unanimously to adopt the Final Regulations – Issuance of Controlled Substances Registration (CSR). (motion by Warriner, second by Boone)

Extension of Emergency Regulations for Issuance of Controlled Substances Registration

Ms. Yeatts announced the staff note on page 145 of the agenda packet regarding the extension of the CSR Regulations.

The emergency regulations for issuance of a CSR to: 1) persons who have been trained in the administration of naloxone in order to possess and dispense the drug to persons receiving training: and 2) an entity for the purpose of establishing a bona fide practitioner-patient for prescribing when treatment is provided by telemedicine in

accordance with federal rules expire on November 7, 2018. The Boards can adopt final regulations fifteen days after the close of the comment period on proposed regulations (comment closes on September 7, 2018), but final regulations cannot be in effect by expiration of the emergency regulations.

MOTION:

The Board voted unanimously to approve the request to extend the Emergency Regulations for Issuance of a Controlled Substance Registration (CSR) for six months beyond the expiration of November 7, 2018. (motion by Warriner, second by Boone)

Consideration of Regulatory Action for White Bagging and Brown Bagging

Ms. Yeatts announced that there is a copy of the NOIRA background document and also a copy of the comments received on the NOIRA included in the agenda packet. Ms. Yeatts reviewed the Staff Note included on page 146 of the agenda which reads: The comment period on the NOIRA has closed. It is recommended that the Regulation Committee consider the comment, regulation in other states, and other related information and draft proposed regulations for the Board's consideration.

MOTION:

The Board voted unanimously to refer the issue of white bagging and brown bagging to the Regulation Committee for it to consider comment received, discuss regulations in effect in other states and other related information, and to draft proposed regulations for the Board's consideration. (motion by Jenkins, second by Nelson)

Summary of 2019 Legislative Proposals Submitted by DHP

Ms. Yeatts reviewed the Summary of Legislative Proposals Submitted by DHP on page 171 of the agenda packet which included:

- E-prescribing implementation (Bill attached to agenda packet);
- Process for placement of drugs under seal or seizure by Board or law enforcement (Bill attached to agenda packet);
- Correction of circular mandatory suspensions and inconsistency in the Code;
- Flexibility in terms of board members to re-balance expiration dates and fill certain vacancies; and,
- Practice by dental hygienists under remote supervision; authority to administer certain topical drugs.

Closed Meeting:

Upon a motion by Ms. Warriner , and duly seconded by Mr. Boone, the Board unanimously voted at 11:03 a.m. to convene a closed session pursuant to Virginia Code Section §2.2-3711(A)(8) to receive legal advice regarding the Virginia Freedom of Information Act and the consideration of the applications for pharmaceutical processor permits. In addition, the Board moved that Caroline Juran, Jim Rutkowski, Allyson Tysinger, Elaine Yeatts, Sammy Johnson, Sheralee Copeland, Scott Maye, and Scott Parsons attend the closed session because their presence was necessary and would reasonably aid the board.

Reconvene:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session just concluded. (motion by Warriner, second by Boone)

Board Member Statements:

Mr. Ratliff announced that he had written a letter of support for one of the pharmaceutical processor applicants prior to being appointed to the Board and that he would recuse himself from the Board's consideration of the pharmaceutical processor applications. Mr. Ratliff exited the room.

Mr. Saenz announced that as part of his responsibilities serving as the Pharmacy Director of the UVA Hospital Pharmacy, he also serves as an assistant dean of VCU School of Pharmacy at a satellite campus located in Charlottesville. He stated that he believes he can render a fair and impartial decision in the consideration of pharmaceutical processor applications.

Closed Meeting:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the board unanimously voted at 12:00 p.m. to convene in closed session pursuant to Virginia Code sections § 54.1-108 and § 2.2-3711(A)(5) to evaluate the applications for pharmaceutical processor permits to determine which, if any, should be awarded conditional approval. In addition, the Board moved that Caroline Juran, Jim Rutkowski, Allyson Tysinger, Elaine Yeatts, Sammy Johnson, Sheralee Copeland, Scott Maye, and Scott Parsons attend the closed session because their presence was necessary and would reasonably aid the Board.

Reconvene:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session just concluded. (motion by Warriner, second by Boone)

MOTION:

Upon a motion by Mr. Logan, and duly seconded by Ms. Richards-Spruill, the Board conditionally approved the applications for a pharmaceutical processor permit of Pharmacann in health service area I, Dalitso in health service area II, Green Leaf in health service area IV, and Columbia Care in health service area V for the reasons that will be stated in the Board's forthcoming orders. In addition, the Board moved that the conditional approval of these applications is conditioned on the satisfactory result of criminal background checks on the owners of each applicant as further detailed in the Board's forthcoming orders. The Board further moved to deny all other applications for a pharmaceutical processor permit in these regions because under Virginia Code § 54.1-3442.6, the Board may only issue one permit for each health service area and for other reasons that will be stated in the Board's forthcoming orders. Finally, under Virginia Code § 2.2-4021, the Board moved that Board staff prepare and issue orders consistent with the Board's decisions within 90 days of today's date. (vote 9:0, Ratliff recused)

MOTION:

Upon a motion by Mr. Boone, and duly seconded by Mr. Bolyard, the Board conditionally approved the application for a pharmaceutical processor permit of Dharma in health service area 3 for the reasons that will be stated in the Board's forthcoming order. In addition, the Board moved that the Board's approval of this application be conditioned on the satisfactory result of criminal background checks on the owners of the applicant as further detailed in the Board's forthcoming order. The Board further moved that the Board deny all other applications for a pharmaceutical processor permit in this region because under Virginia Code § 54.1-3442.6, the Board can only issue one permit for each health service area and for other reasons that will

be stated in the Board's forthcoming orders. Finally, under Virginia Code § 2.2-4021, the Board moved that staff prepare and issue orders consistent with the Board's discussion within 90 days of today's date. (vote 7:0, Ratliff recused, Logan and Nelson abstained)

MOTION:

Upon a motion by Mr. Jenkins, and duly seconded by Ms. Nelson, the Board moved that for the purposes of conducting criminal background checks pursuant to Virginia 18VAC110-60-110 (B)(3), checks be performed for owners with an interest of 5% or more of each conditionally approved applicant.

Chairman's Report:

Mr. Saenz thanked everyone for their hard work in reviewing and considering the pharmaceutical processor applications.

Report on Board of Health Professions:

Report on Licensure Program:

Mr. Logan did not have anything to report.

Mr. Johnson reported the Board currently licenses 37,812 individuals and facilities. The Board issued 1,308 licenses and registrations for the period of June 1, 2018 through August 31, 2018. Inspectors conducted 525 facility inspections including 242 routine inspections of pharmacies: 93 (38%) resulted in no deficiency, 75 (31%) with deficiencies and 74 (31%) with deficiencies and a consent order. There were 9 instances where "First Documented Occurrence" was noted for a deficiency that would have resulted in a monetary penalty. Pharmacies with a "First Documented Occurrence" will incur a monetary penalty if the same deficiency is noted on the next routine inspection.

Report on Disciplinary Program:

Ms. Shinaberry commended and recognized the hard work of Rose DeMatteo and Ileita Redd during the absence of Kennia Butler, Discipline Program Specialist. She also commented on the utilization of overtime assistance from Donna Lee with the Board of Dentistry.

Ms. Shinaberry reported that there are 43 patient care cases at PC as compared to 16 that were reported in June. However, 14 of these cases have been offered a CCA or

PHCO, and 17 of these cases are pending an IFC or FH. There are 5 patient care cases that exceed 250 work days (this is substantially below our 10% threshold for open cases). Non-patient care cases are inspection cases or compliance related cases. We are beginning to see a slight decrease in the number of inspection cases resulting in a PHCO. Possible summary suspension cases have tapered down to a more normal volume. Ms. Shinaberry briefly reviewed the upcoming disciplinary proceedings.

Executive Director's Report:

Ms. Juran reported on the status of the Paperless License Initiative. The goal is to print a one-time license without an expiration date and refer individuals to the online License Lookup feature for information regarding licensure status. She stated this initiative will not be in place prior to the December 31 renewal deadline for pharmacists and pharmacy technicians, but will hopefully be implemented in spring 2019. Ms. Juran announced that a Board e-newsletter was published September 2018. Ms. Juran also discussed the Hurricane Waiver Provisions that were in place for patients displaced to Virginia to get their medications during Hurricane Florence. She also reported on recent presentations and meetings.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 5:38 p.m.

Rafael Saenz, Chairman

Caroline Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARINGS FOR SCHEDULING CERTAIN SUBSTANCES

September 25, 2018
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearings were called to order at 9:05a.m.

PRESIDING: Rafael Saenz, Chairman

MEMBERS PRESENT:

Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Cheryl H. Nelson
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:

Caroline D. Juran, Executive Director
James S. Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Allyson K. Tysinger, Sr. Assistant Attorney General
David E. Brown, Director, DHP
Elaine Yeatts, Senior Policy Analyst, DHP
Sheralee Copeland, Executive Assistant

PUBLIC HEARING FOR SCHEDULING OF CERTAIN CHEMICALS

Mr. Saenz called for comment to consider placement of the following chemical substances into Schedule I:

- 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.

- 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.

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

PULIC COMMENT: No comment was offered.

ADJOURN: The public hearing adjourned at 9:08am.

Rafael Saenz, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
TELEPHONE CONFERENCE CALL MINUTES

Tuesday, October 9, 2018

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

TIME AND PURPOSE:

Pursuant to §54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ('TCC") was held on October 9, 2018 at 11:15am, to consider the summary suspension of the registration of Liam Klavon to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING:

Rafael Saenz, Committee Chair

MEMBERS PRESENT:

James Jenkins
Ryan Logan
Melvin Boone
Rebecca Thornbury
Patricia Richards-Spruill

STAFF PRESENT:

Ellen B. Shinaberry, Deputy Executive Director
Caroline D. Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

POLL OF MEMBERS

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

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular manner to consider this matter.

LIAM SPENCER KLAVON
Registration No. **0230-030174**

James Schliessmann presented a summary of evidence in this case.

DECISION:

Upon a motion by Mr. Jenkins and duly seconded by Ms. Thornbury, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Liam Klavon poses a substantial danger to the public, and therefore, the technician registration of Mr. Klavon shall be summarily suspended.

Further, upon a motion by Ms. Thornbury and duly seconded by Mr. Boone, the Board voted unanimously to Notice for a Formal Hearing, and offer a Consent Order for indefinite suspension of his registration for not less than two years in lieu of a Formal Hearing.

ADJOURN: With all business concluded, the meeting was adjourned at 11:26 am.

Rafael Saenz, Chair

Caroline Juran
Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, October 17, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:15 a.m.
PRESIDING:	Cindy Warriner, Committee Chair
MEMBERS PRESENT:	Patricia Richards-Spruill, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Claire Foley, DHP Adjudication Specialist
AMERICAN ADDICTION TREATMENT CENTER Permit No. 0201-004750	T.W. Taylor, Pharmacist appeared on behalf of American Addiction Treatment Center to discuss allegations that American Addiction Treatment Center may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 1, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of American Addiction Treatment Center. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order with no sanction imposed.
SHORT PUMP PHARMACY dba RX3 PHARMACY Permit No. 0201-004734	Chris Currin, Pharmacist and Owner, and Rebecca Price, Pharmacist, appeared on behalf of Short Pump Pharmacy dba RX3 to discuss allegations that Short Pump Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 14, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Short Pump Pharmacy. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
CYNTHIA JONES-MCINTEER License No. 0202-006070	Cynthia Jones-McInteer, Pharmacist, appeared on her behalf to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 13, 2018 Notice.

Closed Meeting:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Cynthia Jones-McInteer. Additionally, she moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Richards-Spruill and duly seconded by Ms. Warriner, the Committee unanimously voted to issue an Order to dismiss the case.
ADJOURNED:	12:33 PM

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

October 25, 2018
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 9:04 a.m.

PRESIDING: Rafael Saenz, Chair

MEMBERS PRESENT:
Patricia Richards-Spruill
Melvin Boone
Kristopher Ratliff
James Jenkins
Cindy Warriner
Cheryl Nelson

STAFF PRESENT:
Sammy Johnson, Deputy Executive Director
(left at 11:59 am)
Caroline D. Juran, Executive Director
(arrived at 12:00 pm)
Ellen Shinaberry, Deputy Executive Director
(arrived at 12:00 pm)
Sheralee Copeland, Administrative Assistant
James Rutkowski, Assistant Attorney General
James Schliessman, Senior Assistant Attorney General
(arrived at 12:00 pm)
Claire Foley
(arrived at 12:00 pm)
Mykl Egan, DHP Adjudication Specialist
(left at 11:59 am)
Wayne Halbleib, Sr. Assistant Attorney General/Chief
(arrived at 12:00 pm)

QUORUM: With seven (7) members of the Board present, a quorum was established.

MYCKIEALA COOPER
License No. 0202-209657

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

Mykl Egan, DHP Adjudication Specialist, presented the case.

Ms. Cooper was present at the hearing.

Wendy Morris, DHP Senior Investigator and Amy Stuart, HPMP Case Manager, testified in person on behalf of the Commonwealth. Christine Garcia, NP, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(16) of the Code of Virginia ("Code"), for the purpose of discussion of health records of Ms. Cooper. Additionally, she moved that Sammy Johnson and Jim Rutkowski attend the closed meeting.

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

CLOSED MEETING: Upon a motion by Ms. Warriner, and duly seconded by Mr. Jenkins, the panel voted 6-0, to convene a second closed meeting pursuant to § 2.2-3711(A)(16) of the Code of Virginia ("Code"), for the purpose of discussion of health records of Ms. Cooper. Additionally, she moved that Sammy Johnson and Jim Rutkowski attend the closed meeting.

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

CLOSED MEETING: Upon a motion by Ms. Warriner, and duly seconded by Mr. Jenkins, the panel voted 6-0, to convene a second closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Ms. Cooper. Additionally, she moved that Sammy

Johnson and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Ms. Nelson, and duly seconded by Mr. Ratliff, the panel voted unanimously to accept the Findings and Fact and Conclusions of Law proposed by Mr. Egan and amended by the Board.

Upon a motion by Ms. Nelson, and duly seconded by Ms. Richards-Spruill, the panel voted unanimously to issue a reprimand and place Ms. Cooper's license on probation for two years with certain terms and conditions.

POSSIBLE SUMMARY SUSPENSION PRESENTATION

JORDAN BAILEY
Registration No. 0230-016879

Wayne Halbleib, Senior Assistant Attorney General, 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. Ratliff, that with the evidence presented, the practice as a pharmacy technician by Jordan Bailey poses a substantial danger to the public; and therefore, the registration of Ms. Bailey shall be summarily suspended. Further, with the Notice of Formal Hearing, a Consent Order shall be offered to Ms. Bailey for indefinite suspension her technician registration for not less than two years in lieu of the Formal Hearing.

AWAHNEE THOMAS
Registration No. 0230-027492

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

James Schliessmann, Senior Assistant Attorney General, and Claire Foley, DHP Adjudication Specialist, presented the case.

Ms. Thomas was present at the hearing.

Andrea Leist, Pharmacist, testified in person on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Ms. Warriner, 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 in the matter of Awahnee Thomas. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.

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

DECISION: Upon a motion by Ms. Nelson, and duly seconded by Mr. Boone, the panel voted unanimously to accept the Findings and Fact and Conclusions of Law proposed by Mr. Schliessman and amended by the Board.

Upon a motion by Ms. Nelson, and duly seconded by Ms. Richards-Spruill, the panel voted unanimously to suspend Ms. Bailey's registration indefinitely for not less than one year.

ADJOURNED: With all business concluded, the meeting adjourned at 1:35 pm.

_____ _____

Rafael Saenz, Chair Caroline Juran, Executive Director

Date

_____

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, November 27, 2018
Commonwealth Conference Center
Second Floor
Board Room 3

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 9:14 a.m.
PRESIDING:	Patricia Richards-Spruill, 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
WALGREENS #098280 Permit No. 0201-004253	Rusty Maney, Walgreens Regional Healthcare Manager, and Denise Felluca, Walgreens Healthcare Supervisor, appeared on behalf of Walgreens #098280 to discuss allegations that Walgreens #098280 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the September 31, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Walgreens #098280. Additionally, he moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to enter an Order with no sanction imposed.
BEAVERDAM PHARMACY Permit No. 0201-001476	Jeffrey Misenko, Pharmacist and Owner, appeared on behalf of Beaverdam Pharmacy to discuss allegations that Beaverdam Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 31, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Beaverdam Pharmacy. Additionally, he moved that Ellen B. Shinaberry attend the closed meeting because her presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Richards-Spruill, the Committee unanimously voted to refer the matter to the Board for a formal hearing.
JEFFREY MISENKO License No. 0202-010856	Jeffrey Misenko, Pharmacist, appeared on his behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August

31, 2018 Notice.

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

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

Decision: Upon a motion by Mr. Boone and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to refer the matter to the Board for a formal hearing, and offer a Consent Order for revocation of his pharmacist license in lieu of the formal hearing.

ADJOURNED: 2:22 PM

Patricia Richards-Spruill, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

November 28, 2018
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 9:40 a.m.

PRESIDING: Rafael Saenz, Chair

MEMBERS PRESENT:
Patricia Richards-Spruill
Ryan Logan
Kristopher Ratliff
James Jenkins
Cheryl Nelson

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

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

Liam Spencer Klavon
Registration No. 0230-030174

A formal hearing was held in the matter of Liam Spencer Klavon to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Mykl Egan, DHP Adjudication Specialist, presented the case.

Mr. Klavon was not present.
Mark Cranfill, DHP Senior Investigator, testified by telephone on behalf of the Commonwealth.
Josh Ward, Wegman's Assistant Asset Protection Manager, and Audrey Nguyen, Wegman's #044 Pharmacy Manager, testified in person on behalf of the Commonwealth.

CLOSED MEETING:	Upon a motion by Mr. Ratliff, and duly seconded by Mr. Logan, 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 Liam Klavon. Additionally, he moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened an open meeting and announced the decision.
DECISION:	Upon a motion by Ms. Richards-Spruill, and duly seconded by Ms. Nelson, the panel voted unanimously to accept the Findings of Fact and Conclusions of Law as presented by Mr. Egan. Upon a motion by Mr. Logan, and duly seconded by Mr. Jenkins, the panel voted unanimously to revoke Mr. Klavon's pharmacy technician registration.
ADJOURNED:	With all business concluded, the meeting adjourned at 10:41 a.m.

Rafael Saenz, Chair	Caroline D. Juran, Executive Director
Date	Date

Board of Pharmacy

Chart of Regulatory Actions as of December 5, 2018

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] NOIRA - *Register Date: 8/6/18* *Proposed adopted at November meeting*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *Register Date: 10/29/18* *Proposed to be adopted 12/18/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] Proposed - *Register Date: 12/24/18* *Comment from 12/24/18 to 2/22/18* *Public hearing: 1/9/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Proposed - *Register Date: 9/17/18* Comment closed: 11/16/18 Board to adopt final: 12/18/18
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *At Governor's Office for 10 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Rescission of pharmacy permit [Action 5080] Fast-Track – Revised proposed on agenda for 12/1818
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 196 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Final - *Register Date: 12/24/18* *Effective: 1/23/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Placement of chemical in Schedule I [Action 5153] Final - *Register Date: 10/29/18* *Effective: 11/28/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of drug in Schedule V [Action 5186] Final – *At the Attorney General's* Office

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Emergency/NOIRA - *At Governor's Office for 21 days* *Emergency must be effective 12/14/18*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Registration of nonresident warehousers and nonresident third party logistics providers [Action 5083] Fast-Track - *At Governor's Office for 3 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *Register Date: 10/29/18* *Proposed at the Attorney's General office*

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 **9:00 a.m. on December 18, 2018** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 7, 2018 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified seven (7) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description, chemical name, and common name for each compound.

The following compound is 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-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.

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.

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

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

6. **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.

Project 5776 - none

BOARD OF PHARMACY

Scheduling of chemicals 12-18

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

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

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

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

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

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

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

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

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

7. Synthetic opioids:

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

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

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

8. Central nervous system stimulants:

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

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

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

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

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

2. Synthetic opioids:

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

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

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

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

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

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

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

The placement of drugs listed in this subsection shall remain in effect until March 4, 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. 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.

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-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 (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of NOIRA – Definition of Storage Temperature, Freezer

Staff note:

Board staff was informed via email that USP has revised the allowable temperature range for drug storage in a freezer.

Included in your agenda package are:

An excerpt from USP Chapter <659> for Temperature and Storage Definitions.

Draft amendment to 18VAC110-20-10

Board action:

Adoption of a Notice of Intended Regulatory Action (NOIRA) to amend the allowable temperature range for drug storage in a freezer within the definition of "storage temperature" in 18VAC110-20-10.

https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/659_rb_notice.pdf

<659> Packaging and Storage Requirements
Type of Posting Revision Bulletin, Postponement
Posting Date 28-Apr-2017, revised 26-May-2017[1]
Official Date 01-May-2017
Expert Committee General Chapters—Packaging and Distribution

Reason for Revision Compliance

TEMPERATURE AND STORAGE DEFINITIONS

Freezer: A place in which the temperature is controlled between −25° and −10° (−13° and 14° F). It is noted that, in some instances, articles may have a recommended storage condition below −20° (−4° F). In such cases, the temperature of the storage location should be controlled to ±10°.

Excerpt from 18VAC110-20-10

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is ~~maintained thermostatically between -20° and -10°C (-4° and 14°F).~~ controlled between −25° and −10° (-13° and 14° F). It is noted that, in some instances, articles may have a recommended storage condition below -20° (-4° F). In such cases, the temperature of the storage location should be controlled to +/-10° .

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

Agenda Item: Adoption of Final Regulations – e-profile number

Included in your agenda package are:

A copy of the proposed regulations

There were no comments sent, posted on Townhall, or provided at the public hearing.

Board action:

Adoption of final regulation identical to the proposed regulation

Project 5278 - Proposed

BOARD OF PHARMACY

Requirement for applicants and licensees to have an e-profile ID number

18VAC110-20-22. Application to include e-profile number.

An application for licensure as a pharmacist by examination or endorsement or for registration as a pharmacy intern or pharmacy technician shall include an e-profile number issued by NABP.

18VAC110-20-80. Renewal and reinstatement of license.

A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, an e-profile number issued by NABP, and statement of compliance with continuing education requirements.

B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.

C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.

D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.

E. A pharmacist who has been registered as inactive for more than one year must apply for reinstatement, submit documentation showing compliance with continuing education requirements, and pay the current year active renewal fee in order to resume active licensure.

F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.

G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:

1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

I. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the licensee of the obligation to comply.

18VAC110-20-105. Renewal and reinstatement of registration.

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

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

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

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

Agenda Item: Proposed action on Labeling of Dispensed Prescriptions

Included in your package are copies of:

Copy of the posting on the Virginia Regulatory Townhall

Copy of comment on NOIRA

Draft Proposed regulations

Action:

Motion to adopt the proposed regulations as drafted or as amended by the Board

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.

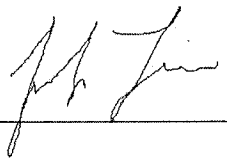
Lastly, the addition of a depot pharmacy name and address to a label, for the sole purpose of providing the patient information on which pharmacy held the prescription for pick-up or further delivered it is a redundancy. The patient would likely be provided additional information or documentation (i.e. 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

VIRGINIA
REGULATORY TOWN HALL

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	Delivery of dispensed prescriptions
Date this document prepared	7/16/18

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board intends to amend section 275 of Chapter 20 pertaining to the procedure for identifying all pharmacies involved in the filling and dispensing of a prescription. The amendment would specify that a unique identifier on the prescription label is not required to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific

provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

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

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

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.
B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of the proposed regulatory action is to respond 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. The petitioner noted that identification of multiple pharmacies is confusing; the dispensing pharmacy is best able to answer questions and respond to problems or concerns by a patient about his/her medication. The Board believes an amendment to its regulation will safeguard patient health and safety by ensuring that a prescription label has pertinent information.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

An amendment to section 275 would specify that a unique identifier on the prescription label is not required to identify a pharmacy that is 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.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

CVS Health has petitioned the Board for an amendment that will result in a less restrictive and less costly requirement for prescription labels. There is no alternative other than amending the current rule to achieve that purpose.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

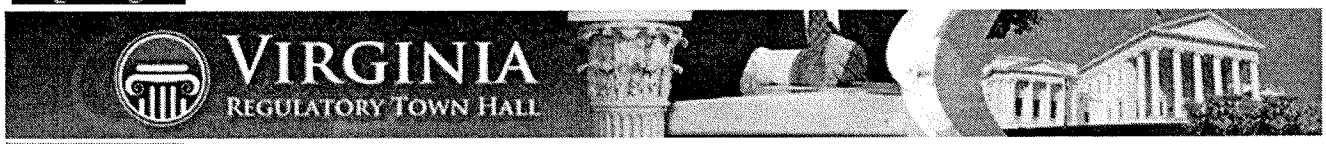
The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used for development of regulatory changes; the amendments will be drafted by the Regulation Committee.

Virginia.gov Agencies | Governor



Agency Department of Health Professions

Board Board of Pharmacy

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

Public Comment Forum

Public Petition for Rulemaking: **Unique identifier on prescription labels**

View petition details

CLOSED Opened on 10/30/2017 and Ended on 11/22/2017

More about public comment forums and policies

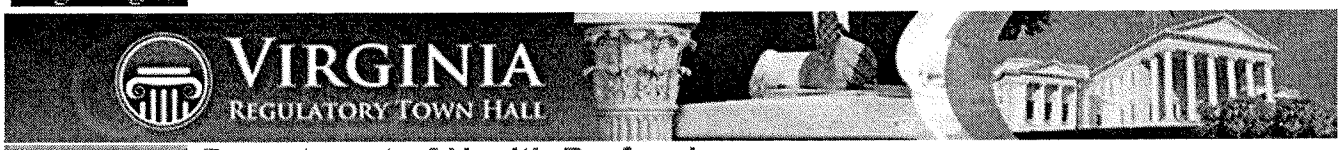
View all comments on one page

Comment Title	Commenter	Date
Rx Partnership favors amendment	Rx Partnership	11/17/17 2:57 pm
Reply	Keith Richardson	11/6/17 9:04 am

2 comments

Trouble posting comments? These pages have been tested with multiple versions of all the major browsers. If you have trouble: (1) try another computer if you have access to one, (2) try another browser if your computer has one installed (3) contact **Town Hall support staff** for assistance.

Virginia.gov Agencies | Governor



Agency Department of Health Professions

Board Board of Pharmacy

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

Previous Comment Back to List of Comments

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

Rx Partnership favors amendment

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

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

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Next Comment Back to List of Comments

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

Reply

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

However to the best of my knowledge

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

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

National Provider Identifier (NPI) is a ten digit number

A npi is searchable and accessible online

A npi is synonymous to an individual

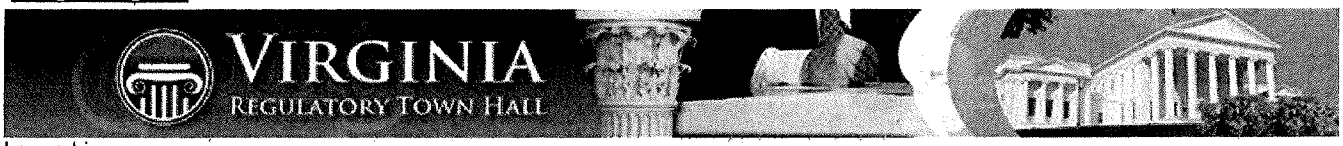
If the unique identifer is to be removed

Other than payor sheets

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

Is there a way to find a pharmacy?

Virginia.gov Agencies | Governor



Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

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

Back to List of Comments

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

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

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

CVSHealth

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

November 16, 2018

Elaine Yeatts
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463
Caroline.juran@dhp.virginia.gov

Re: CVS Health's comments on NOIRA in regard to 18VAC110-20-275. Delivery of dispensed prescriptions.

Dear Ms. Yeatts:

I am writing to you in my capacity as Sr Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy Notice of Intended Regulatory Action with proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Virginia patients.

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

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

Sincerely,

Lauren Paul, PharmD

Lauren Paul, PharmD, MS

CVSHealth

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

Sr Director, Pharmacy Regulatory Affairs
CVS Health

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 the patient to identify ~~identifying~~ on the prescription label all pharmacies involved in filling and dispensing the prescription. The identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the prescription label, or may be included in a unique identifier, 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 Fast-track Regulations – Pharmacy permit rescission

Staff note:

This proposed regulatory action was previously adopted by the Board, but Board counsel advised that it was not consistent with statutory authority and needed to be revised.

Included in your agenda package are:

A copy of the proposed regulation as revised

Board action:

Adoption of amendment to section 140 to require a pharmacy to be operational 90 days after issuance of a permit. Failure to do so would provide grounds for disciplinary action (rescission of the permit).

Project 5528 - Fast-Track

BOARD OF PHARMACY

Rescission of pharmacy permit

18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by § 32.1-127.1:03 of the Code of Virginia.

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

1. Pharmacy permit applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-20-20 prior to a reinspection being conducted.

D. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

E. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

F. Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.

Agenda Item: Review of Guidance Documents

Included in your agenda package:

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

Board Action:

The Board will receive staff recommendations for re-affirmation of current guidance, revision, or deletion of the guidance documents highlighted on the list.

BOARD OF PHARMACY

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

Guidance Documents:

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

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

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

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

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

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

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

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

110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide, revised June 22, 2018

110-10, Board guidance on dispensing of drugs from mobile vans, revised June 21, 2018

110-11, Board guidance on proof of identity for Schedule II drugs, revised June 21, 2018

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

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

110-16, Board guidance on performing inventories, revised June 21, 2018

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

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

110-19, Transferring valid orders between medical equipment providers, revised June 21, 2018

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

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

110-22, Dispensing records; identification of pharmacist, revised June 21, 2018

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

110-24, Competency examination required and passing score, revised June 21, 2018

110-25, Guidance for life of a prescription after a prescriber no longer in practice, revised June 21, 2018

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Adopted: December 8, 2005
Revised September 9, 2014

Virginia Board of Pharmacy

ALTERNATE DELIVERY OF PRESCRIPTIONS IN VIRGINIA

Pharmacy to Physician or Pharmacy to Controlled Substances Registration Type of Delivery

Reference: §54.1-3420.2 of the Code of Virginia, 18VAC 110-20-275 of the Regulations of the Virginia Board of Pharmacy

The following are examples of the Board's interpretation of 18VAC110-20-275 for delivery of dispensed prescriptions:

18 VAC 110-20-275. Delivery of dispensed prescriptions.

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 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;

- Example:
  - The pharmacy will prepare a log of all the prescriptions. The employee delivering the prescriptions will sign this log. All of the prescriptions prepared for delivery and the signed log will be placed in a sealed tote/container prior to the employee leaving the pharmacy.
  - The agent at the receiving location will sign for receipt of the sealed container, then open the sealed container and check the prescriptions against the delivery log to insure that all prescriptions have been received and sign the log as being complete. The delivered prescriptions shall be stored in accordance with law and regulations.
  - Patients picking up their prescription(s) will sign the log indicating receipt of the prescription.

b. Procedure for providing counseling;

Example: The prescriptions for a patient will be placed in a tamper-resistant bag with the Medi-Span Patient Information Leaflet for each prescription and a written offer for counseling by a pharmacist available by a toll free phone number to include the hours of operation for the pharmacy when counseling may be obtained. A label identifying the patient will be placed on the outside of the bag.

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

Example: Completed logs are to be returned to the originating pharmacy within 14 days, and maintained in chronological order for a period of 2 years. Any prescriptions not picked up within 14 days are to be returned to the originating pharmacy in a sealed tote/container.

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

Example: The only personnel handling the prescriptions will be employees of the pharmacy or employees of the permitted physician who already have access to these patients' medical records.

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

Example: A form explaining the service and explicitly requesting the patient's consent to participate in the service.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

Other notes:

- Copies of forms to be utilized should be included in the policy and procedure manual.
- Description of supplies used to deliver prescriptions should be included in the policy and procedure manual.
- Designation of other persons who may access the dispensed drugs shall be in writing and available for review by an agent of the board.

- Access by a designee shall occur at a time when a prescriber or pharmacist is present at all times with the exception of those qualifying facilities pursuant to 18VAC110-20-275 (E).

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.

Example: A Virginia Department of Health department has been issued a controlled substances registration as an alternate delivery site without a prescriber or pharmacist present at all times the site is open because of the unique needs of the patients receiving services and the medical conditions being treated.

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.

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).

Virginia Board of Pharmacy

Allowances to Purchase, Possess, and Administer Drugs within an Animal Shelter or Pound

The Board of Pharmacy provides the following guidance regarding drugs maintained and administered within an animal shelter or pound. Pursuant to §54.1-3423 E, an animal shelter or pound may obtain a controlled substances registration certificate from the Board of Pharmacy for purchasing, possessing, and administering drugs for two purposes: euthanasia of injured, sick, homeless and unwanted domestic pets and animals; and prevention, control, and treatment of certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. These drugs shall only be stored and administered at the address of the humane society or shelter and shall not be taken off-site for administration. Additionally, the training requirements for persons to administer drugs for these two purposes differ and are highlighted below. Lastly, this guidance document does not apply to the purchase, possession, or administration of drugs for the purpose of chemical capture of animals in accordance with the State Veterinarian's directive concerning such.

Drugs for Euthanasia

Only controlled substances in Schedules II-VI approved by the State Veterinarian for euthanasia of injured, sick, homeless and unwanted domestic pets and animals may be purchased, possessed, and administered. The drugs used for euthanasia shall be administered only in accordance with the facility protocol and only by persons trained and certified as to competency in accordance with the State Veterinarian's directives.

Training for administering drugs for euthanasia

The training for persons administering drugs in accordance with protocols established by the State Veterinarian for euthanasia shall be approved by the State Veterinarian. A current certification of competency signed by the supervising veterinarian for the facility shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering. To access the most recent State Veterinarian's directive on Methods Prescribed or Approved for Animal Euthanasia and Competency Certification Requirements click on:
http://www.vdacs.virginia.gov/animals/pdf/euthansiadirective.pdf

Drugs for Communicable Disease Prevention, Control and Treatment

Only certain Schedule VI controlled substances 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 may be purchased, possessed, or administered unless prescribed to a specific animal by a licensed veterinarian. These drugs shall not be used for the treatment of a non-transmissible malady or condition such as an injury; controlled substances

required for the treatment of such conditions must be prescribed to a specific animal by a licensed veterinarian.

The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the animal shelter or pound shall be determined by the supervising veterinarian of the shelter or pound. Additionally, the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter or pound and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter or pound shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter or pound.

The written protocols established or approved by the supervising veterinarian shall, at a minimum, include the following information:

- name and contact information for the animal shelter or pound and the supervising veterinarian;
- name of communicable disease to be prevented, controlled, or treated;
- name of the species, and other signalments as applicable, for which the protocol is intended;
- symptoms or other qualifiers which must be present prior to administering the drug;
- name of drug and dosage guidelines;
- method of administration;
- dosing frequency, duration of administration, and expected response;
- cautions and contraindications;
- instructions for when to contact the supervising veterinarian or designated veterinarian for additional direction which shall address, at a minimum, the development of side effects of the drug, allergic responses to the drug, and ineffective responses to the drug;
- date and signature of supervising veterinarian.

Training for administering certain Schedule VI for communicable diseases

The person offering the training for administering certain Schedule VI drugs for the prevention and treatment of communicable diseases in accordance with instructions established or approved by the supervising veterinarian shall be a veterinarian, but is not required to be the supervising veterinarian for the animal shelter or pound. The training records of those persons administering Schedule VI drugs shall be maintained on the premises of the shelter or pound, retained for not less than two years after the person ceases administering, and updated as protocols are amended. Additionally, the training record shall include, at a minimum, the following information:

- name and contact information for the animal shelter or pound;
- name of person being trained and veterinarian offering training;
- name of Schedule VI drugs and routes of administration person has been properly trained to administer in accordance with instructions established or approved by the supervising veterinarian;
- name of species to which drugs may be administered;
- date and signature of veterinarian providing the training.

Controlled Substances Registration Certificate

The application for a controlled substances registration certificate requires the designation and signature of a responsible party and supervising practitioner.

- **Responsible party**

The responsible party shall be an individual who is properly trained to administer and access the controlled substances and shall maintain proper security and required records of all controlled substances obtained and administered. If the responsible party ceases employment with the facility or relinquishes his position, he shall immediately return the controlled substances registration certificate to the board and shall take a complete and accurate inventory of all drugs in stock in compliance with §54.1-3404 of the Drug Control Act . An application for a controlled substances registration certificate indicating a change in responsible party shall be filed within 14 days. At that time, the new responsible party shall take a complete and accurate inventory of all drugs in stock.

- **Supervising practitioner**

The supervising practitioner within the animal shelter or pound shall be a licensed veterinarian who may provide the training for administering Schedule VI drugs for the prevention and treatment of communicable diseases and shall assume the following responsibilities to include, but not limited to,:

1. providing general supervision for the facility;
2. providing a list of Schedule VI drugs used for treatment and prevention of communicable diseases;
3. establishing or approving written protocols for administering the drugs for the prevention and treatment of communicable diseases; and,
4. certifying competency in the performance of euthanasia in accordance with guidelines set forth by the State Veterinarian.

Within 14 days of a change in the supervising practitioner, the board of pharmacy shall be notified and an application for the controlled substances registration certificate shall be submitted indicating the name and license number, if applicable, of the new supervising practitioner.

Related Cites from the Code of Virginia and Regulations of the Board of Pharmacy

from the Code of Virginia
§54.1-3423
E. The Board may register an animal shelter or pound as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase, possess, and administer certain Schedule VI controlled substances 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. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the animal shelter or pound shall be determined by the supervising veterinarian of the shelter or pound and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter or pound and only by persons who have been trained in accordance with instructions established or approved by the supervising

veterinarian. The shelter or pound shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter or pound.

from Regulations Governing the Practice of Pharmacy

18VAC110-20-580. Humane societies and animal shelters.

A humane society or animal shelter, after having obtained the proper registrations pursuant to state and federal laws, may purchase, possess and administer controlled substances in accordance with provisions of §54.1-3423 of the Code of Virginia provided that these procedures are followed:

1. Drugs ordered by a humane society or animal shelter shall only be stored and administered at the address of the humane society or shelter.

2. A veterinarian shall provide general supervision for the facility and shall provide and certify training in accordance with guidelines set forth by the State Veterinarian to the person(s) responsible for administration of the drugs. Certification of training signed by the veterinarian providing the training shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering.

3. The person in charge of administration of drugs for the facility shall obtain the required permit and controlled substances registration from the board and shall be responsible for maintaining proper security and required records of all controlled substances obtained and administered.

a. If that person ceases employment with the facility or relinquishes his position, he shall immediately return the registration to the board and shall take a complete and accurate inventory of all drugs in stock.

b. An application for a new registration shall be filed with the required fee within 14 days on a form provided by the board. At that time, the new responsible person shall take a complete and accurate inventory of all drugs in stock.

4. Drugs shall be stored in a secure, locked place and only the person(s) responsible for administering may have access to the drugs.

5. All invoices and order forms shall be maintained for a period of two years.

6. Complete and accurate records shall be maintained for two years on the administration of the drug. The record shall show the name and strength of the drug, date of administration, the species of the animal, the weight of animal, the amount of drug administered and the signature of the person administering the drug.

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternative delivery sites, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of §54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved by the board who is authorized to administer or otherwise possess the controlled substances for that type entity.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to §54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, or to other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, and overseeing delivery of dispensed prescriptions at an alternate delivery site.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-710. Requirements for storage and security for controlled substances registrants.

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking which meets the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, or alternate delivery sites as provided in 18VAC110-20-275.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of §54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity which is open 24 hours a day shall clearly

document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

4. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia).

5. The Department of Forensic Science may exclude from any inventory quantities of controlled substances used to conduct chemical analyses and controlled substances received for analyses as evidentiary material as provided in §54.1-3404 G of the Code of Virginia.

Virginia Board of Pharmacy

Guidance Document 110-32
The Use of a Drop Box for the Collection of Prescriptions

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

Virginia Board of Pharmacy

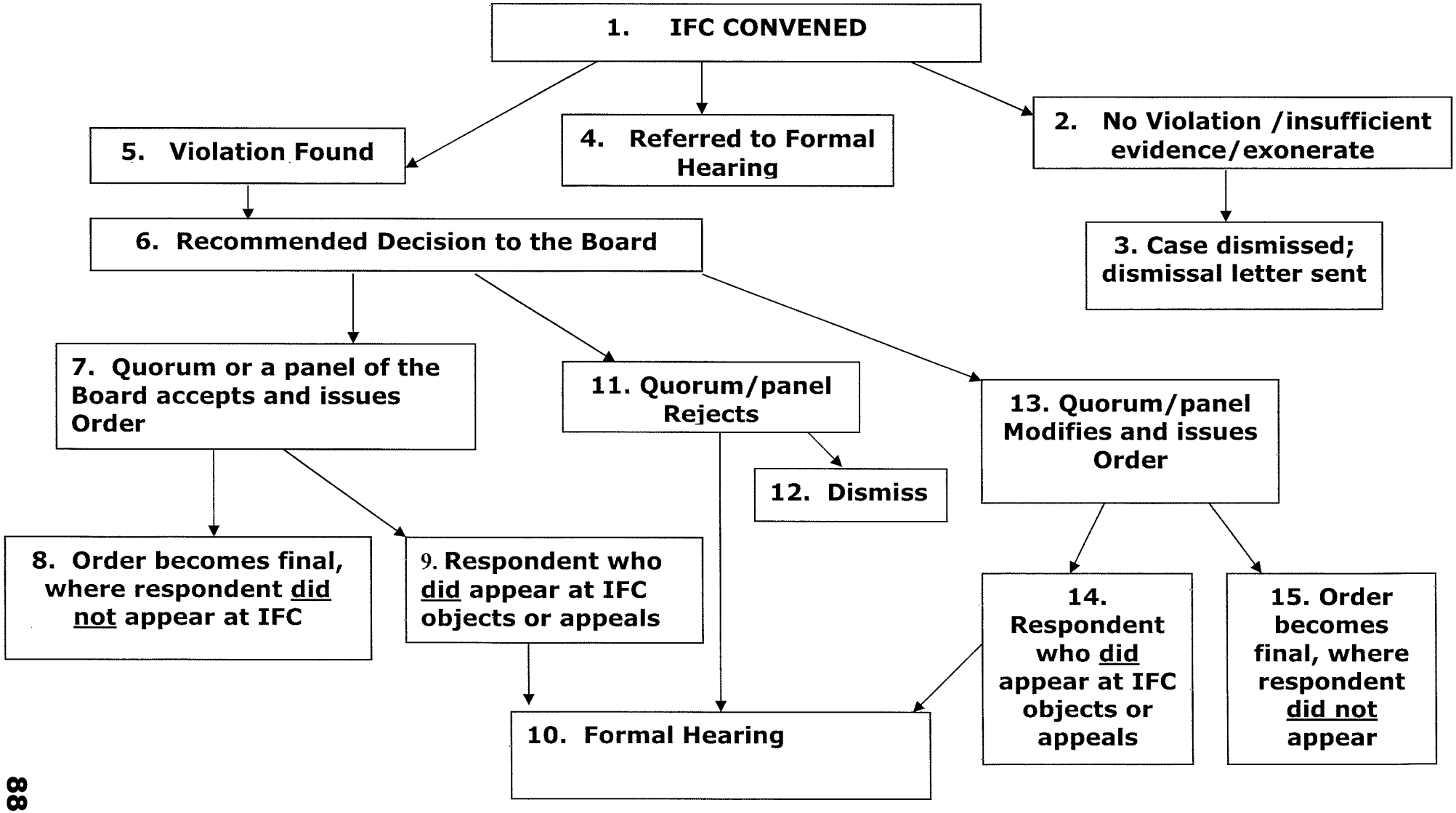
Pharmacy Interns as Pharmacy Technicians Pharmacy Technician Ratio

For the purpose of gaining practical experience to meet requirements for becoming a pharmacist, a registered pharmacy intern is by law allowed to perform tasks restricted to pharmacists provided they are directly monitored by a pharmacist. When a pharmacy intern is engaged in obtaining required practical experience hours, to be used either by the college of pharmacy or submitted to the Board on an affidavit, the pharmacy intern is not counted in the pharmacist to pharmacy technician ratio. For example, one pharmacist could be supervising a pharmacy intern for experience and up to four pharmacy technicians at the same time.

The Board has determined that properly registered pharmacy interns may also act as pharmacy technicians without being registered as such during times when they are not gaining practical experience. Pharmacy interns when acting as pharmacy technicians, shall be considered part of the 1:4 pharmacist to technician ratio.

Pharmacy technician trainees who are not yet registered but performing technician tasks in a pharmacy within the allotted nine months time in an approved training program, are considered to be acting as pharmacy technicians and as such, are included in the 1:4 pharmacist to technician ratio.

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



Narrative explanation of Flow Chart on Delegation to an Agency Subordinate

This describes the process in which a subordinate hears a case at an informal conference up to a case that may be referred to a formal hearing.

1. Pursuant to a notice, the designated agency subordinate ("subordinate") will convene the informal conference ("IFC"). An IFC before a subordinate is conducted in the same manner as an IFC before a committee of the board. Following the presentation of information by the parties, the subordinate will consider the evidence presented and render a recommended decision regarding the findings of fact, conclusions of law, and if appropriate, the sanction to be imposed.

2. The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory and/or regulatory violation has occurred.

3. If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4. The subordinate may decide that the case should be referred to a formal hearing. A hearing before the board would then be scheduled and notice sent to the respondent.

5. The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

6. With the assistance of APD, the subordinate drafts a recommended decision, which includes the findings of fact, conclusions of law and sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board or a panel consisting of at least five members of the board.

7. If the quorum or panel of the board accepts the recommended decision and:

8. If the respondent <u>did not appear</u> at the IFC, the board's decision becomes a final order that can only be appealed to a circuit court; or

9-10. If the respondent <u>did appear</u> at the IFC and objects to and appeals the order, he may request a

formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

11. A quorum or panel of the board may reject the recommended decision of the subordinate, in which case:

The quorum/panel may decide to refer the case for a formal hearing **(10)**; or the quorum/panel may decide to dismiss the case and a dismissal letter is issued to the respondent notifying him of the decision of the board **(12)**.

13. A quorum or panel of the board may modify the subordinate's recommended decision and issue an order reflecting the modified decision to the respondent.

15. If the respondent did not appear at the informal conference, then the board's decision becomes a final order that can only be appealed to a circuit court.

14-10. If the respondent did appear at the informal conference and objects to and appeals the order, he may request a formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

Virginia Board of Pharmacy

Storage of Schedule II Drugs in a Pharmacy

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

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

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

Guidance Document 110-41

Virginia Board of Pharmacy

Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance

On November 19, 2007, the DEA published in the Federal Register the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally." This, however, is in opposition to DEA's previous policy which permitted the pharmacist to make limited changes to a prescription written for a Schedule II controlled substance after oral consultation with the prescriber. DEA plans to resolve this confusion through future rulemaking and instructs pharmacists to adhere to state regulations or policy regarding changes that a pharmacist may make to a schedule II prescription. Therefore, through policy, the Board will allow a pharmacist to make limited changes to a schedule II prescription as stated below.

When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the controlled substance prescribed (except for generic substitution permitted by law) or the prescriber's signature.

Adopted March 11, 2009
Revised December 14, 2011

Virginia Board of Pharmacy

Continuing Education Audit

Procedure for enforcement of CE requirements:

Following each renewal cycle, Board staff may audit the following persons for CE compliance:

- Persons checking "no" to the CE attestation on the annual license renewal form, either paper or online
- Persons who requested a continuance from the previous year
- Persons selected for random audit. The audit will be conducted pursuant to procedures established by the Department of Health Professions to ensure a statistically valid audit sample and randomness of those selected.

This procedure does not preclude the auditing and special handling of CE non-compliance as may be specified in a Board order.

If the response to the audit does not show compliance with CE requirements, Board staff will send a letter to the respondent offering resolution of the matter by consent, payment of an established monetary penalty, and proof of late compliance with CE requirements. The letter will also offer an additional opportunity for the respondent to furnish proof that CE requirements were actually met during the specified time period or the opportunity to request an informal conference. A signed letter will constitute an order of the Board and the licensee's consent to the imposition of a monetary penalty and an agreement to the submission of documentation of late CE compliance. If there is no response to the letter, within 30 days, an informal conference before an agency subordinate, or IFC if more expedient, will be scheduled.

The monetary penalty offered in the letter shall be $250 for each year a pharmacist does not meet CE requirements. Because the maximum audit period is 2 years, the maximum penalty would be $500. The monetary penalty offered for each year that a pharmacy technician does not meet CE requirements will be $50, for a maximum penalty of $100. Board-imposed penalties for CE non-compliance not resolved by consent may result in additional penalties following the informal conference proceedings.

Virginia Board of Pharmacy

Dispensing with an Authorized Generic

The term "authorized generic" is defined in 21CFR314.3 as a listed drug that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug. Because authorized generics are identical to the branded drug product, sharing both the same active and inactive ingredients as the branded product, the FDA does not specifically list these drugs as a therapeutically equivalent drug product of the branded drug. However, according to the preface of the 32nd edition of the FDA's Orange Book, page vii, "Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder's drug product even if the application holder's drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder."

Therefore, consistent with the provisions for dispensing therapeutically equivalent drug products as listed in 54.1-3408.03 the Board affirmed that a pharmacist may substitute an authorized generic when dispensing a prescription written for a branded drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product. A listing of authorized generics is provided by the FDA at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.

Related statutes:

§54.1-3401

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.

A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.

In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.

B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.

C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.

D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.

Sanctioning Reference Points Instruction Manual

Board of Pharmacy

Adopted September 2007
Revised June 2013
Revised September 2013
Guidance Document 110-21

Prepared for
Virginia Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463
804-367-4400 tel
dhp.virginia.gov

Prepared by
VisualResearch, Inc.
Post Office Box 1025
Midlothian, Virginia 23113
804-794-3144 tel
vis-res.com

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
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

July 2013

Dear Interested Parties:

In the spring of 2001, the Virginia Department of Health Professions approved a workplan to study sanctioning in disciplinary cases for Virginia's 13 health regulatory boards. The purpose of the study was to "*...provide an empirical, systematic analysis of board sanctions for offenses and, based on this analysis, to derive reference points for board members...*" The purposes and goals of the study were consistent with state statutes which specify that the Board of Health Professions (BHP) periodically review the investigatory and disciplinary processes to ensure the protection of the public and the fair and equitable treatment of health professionals.

After interviewing Board of Pharmacy's members and staff, a committee of board members, staff, and research consultants assembled a research agenda involving the most exhaustive statistical study of sanctioned Pharmacists ever conducted in the United States. The analysis included collecting over 100 factors on all Board of Pharmacy sanctioned cases in Virginia over a six year period. These factors measured case seriousness, respondent characteristics, and prior disciplinary history. After identifying the factors that were consistently associated with sanctioning, it was decided that the results provided a solid foundation for the creation of sanctioning reference points. Using both the data and collective input from the Board of Pharmacy and staff, analysts developed a usable sanction worksheet as a way to implement the reference system.

In 2010, BHP recommended that the SRPs be evaluated to determine if the program had met the objectives set forth in 2001. The outcomes related to the Board of Pharmacy resulted in several changes to the Sanctioning Reference Points worksheet. This manual is the product of those adopted changes.

Sincerely yours,

D. Reynolds-Cane M.D.

Dianne L. Reynolds-Cane, M.D.
Director
Virginia Department of Health Professions

Cordially,

Elizabeth A. Carter, Ph.D.

Elizabeth A. Carter, Ph.D.
Executive Director
Virginia Board of Health Professions

Table of contents

GENERAL INFORMATION

Overview

The Virginia Board of Health Professions (BHP) has spent the last 10 years studying sanctioning in disciplinary cases. The study has examined all of the Department of Health Professions' (DHP) 13 health regulatory boards. Focusing on the Board of Pharmacy (BOP), this manual contains background on the project, the goals and purposes of the Sanctioning Reference Points (SRP) system, and a revised offense-based worksheet and grid used to help board members determine how similarly situated respondents have been treated in the past.

This SRP system is based on a specific sample of cases, and thus only applies to those persons sanctioned by the Virginia Board of Pharmacy. Moreover, the worksheets and grids have not been tested or validated on any other groups of persons. Therefore, they should not be used to sanction respondents coming before other health regulatory boards, other states, or other disciplinary bodies.

The original SRP system was comprised of a single worksheet created for use in cases involving a Pharmacist. Since adoption of the SRP system in 2007, the BOP has begun regulating the work of Pharmacy Technicians. During the interview process, it became clear that Pharmacists and Pharmacy Technicians were involved in different types of cases and, consequently, were sanctioned differently. Thus, these two groups would need to be studied separately which would result in separate worksheets.

The SRP worksheet used for Pharmacists, as well as the worksheet used for Pharmacy Technicians, scores case type and offense and respondent factors identified using statistical analysis. Both were built upon the Department's effort to maintain standards of practice over time. The factors were isolated and tested in order to determine their influence on sanctioning outcomes. Sanctioning thresholds found on each worksheet recommend a range of sanctions from which the board may select in a particular case.

In addition to this instruction booklet, separate coversheets and worksheets are available to record the respondent's score, recommended sanction, actual sanction and any reasons for departure (if applicable). The completed coversheets and worksheets will be evaluated as part of an on-going effort to monitor and refine the SRPs.

These instructions and the use of the SRP system fall within current DHP and BOP policies and procedures. Furthermore, all sanctioning recommendations are those currently available to and used by the board and are specified within existing Virginia statutes. If an SRP worksheet recommendation is more or less severe than a Virginia statute or DHP regulation, the existing laws or policy supersedes the worksheet recommendation.

Background

In April of 2001, BHP approved a work plan to conduct an analysis of health regulatory board sanctioning and to consider the appropriateness of developing historically-based sanctioning reference points for health regulatory boards, including the BOP. In 2010, BHP recommended that the SRPs be evaluated to determine if the program had met the objectives set forth in 2001. The purpose of this study was to evaluate the SRP system against its own unique set of objectives. The SRPs were designed to aid board members, staff and the public in a variety of ways. This Effectiveness Study sought to examine whether or not the SRPs were successful, and if not, which areas required improvement.

The Effectiveness Study relied heavily on the completed coversheets and worksheets which record the offense score, respondent score, recommended sanction, actual sanction and any reasons for departure (if applicable). The study resulted in changes to the manual for the BOP. This manual is the result of those adopted changes.

Goals

In 2001, BHP and the BOP cited the following purposes and goals for establishing SRPs:

- Making sanctioning decisions more predictable
- Providing an education tool for new board members
- Adding an empirical element to a process/system that is inherently subjective
- Providing a resource for BOP members and those involved in proceedings
- Neutralizing sanctioning inconsistencies
- Validating board member or staff recall of past cases

- Reducing the influence of undesirable factors—e.g., board member ID, overall board makeup, race or ethnic origin, etc.
- Helping predict future caseloads and need for probation services and terms

Methodology

The fundamental question when developing a sanctioning reference system is deciding whether the supporting analysis should be grounded in historical data (a descriptive approach) or whether it should be developed normatively (a prescriptive approach). A normative approach reflects what policymakers feel sanction recommendations should be, as opposed to what they have been. SRPs can also be developed using historical data analysis with normative adjustments. This approach combines information from past practice with policy adjustments, in order to achieve a more balanced outcome. The SRP manual adopted in 2007 was based on a descriptive approach with a limited number of normative adjustments. The Effectiveness Study was conducted in a similar manner, drawing from historical data to inform worksheet modification.

Qualitative Analysis

Researchers conducted in-depth personal interviews with BOP members and staff. Researchers also had informal conversations with representatives from the Attorney General's office and the Executive Director of BHP. The interview results were used to build consensus regarding the purpose and utility of SRPs and to further guide the Effectiveness Study's analysis. Additionally, interviews helped ensure the factors that board members consider when sanctioning continued to be included during the quantitative phase of the study. Previous scoring factors were examined for their continued relevance and sanctioning influence.

Quantitative Analysis

In 2002, researchers collected detailed information on all BOP disciplinary cases ending in a violation between 1997 and 2002; approximately 361 sanctioning "events" covering close to 450 cases. Over 100 different factors were collected on each case in order to describe the case attributes board members identified as potentially impacting sanction decisions. Researchers used data available through the DHP case management system combined with primary data collected from hard copy files. The hard copy files contained investigative reports, board notices, board orders, and all other documentation that is made available to board members when deciding a case sanction.

A comprehensive database was created to analyze the offense and respondent factors which were identified as potentially influencing sanctioning decisions. Using statistical analysis to construct a "historical portrait" of past sanctioning decisions, the significant factors along with their relative weights were derived. These factors and weights were formulated into a sanctioning worksheet with three thresholds, which became the SRPs.

During the Effectiveness Study, researchers used 72 Pharmacist SRP worksheets and coversheets previously completed by board members to create a database. Additionally, researchers collected data on approximately 100 Pharmacy Technician cases. The worksheets' factors, scores, sanction recommendations, sanctions handed down, and departure reasons (if any) were coded and keyed over the course of several weeks, creating a database. That database was then merged with DHP's data system L2K, making more variables eligible for analysis. The resulting Pharmacy Technician database was analyzed to determine which factors had an influence on sanctioning outcomes and the Pharmacist database was analyzed to determine any changes in board sanctioning that may have had an effect on the worksheet recommendations.

Offense factors such as patient injury, financial gain, and case type were analyzed as well as prior history factors such as substance abuse and previous board orders. Some factors were deemed inappropriate for use in a structured sanctioning reference system. For example, respondent age or region are considered "extra-legal" factors, and were explicitly excluded from the sanction reference points. Although, both "legal" and "extra-legal" factors can help explain sanction variation, only those "legal" factors the board felt should consistently play a role in a sanction decision continued to be included on the worksheets. By using this method, the goal is to achieve more neutrality in sanctioning by making sure the board considers the same set of "legal" factors in every disciplinary case ending in a violation.

Characteristics of the SRP System

Wide Sanctioning Ranges

The Sanctioning Reference Points consider and weigh the circumstances of an offense and the relevant characteristics of the respondent, providing the board with a sanction range that encompasses roughly 79% of historical practice for Pharmacists and roughly 88% for Pharmacy Technicians. This means that 21% (Pharmacists) and 12% (Pharmacy Technicians) of past cases had received sanctions either higher or lower than what the reference points indicate, acknowledging that aggravating and mitigating factors play a role in sanctioning. The wide sanctioning ranges allow the board to customize on a particular sanction within the broader SRP recommended range.

Voluntary Nature

The SRP system should be viewed as a decision-aid to be used by the Board of Pharmacy. Sanctioning within the SRP ranges is "totally voluntary," meaning that the system is viewed strictly as a tool, and the board may choose any sanction outside the recommendation. The board maintains complete discretion in determining the sanction handed down. However, a structured sanctioning system is of little value if the board is not provided with the appropriate coversheet and worksheet in every case eligible for scoring. A coversheet and worksheet should be completed in cases resolved by Informal Conference or Pre-Hearing Consent Order. This includes cases resolved at an informal conference and those resolved using prehearing consent orders offered by staff or board members. The coversheet and worksheets will be used only after a violation has been determined.

Coversheets and Worksheets

Coversheets are completed to ensure a uniform record of each case and to facilitate recordation of other pertinent information critical for continued system monitoring, evaluation and improvement. If the board feels the sanctioning grid does not recommend an appropriate sanction, the board should depart either high or low when handing down a sanction, "Yes" should be checked and a short explanation should be recorded on the coversheet. The explanation should identify the factors and reasons for departure. This process ensures worksheets are revised to reflect current board practice and to maintain the dynamic nature of the system. For example, if a particular reason is continually cited, the board can examine the issue more closely to determine if the worksheets should be modified to better reflect board practice

Worksheet Not Used In Certain Cases

The Sanctioning Reference Points will not be applied in any of the following circumstances:

- Action by Another Board – When a case which has already been adjudicated by a board from another state appears before the Virginia Board of Pharmacy, the board often attempts to mirror the sanction handed down by the other board. The Virginia Board of Pharmacy usually requires that all conditions set by the other board are completed or complied with in Virginia. The SRPs do not apply to cases previously heard and adjudicated by another board.
- Compliance/Reinstatement – The SRPs should be applied to new cases only.
- Confidential Consent Agreements (CCA) – SRPs will not be used in cases settled by CCA.
- Continuing Education (CE)
- Formal Hearings — Sanction Reference Points will not be used in cases that reach a Formal Hearing level.
- Mandatory Suspensions – Virginia law requires that under certain circumstances (conviction of a felony, declaration of legal incompetence or incapacitation, license revocation in another jurisdiction) the license of a pharmacist or pharmacy technician must be suspended. The sanction is defined by law and is therefore excluded from the Sanctioning Reference Point system.

Sanctioning Reference Points for Pharmacists Only

Using the SRP System for Pharmacists

Case Types Covered by the Sanctioning Reference Points

Pharmacists are scored on one SRP worksheet for all case types. The case types are grouped into 3 categories: Inability to Safely Practice, Professional Practice Issues and Prescription Error. This organization is based on the most recent historical analysis of board sanctioning. The SRP factors found on the worksheet are those which proved important in determining sanctioning outcomes.

When multiple cases have been combined for disposition by the board into one order, only one coversheet and worksheet, which encompasses the entire event. In these instances, the worksheet completed is selected according to the case type group which appears highest on the following table and receives the most points. For example, a pharmacist found in violation of both a labeling error and personal use would receive seventy points, since Inability to Safely Practice is above Prescription Error on the list and receives the most points. If an offense type is not listed, find the most analogous offense type and use the appropriate score. The case type that has been selected from the list below is the only case type that receives points on the sanctioning worksheet.

Sanctioning Reference Points Case Type Table

Inability to Safely Practice	Impairment due to use of alcohol, illegal substances, or prescription drugs, or incapacitation due to mental, physical or medical conditions Dispensing in violation of DCA (to include dispensing for non medicinal purposes, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use	70
Professional Practice Issues	Falsification/alteration of patient records Business Practice Issues Advertising, default on guaranteed student loan, solicitation, records, audits, required report not filed or disclosure Failure to maintain security of controlled substances Disclosing unauthorized client information without permission or necessity	25
Prescription Error	Labeling, dispensing, and administration errors Failure to provide counseling Standard of Care - Other: cases involving patient care that cannot fit adequately into any other case type	10

Two Sets of Sanctioning Factors

The board indicated early in the SRP study that sanctioning is not only influenced by circumstances directly associated with the case, but also by the respondent's past history. The empirical analysis supported the notion that case type as well as offense and respondent factors impacted sanction outcomes. Subsequently, the SRP worksheet for Pharmacists makes use of two sets of factors that combine for a sanctioning outcome that lies within one of three thresholds. The first dimension assesses factors related to case type, the second assesses factors related to the offense and respondent. So a respondent before the board for a Prescription Error case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations.

Determining a Specific Sanction

The thresholds have three separate sanctioning outcomes: No Sanction/Reprimand/CE, Monetary Penalty, and Treatment/Monitoring/ Recommend Formal. The table below lists the most frequently cited sanctions under the three sanctioning outcomes that are part of the sanction threshold. After considering the sanction recommendation, the board should fashion a more detailed sanction(s) based on the individual case circumstances.

Expanded Sanctioning Grid Outcomes

Worksheet Threshold	Available Sanction	Fine Amounts
No Sanction/Reprimand/CE	No Sanction Reprimand Continuing Education	N/A
Monetary Penalty	Monetary Penalty	$250 to $1500
Treatment/Monitoring/ Recommend Formal	Probation Stayed Suspension Revocation Suspension Revoke Right to Renew Suspend Right to Renew Recommend Formal Terms: Begin/ continue AA, NA, Caduceus, HPMP Random drug screenings Drug, alcohol, mental or physical evaluation Quarterly self reports Quarterly performance evaluation from employer Written notification to PIC Inform board of any changes in employment Notarized affidavit attesting to read/follow Ch.25.2 of Code of VA Take/pass VA Drug Law Exam Shall not be Pharmacist in Charge Inform board upon resuming practice Inspection Written evidence to board of proper recordation of ingredients of compounded drugs Report any medication errors to board within 10 days of occurrence Other practice restriction	$1000 and up

Sanctioning Reference Points Coversheet, Worksheet and Instructions for Pharmacists Only

Sanctioning Reference Points Coversheet for Pharmacists

Case Number(s): | | | | | | | | | | | | | | | | | | |

Respondent Name: _____ _____ _____

License Number: _____

Sanction Threshold Level:
____ 0-35
____ 36-115
____ 116 and up

Imposed Sanction(s):
____ No Sanction
____ Reprimand
____ Continuing Education
____ Monetary Penalty
____ Probation: _____ duration in months
____ Stayed Suspension: _____ duration in months
____ Revocation
____ Suspension
____ Revoke Right to Renew
____ Suspend Right to Renew
____ Recommend Formal
____ Other Sanction: _____
____ Terms: _____

Was imposed sanction a departure from the recommendation? ___No ___Yes, give reason below

Reasons for Departure from Sanction Grid Result: _____

_____

_____

Worksheet Preparer's Name: _____

Date Worksheet Completed: _____

SRP Worksheet for Pharmacists

Board of Pharmacy
Adopted 9/10/2013

Case Type (score only one)	Points	Score
A. Inability to Safely Practice	70	
B. Professional Practice Issues	25	
C. Prescription Error	10	

Offense and Repsondent (score all that apply)		
A. Financial/Material gain	60	
B. Respondent impaired during incident	50	
C. Any past substance abuse or treatment	50	
D. Multiple violations associated with case	35	
E. Act of commission	35	
F. Patient injury	15	
G. Any prior violations	5	

Total Worksheet Score ☐

Score	Sanctioning Recommendations	Fine Amounts
0-35	No Sanction/Reprimand/CE	N/A
36-115	Monetary Penalty	$250 to $1500
116 and up	Treatment/Monitoring/Recommend Formal	$1000 and up

Respondent Name: _____ Date: _____

SRP Worksheet Instructions for Pharmacists

Board of Pharmacy
Adopted 9/10/2013

Case Type

Step 1: (score only one)
Enter the point value that corresponds to the case type. If a case has multiple aspects, enter the point value for the one most serious case type that is highest on the list.

A. Enter "70" if case involves an Inability to Safely Practice. These cases include:
   - Inability to Safely Practice: Impairment due to use of alcohol, illegal substances, or prescription drugs, or incapacitation due to mental, physical or medical conditions
   - Drug Related – Patient Care: Dispensing in violation of DCA (to include dispensing for non-medicinal purposes, excessive prescribing, not in accordance with dosage, filling an invalid prescription, or dispensing without a relationship), prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use

B. Enter "25" if the case involves Professional Practice Issues. These cases include:
   - Business Practice Issues: records, audits, required report not filed, or disclosure
   - Drug Related – Security: Failure to maintain security of controlled substances
   - Fraud – Patient Care: falsification/alteration of patient records
   - Confidentiality Breach: disclosing unauthorized client information without permission or necessity

C. Enter "10" if the case involves a Prescription Error. These cases include:
   - Standard of Care – Medication/Prescription: labeling, dispensing, and administration errors, failure to provide counseling as well as other medication/prescription related issues
   - Standard of Care – Other

Offense and Respondent

Step 2: (score all that apply)

A. Enter "60" if there was financial or other material gain from the offense.
B. Enter "50" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
C. Enter "50" if the respondent has had any past difficulties or treatment in any of the following areas: drugs, alcohol, mental health and/or physical health. Difficulties in these areas must be relevant to the current case and treatment must have been provided by a bona fide health care practitioner.
D. Enter "35" if there are two or more concurrent founded violations during the same proceeding. This includes two or more cases against a respondent heard at the same time, with violations for each case.
E. Enter "35" if there was an act of commission. An act of "commission" is interpreted as purposeful, intentional, or clearly not accidental.
F. Enter "15" if the patient was injured. Patient injury includes any injury reported by the consumer regardless of follow up treatment.
G. Enter "5" if the respondent has had one or more prior board violations.

Step 3: Combine all for Total Worksheet Score. Locate the Total Worksheet Score with the Sanction Threshold Levels table at the bottom of the worksheet. The scores correspond to one of the three SRP recommendations.

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Monetary Penalty" area with a score of 40, the board may choose a sanction package that includes a "Monetary Penalty" and a "Reprimand" and still be in agreement with the SRP recommendation.

Sanctioning Reference Points for Pharmacy Technicians Only

Using the SRP System for Pharmacy Technicians

Case Types Covered by the Sanctioning Reference Points

Pharmacy Technicians are scored on one SRP worksheet for all case types. The case types are grouped into 3 categories: Inability to Safely Practice, Standard of Care and Professional Practice Issues. This organization is based on the most recent historical analysis of board sanctioning. The SRP factors found on the worksheet are those which proved important in determining sanctioning outcomes.

When multiple cases have been combined for disposition by the board into one order, only one coversheet and worksheet is completed that encompasses the entire event. In these instances, the worksheet completed is selected according to the case type group which appears highest on the following table and receives the most points. For example, a pharmacy technician found in violation for both unlicensed activity and personal use would receive thirty five points, since Inability to Safely Practice is above Standard of Care on the list and receives the most points. If an offense type is not listed, find the most analogous offense type and use the appropriate score. The case type that has been selected from the list below is the only case type that receives points on the sanctioning worksheet.

Sanctioning Reference Points Case Type Table

Case Types		Points
Inability to Safely Practice	Impairment due to use of alcohol, illegal substances, or prescription drugs, or incapacitation due to mental, physical or medical conditions. Prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use. Felony or misdemeanor conviction.	**35**
Standard of Care	Medication/Prescription: Labeling or dispensing process errors. Exceeding Scope: practicing outside the permitted functions of registration granted. Confidentiality Breach: disclosing unauthorized patient information without permission or necessity.	**25**
Professional Practice Issue	Drug Related – Security: Unauthorized access to controlled substances. Unlicensed Activity: Practicing a profession or occupation without holding a valid registration as required by statute or regulation to include: practicing on a revoked, suspended, lapsed, non-existent or expired registration. Fraud – Non-Patient Care: Falsification of licensing/renewal documents.	**5**

Two Sets of Sanctioning Factors

The board indicated early in the SRP study that sanctioning is not only influenced by circumstances directly associated with the case, but also by the respondent's past history. The empirical analysis supported the notion that case type as well as offense and respondent factors impacted sanction outcomes. Subsequently, the SRPs make use of two sets of factors that combine for a sanctioning outcome that lies within one of three thresholds. The first dimension assesses factors related to case type, the second assesses factors related to the offense and respondent. So a respondent before the board for a Prescription Error case may also receive points for having had substance abuse problems, or for having a history of disciplinary violations for other types of cases.

Determining a Specific Sanction

The Sanction thresholds have three separate sanctioning outcomes: No Sanction/Reprimand/ Monetary Penalty, Treatment/Monitoring, and Loss of License/Refer to Formal. The table below lists the most frequently cited sanctions under the three sanctioning outcomes that are part of the sanction threshold. After considering the sanction recommendation, the board should fashion a more detailed sanction(s) based on the individual case circumstances.

Expanded Sanctioning Grid Outcomes

Worksheet Threshold	Available Sanction	Fine Amounts
No Sanction/ Reprimand/ Monetary Penalty	No Sanction Reprimand Monetary Penalty	$50-$250
Treatment/ Monitoring	Stayed Suspension Probation Terms: HPMP CE Inform board upon resuming practice Inform board of any changes in employment Quarterly performance evaluation from employer Begin/continue AA or NA Chemical dependency/ psychological/ mental/ physical evaluation Continue in therapy and therapist provides quarterly reports Written notification to PIC Quarterly self reports	N/A
Loss of License/ Refer to Formal	Revocation Suspension Surrender Refer to Formal	N/A

Sanctioning Reference Points Coversheet, Worksheet and Instructions for Pharmacy Technicians Only

Sanctioning Reference Points Coversheet for Pharmacy Technicians

Case Number(s): | | | | | | | | | | | | | | | | | | |

Respondent Name: _____ _____ _____

License Number: _____

Sanction Threshold Level:
____ 0-60
____ 61-90
____ 91 and up

Imposed Sanction(s):
____ No Sanction
____ Reprimand
____ Monetary Penalty
____ Probation: _____ duration in months
____ Stayed Suspension: _____ duration in months
____ Revocation
____ Suspension
____ Recommend Formal
____ Other Sanction: _____
____ Terms: _____

Was imposed sanction a departure from the recommendation? ___No ___Yes, give reason below

Reasons for Departure from Sanction Grid Result: _____

_____

_____

Worksheet Preparer's Name: _____

Date Worksheet Completed: _____

SRP Worksheet for Pharmacy Technicians

Board of Pharmacy
Adopted 9/10/2013

Case Type (score only one)	Points	Score
A. Inability to Safely Practice	35	
B. Standard of Care	25	
C. Professional Practice Issues	5	

Offense and Respondent Factors (score all that apply)		
A. Financial/Material gain	70	
B. Respondent impaired during incident	55	
C. Any Patient Involvement	35	
D. DCA Violation	30	
E. Case involved any type of drug	25	
F. Case involved opioids	30	
G. Any prior violations	15	

Total Respondent Score ☐

Score	Sanctioning Recommendations	Fine Amounts
0-60	No Sanction/Reprimand/Monetary Penalty	$50-$250
61-90	Treatment/Monitoring	N/A
91 and up	Loss of License/Refer to Formal	N/A

Respondent Name: _____ Date: _____

Case Type

Step 1: (score only one)
Enter the point value that corresponds to the case type. If a case has multiple aspects, enter the point value for the one most serious case type that is highest on the list.

D. Enter "35" if case involves an Inability to Safely Practice. These cases include:
- Impairment due to use of alcohol, illegal substances, or prescription drugs or incapacitation due to mental, physical or medical conditions.
- Prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use.
- Felony or misdemeanor conviction.

E. Enter "25" if the case involves Standard of Care. These cases include:
- Medication/Prescription: Labeling or dispensing process errors.
- Exceeding Scope: practicing outside the permitted functions of registration granted.
- Confidentiality Breach: disclosing unauthorized patient information without permission or necessity.

C. Enter "5" if the case involves Professional Practice Issues. These cases include:
- Drug Related – Security: Unauthorized access to controlled substances.
- Unlicensed Activity: Practicing a profession or occupation without holding a valid registration as required by statute or regulation to include: practicing on a revoked, suspended, lapsed, non-existent or expired registration.
- Fraud – Non-Patient Care: Falsification of licensing/renewal documents.

Offense and Respondent Factors

Step 2: (score all that apply)

H. Enter "70" if there was financial or other material gain from the offense.
I. Enter "55" if the respondent was impaired at the time of the incident. Impairment can include drugs, alcohol, mental and/or physical.
J. Enter "35" if there was any patient involvement. Patient involvement may include an error in the delivery of a drug to a patient.
K. Enter "30" if the case involves prescription forgery, drug adulteration, patient deprivation, stealing drugs from patients, or personal use.
L. Enter "25" if the case involved any type of prescription drug.
M. Enter "30" if the case involved an Opioid. This factor is scored in addition to the previous factor, "Case involved any type of Drug."
N. Enter "15" if the respondent has had one or more prior board violations.

Step 3: Combine all for Total Worksheet Score. Locate the Total Worksheet Score with the Sanction Threshold Levels table at the bottom of the worksheet. The scores correspond to one of the three SRP recommendations.

The use of the Sanction Reference Points is voluntary. In addition, the worksheet sanction result may be combined with sanctions from lower sanction thresholds. For example, should a respondent fall within the "Treatment/Monitoring" area with a score of 75, the board may choose a sanction package that includes a Probation and a Monetary Penalty and still be in agreement with the SRP recommendation.

Virginia Department of Health Professions
Board of Pharmacy

Virginia Board of Pharmacy
Pharmaceutical Processor Inspection Report

9960 Mayland Drive, Suite 300
Henrico, VA 23233

www.dhp.virginia.gov/pharmacy
Email: pharmbd@dhp.virginia.gov

Main: 804.367.4456
Fax: 804.527.4472

Pharmaceutical Processor Name:		**Inspection Type:**	
Pharmaceutical Processor Permit Number:		**Inspection Results:**	
Legal Business Name:		**Date of Last Inspection:**	
Doing Business As (DBA):		**Day 1:**	
Address:		**Start Time:** 24-hour format (13:00)	
City:		**End Time:** 24-hour format (13:00)	
City:		**Day 2:**	
State:		**Start Time:** 24-hour format (13:00)	
Zip Code:		**End Time:** 24-hour format (13:00)	
Designated Health Service Area:		**Inspector Name:**	
Telephone number:		**Observer Name/Affiliation (if applicable):**	
Toll free number:		**Pharmacist on Duty:**	
Fax number:		**Pharmacist on Duty License Number:**	
Email address:		**Inspection Emailed To (person):**	
Website:		**Inspection Emailed To (email address):**	

Pharmacy Hours of Operation	**Is facility opne 24/7?**		
	Open		**Closed**
	Start Time: (24-hour format hh:mm)	**End Time: (24-hour format hh:mm)**	
Sunday			
Monday			
Tuesday			
Wednesday			
Thursday			
Friday			
Saturday			

Business Licensure Information for State of Residence and Federal
(board of pharmacy, state controlled substance, DEA, FDA, etc.)

License/Registration Agency	**Business Name on License/Registration**	**License Type/Number**	**Expiration Date**

Personnel

Personnel present at the time of inspection:

Pharmacists:		Pharmacist:Pharmacy Technician Ratio			
Pharmacy Technicians:		Pharmacy Interns:		Unlicensed Staff:	

List all personnel employed by the processor (Attach list if additional space is required):

Position	Name	License Number	Activity	Describe Degree or Experience. Check box if training completed.
Pharmacist-in-Charge				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐
				☐

Inspector Notes:

Permit & Personnel			
		Result	Notes
	Processor Permit		§54.1-3442.6
	The processor holds a current active permit.		
	Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.		
	Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.		
	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. **[§54.1-3342.6 & 18 VAC 110-60-110]**		
	Employee Licenses & Registration 18 VAC 110-60-170		18 VAC 110-60-170
	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.		
	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.		
	No person shall perform the duties in 18 VCA 110-60-170 (C) under pharmacist supervision without maintaining a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and having been registered with the board or registered or certified by the board of another United States jurisdiction as a pharmacy technician for the previous two years.		
	Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician but have received a degree in horticulture or have at least two years of experience cultivating plants may perform duties associated with the **cultivation** of Cannabis, as authorized by the PIC.		
	Persons who do not maintain licensure as a pharmacist or registration as a pharmacy technician, but have received a degree in chemistry or pharmacology or have at least two years of experience extracting chemicals from plants may perform duties associated with the **extraction** of cannabidiol oil and THC-A oil, as authorized by the PIC.		
	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.		Check if process approved by the Board ☐
	At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.		
	No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.		
	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.		
	Employee Training		18 VAC 110-60-180
	All employees of a pharmaceutical processor shall complete training, prior to the employee commencing work at the pharmaceutical processor, at a minimum, in the following: *(Document training completed in Personnel section)*		
	1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil, and THC-A oil;		

		Result	Notes
	2. Procedures and instructions for responding to an emergency;		
	3. Professional conduct, ethics, and state and federal statutes and regulations regarding patient confidentiality; and		
	4. Developments in the field of the medical use of cannabidiol oil or THC-A oil.		
	Prior to regular performance of assigned tasks, the employee shall also receive on-the-job training and other related education, which shall be commensurate with the tasks assigned to the employee.		
	The PIC shall assure the continued competency of all employees through continuing in-service training designed to supplement initial training, which shall include any guidance specified by the board.		
	The PIC shall be responsible for maintaining a written record documenting the initial and continuing training of all employees, which shall contain:		
	1. The name of the person receiving the training;		
	2. The dates of the training;		
	3. A general description of the topics covered;		
	4. The name of the person supervising the training; and		
	5. The signatures of the person receiving the training and the PIC.		
	When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.		
	A pharmaceutical processor shall maintain the record documenting the employee training and make it available in accordance with regulations.		
	Pharmacy Technicians 18 VAC 110-20-190		**18 VAC 110-60-190**
	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. *(Record ratio in Personnel section)*		
	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.		
	Pharmacy technicians shall not:		
	1. Counsel a registered patient or the patient's parent or legal guardian regarding cannabidiol oil, THC-A oil, or other drugs, either before or after cannabidiol oil or THC-A oil has been dispensed, or regarding any medical information contained in a patient medication record; 2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking; 3. Interpret the patient's clinical data or provide medical advice; 4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or 5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.		
	PIC Responsibilities		**18 VAC 110-60-200**
	No person shall be PIC for more than one pharmaceutical processor at any time.		
	A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board. *(Describe how verified)*		

		Result	Notes
	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.		
	The pharmaceutical processor PIC shall be responsible for ensuring that:		
	1. Pharmacy technicians are registered and all employees are properly trained;		
	2. All record retention requirements are met;		
	3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, and THC-A oil are met;		
	4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed;		
	5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, or legal guardians:		
	a. Pharmaceutical processor permit;		
	b. Licenses for all pharmacists practicing at the pharmaceutical processor; and		
	c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor; and		
	6. Any other required filings or notifications are made on behalf of the processor as set forth in regulation.		
	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.		
	An application for a permit designating the new PIC shall be filed with the required fee within 15 days of the original date of resignation or termination of the PIC on a form provided by the board.		
	Prescription Monitoring Program		**§54.1-2521**
	Upon dispensing a covered substance, a dispenser of such covered substance shall submit a report to the Prescription monitoring program. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.		
	§54.1-2519: "Covered substance" means all controlled substances included in Schedules II, III, and IV; controlled substances included in Schedule V for which a prescription is required; naloxone; and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. "Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.		

Operations			
		Result	Notes
	Processor Permit		**18 VAC 110-60-130**
	Once the permit is issued, Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application.		
	Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis.		
	Notification of Changes		**18 VAC 110-60-140**
	Prior to making any change to the pharmaceutical processor name, the pharmaceutical processor shall submit an application for such change to the board and pay the fee.		
	Any person wishing to engage in the acquisition of an existing pharmaceutical processor, change the location of an existing pharmaceutical processor, make structural changes to an existing pharmaceutical processor, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.		
	The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.		
	Cannabis shall not be moved to a new location until approval is granted by the inspector or board staff.		
	Closings, Going Out of Business, Change of Ownership		**18 VAC 110-60-150**
	At least 14 days prior to any change in ownership of an existing pharmaceutical processor, the owner shall notify the board of the pending change.		
	Upon any change in ownership of an existing pharmaceutical processor, the dispensing records for the two years immediately preceding the date of change of ownership and other required patient information shall be provided to the new owners on the date of change of ownership in substantially the same format as previously used immediately prior to the transfer to provide continuity of services.		
	General Provisions		**18 VAC 110-60-210**
	A pharmaceutical processor shall sell cannabidiol oil or THC-A oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.		
	Only a pharmacist may dispense cannabidiol oil or THC-A oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board. A pharmacy technician who meets the requirements of 18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabidiol oil or THC-A oil.		
	The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor to:		
	1. Such persons whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or		
	2. Such person who is a registered patient, parent, or legal guardian, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil is stored.		
	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.		

		Result	Notes
	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.		
	A pharmaceutical processor shall be open for registered patients, parents, or legal guardians to purchase cannabidiol oil or THC-A oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.		
	A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, and legal guardians of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs.		
	If the pharmaceutical processor is, or will be, closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.		
	A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil;		
	The pharmaceutical processor shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy, which shall be available to the board or the board's agent upon request.		
	Prohibitions		**18 VAC 110-60-220**
	No pharmaceutical processor shall:		
	1. Cultivate Cannabis plants, produce, or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;		
	2. Sell, deliver, transport, or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility;		
	3. Produce or manufacture cannabidiol oil or THC-A oil for use outside of Virginia; or		
	4. Provide cannabidiol oil or THC-A oil samples.		
	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.		
	No pharmaceutical processor shall sell anything other than cannabidiol oil or THC-A oil products from the pharmaceutical processor.		
	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; and		
	5. Directions to the processor facility.		
	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.		

		Result	Notes
	No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.		
	Notwithstanding the requirements of 18 VAC 110-60-220 (F), an agent of the board, local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.		
	All persons who have been authorized, in writing, to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee, prior to entering the pharmaceutical processor.		
	1. An employee shall escort and monitor such a visitor at all times the visitor is in the pharmaceutical processor. 2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor. 3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log, which shall include the date, time, and purpose of the visit, and that shall be available to the board. 4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.		
	No cannabidiol oil or THC-A oil shall be sold, dispensed, or **distributed via a delivery service** or any other manner outside of a pharmaceutical processor, except that a registered parent or legal guardian may deliver cannabidiol oil or THC-A oil to the registered patient or in accordance with subsection A of 18VAC110-60-310 .		
	Inventory Requirements 18 VAC 110-60-230		**18 VAC 110-60-230**
	Each pharmaceutical processor, prior to commencing business, shall:		
	1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and		
	2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, which shall enable the facility to detect any diversion, theft, or loss in a timely manner.		
	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.		

		Result	Notes
	The weekly 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.		
	The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale, the name of the pharmaceutical processor, registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold, the address of such person, and the kind and quantity of cannabidiol oil or THC-A oil sold.		
	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.		
	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.		
	Inventory records shall be maintained for **three years** from the date the inventory was taken.		
	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.		
	Security Requirements		**18 VAC 110-60-240**
	A pharmaceutical processor shall **initially** cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the **first nine months** of operation. *Record number of anticipated patients and number of plants.*		
	Thereafter, the processor shall:		
	1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days. *Record number of patients and number of plants*		
	2. Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation.		
	3. Maintain all Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation.		
	4. Store all cut parts of Cannabis plants, extracts, cannabidiol oil, or THC-A oil in an approved safe or approved vault within the pharmaceutical processor.		
	Shall not sell cannabidiol oil or THC-A oil products when the pharmaceutical processor is closed.		
	5. Keep all approved safes, approved vaults, or any other approved equipment or areas used for the production, cultivation, harvesting, processing, manufacturing, or storage of cannabidiol oil or THC-A oil securely locked or protected from entry, except for the actual time required to remove or replace the Cannabis, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil.		
	6. Keep all locks and security equipment in good working order.		
	7. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas to pharmacists practicing at the pharmaceutical processor.		
	8. Not allow keys to be left in the locks or accessible to nonpharmacists.		

		Result	Notes
	The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, cannabidiol oil, or THC-A oil. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor. The installation and the device shall be based on accepted alarm industry standards and shall be subject to the following conditions:		
	1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.		
	2. The device shall be monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.		
	3. The device shall fully protect the **entire processor facility** and shall be capable of detecting breaking by any means when activated.		
	4. The device shall include a **duress alarm, a panic alarm**, and **automatic voice dialer.**		
	5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.		
	A pharmaceutical processor shall keep the outside perimeter of the premises well-lit.		
	A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.		
	1. The processor shall direct cameras at all approved safes, approved vaults, dispensing areas, cannabidiol oil, or THC-A oil sales areas and any other area where Cannabis plants, seeds, extracts, cannabidiol oil, or THC-A oil are being produced, harvested, manufactured, stored, or handled. At entry and exit points, the processor shall angle cameras so as to allow for the capture of clear and certain identification of any person entering or exiting the facility.		
	2. The video system shall have:		
	a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message.		
	b. The ability to immediately produce a clear color still photo that is a minimum of 9600 dpi from any camera image (live or recorded).		
	c. A date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture.		
	d. The ability to remain operational during a power outage.		
	3. All video recording shall allow for the exporting of still images in an industry standard image format.		
	4. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system.		

		Result	Notes
	5. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility.		
	6. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days.		
	7. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, it shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.		
	The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations.		
	All security equipment shall be maintained in good working order and shall be tested no less than two times per year. *Review documentation of test.*		
	A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board.		
	A processor shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor. *Submit list with inspection report.*		
	The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.		
	Storage & Handling		**18 VAC 110-60-250**
	A pharmaceutical processor shall have:		
	1. Storage areas that provide adequate conditions for the cultivation of Cannabis, and the production and dispensing of cannabidiol oil or THC-A oil:		
	a. Lighting		Referto cGMP section
	b. Sanitation		Referto cGMP section
	c. Ventilation		Referto cGMP section
	d. Space		Referto cGMP section
	e. Equipment		Referto cGMP section
	f. Temperature as defined in 18 VAC 110-60-10		
	g. Humidity as defined in 18 VAC 110-60-10		
	2. Separate for storage in a quarantined area Cannabis plants, seeds, parts of plants, extracts, including cannabidiol oil or THC-A oil, that is outdated, damaged, deteriorated, misbranded, or adulterated, or whose containers or packaging have been opened or breached, until such Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil is destroyed.		

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

		Result	Notes
	3. Be maintained in a clean, sanitary, and orderly condition.		
	4. Be free from infestation by insects, rodents, birds, or vermin of any kind.		
	A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments.		
	Policies & Procedures		**18 VAC 110-60-250**
	The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of Cannabis and production of cannabidiol oil or THC-A oil. These shall include policies and procedures that:		
	1. Restrict movement between compartments.		
	2. Provide for different colored identification cards for facility employees based on the compartment to which they are assigned at a given time so as to ensure that only employees necessary for a particular function have access to that compartment of the facility.		
	3. Require pocketless clothing for all production facility employees working in an area containing Cannabis plants, seeds, and extracts, including cannabidiol oil or THC-A oil.		
	4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, cannabidiol oil, and THC-A oil products.		
	The PIC shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil.		
	Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories.		
	Pharmaceutical processors shall include in their written policies and procedures, a process for the following:		
	1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. Such process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to remove defective or potentially defective cannabidiol oil or THC-A oil from the market or any action undertaken to promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;		
	2. Preparing for, protecting against, and handling any crises that affect the security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;		
	3. Ensuring that any outdated, damaged, deteriorated, misbranded, or adulterated Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, is segregated from all other Cannabis, seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil and destroyed. This procedure shall provide for written documentation of the Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil disposition; and		
	4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil product is used first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.		
	The processor shall:		
	1. Store all Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss.		

		Result	Notes
	2. Make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation.		
	3. Return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day.		
	If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, inside an area or building that affords adequate security.		
	Record Keepting Requirements		**18 VAC 110-60-260**
	If a pharmaceutical processor uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabidiol oil or THC-A oil, the pharmaceutical processor shall use a system that:		
	1. Guarantees the confidentiality of the information contained therein.		
	2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist.		
	3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.		
	All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of **three** years and shall be made available to the board upon request.		
	Reportable Events & Security		**18 VAC 110-60-270**
	Upon becoming aware of diversion, theft, loss, discrepancies identified during inventory, or unauthorized destruction of any cannabidiol oil or THC-A oil or of any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall **immediately** notify appropriate law-enforcement authorities and the board.		
	A pharmacist or processor shall provide the notice required by 18 VAC 110-20-270 (A) to the board by way of a signed statement that details the circumstances of the event, including an accurate inventory of the quantity and brand names of cannabidiol oil or THC-A oil diverted, stolen, lost, destroyed, or damaged and confirmation that the local law-enforcement authorities were notified.		
	A pharmacist or processor shall make such notice no later than 24 hours after discovery of the event.		
	A pharmacist or pharmaceutical processor shall notify the board no later than the next business day, followed by written notification no later than 10 business days, of any of the following:		
	1. An alarm activation or other event that requires a response by public safety personnel.		
	2. A breach of security.		
	3. The failure of the security alarm system due to a loss of electrical support or mechanical malfunction that is expected to last longer than eight hours.		
	4. Corrective measures taken, if any.		

Cultivation			
		Result	Notes
	Cultivation & Production		**18 VAC 110-60-280**
	No cannabidiol oil or THC-A oil shall have had pesticide chemicals or petroleum-based solvents used during the cultivation, extraction, production, or manufacturing process, except that the board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of Cannabis crops. *Verifiy Board authorization if prohibited products have been used.*		
	Cultivation methods for Cannabis plants and extraction methods used to produce the cannabidiol oil and THC-A shall be performed in a manner deemed safe and effective based on current standards or scientific literature.		
	Any Cannabis plant, seed, parts of plant, extract, cannabidiol oil, or THC-A oil not in compliance with this section shall be deemed adulterated.		
	Registration of Products		**18 VAC 110-60-285**
	A pharmaceutical processor shall assign a brand name to each product of cannabidiol oil or THC-A oil.		
	The pharmaceutical processor shall register each brand name with the board, on a form prescribed by the board, prior to any dispensing.		
	The pharmaceutical processor shall associate each brand name with a specific laboratory test that includes a terpenes profile and a list of all active ingredients, including:		
	1. Tetrahydrocannabinol (THC).		
	2. Tetrahydrocannabinol acid (THCA).		
	3. Cannabidiols (CBD).		
	4. Cannabidiolic acid (CBDA).		
	5. Any other active ingredient that constitutes at least 1% of the batch used in the product.		
	A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed within 18 VAC 110-60-285 (A) within a range of 97% to 103%.		

Production			
		Result	Notes
	Concentration & Stability of THC-A Oil		**§54.1-3442.7**
	A pharmaceutical processor shall :		
	1. Ensure that the concentration of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling.		
	2. Establish a stability testing schedule of THC-A oil.		
	Labeling of Batch of CBD or THC-A Products		**18 VAC 110-60-290**
	Cannabidiol oil or THC-A oil produced shall not be adulterated and shall be:		
	1. Processed, packaged, and labeled according to the Food and Drug Administration's Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements," 21 CFR Part 111.		
	2. Labeled with :		
	a. The name and address of the pharmaceutical processor.		
	b. The brand name of the cannabidiol oil or THC-A oil product that was registered with the board pursuant to 18VAC110-20-285.		
	c. A unique serial number that will match the product with the pharmaceutical processor batch and lot number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate.		
	d. The date of final testing and packaging.		
	e. The expiration date.		
	f. The quantity of cannabidiol oil or THC-A oil contained therein.		
	g. A terpenes profile and a list of all active ingredients, including:		
	i. tetrahydrocannabinol (THC).		
	ii. tetrahydrocannabinol acid (THCA).		
	iii. cannabidiol (CBD).		
	iv. cannabidiolic acid (CBDA).		
	v. any other active ingredient that constitute at least 1% of the batch used in the product.		
	h. A pass or fail rating based on the laboratory's microbiological, mycotoxins, and heavy metals and chemical residue analysis.		
	Laboratory Requirements & Testing		**18 VAC 110-60-300**
	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.		
	2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or a bachelor's degree in biological sciences and a minimum of four years of post-degree laboratory experience. *Record name. egree and experience*		

		Result	Notes
	Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches.		
	A pharmaceutical processor shall make a sample available from each batch for a laboratory to test for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue, and for purposes of conducting an active ingredient analysis.		
	From the time that a batch of Cannabis has been homogenized for sample testing and eventual packaging, until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch of Cannabis, except the samples that have been removed by the laboratory for testing.		
	During this period of segregation, the pharmaceutical processor shall maintain the Cannabis in a secure, cool, and dry location so as to prevent the Cannabis from becoming contaminated or losing its efficacy.		
	Under no circumstances shall a pharmaceutical processor include Cannabis in a cannabidiol oil or THC-A oil product or sell it prior to the time that the laboratory has completed its testing and analysis and provided those results, in writing, to the pharmaceutical processor or other designated facility employee.		
	The processor shall require the laboratory to immediately return or properly dispose of any Cannabis upon the completion of any testing, use, or research.		
	If a sample of Cannabis does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.		
	1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.		
	2. For purposes of the mycotoxin test, a Cannabis sample shall be deemed to have passed if it meets the following standards:		
	<table><tr><td>Test Specification</td><td></td></tr><tr><td>Aflatoxin B1</td><td><20 uG/KG of Substance</td></tr><tr><td>Aflatoxin B2</td><td><20 uG/KG of Substance</td></tr><tr><td>Aflatoxin O1</td><td><20 uG/KG of Substance</td></tr><tr><td>Aflatoxin O2</td><td><20 uG/KG of Substance</td></tr><tr><td>Ochratoxin A</td><td><20 uG/KG of Substance</td></tr></table>		
	3. For purposes of the heavy metal test, a Cannabis sample shall be deemed to have passed if it meets the following standards:		
	<table><tr><td>Metal</td><td>Natural Health Products Acceptable Limits uG/KG BW/Day</td></tr><tr><td>Arsenic</td><td><0.14</td></tr><tr><td>Cadmium</td><td><0.09</td></tr><tr><td>Lead</td><td><0.29</td></tr><tr><td>Mercury</td><td><0.29</td></tr></table>		

		Result	Notes
	For purposes of the pesticide chemical residue test, a Cannabis sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180. If a sample of Cannabis passes the microbiological, mycotoxin, heavy metal, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate manufacturing, packaging and labeling for sale.		
	For any batch that does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test:		
	1. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result at the same time that it transmits those results to the pharmaceutical processor.		
	2. The laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.		
	Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, or legal guardians and registered practitioners who have certified qualifying patients.		

Dispensing			
		Result	Notes
	Dispensing of CBD or THC-A Oil		**§54.1-3442.7**
	A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil **only in person** to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3.		
	Prior to dispensing, the pharmaceutical processor shall verify that the practitioner issuing the written certificationis registered with the Board.		
	Prior to dispensing, the pharmaceutical processor shall verify that the the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board.		
	A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.		
	No pharmaceutical processor shall dispense more than a 90-day supply for any patient during any 90-day period.		
	18 VAC 110-60-10: "Ninety-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients, which cannot exceed 60 fluid ounces.		
	Dispensing of CBD or THC-A Oil		**§ 54.1-3442.7 & 18 VAC 110-60-310**
	A pharmacist, in good faith, may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification.		
	1. Prior to the **initial** dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian. *Note: The initial dispensing cannot be delivered to the patient. It must be dispensed at the pharmaceutical processor location. Subsequent dispensing can be deilvered.*		
	2. The pharmacist or pharmacy technician shall verify in the prescription monitoring program or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.		
	3. The pharmacist or pharmacy technician shall make and maintain for two years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.		
	4. Prior to any **subsequent** dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, or legal guardian and shall maintain **record** of such viewing in accordance with policies and procedures of the processor.		
	A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, or legal guardian shall receive more than a 90-day supply of cannabidiol oil or THC-A oil in a 90-day period from any pharmaceutical processor.		
	A dispensing record shall be maintained for **three** years from the date of dispensing.		

		Result	Notes
	The pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil which contains:		
	1. A serial number assigned to the dispensing of the oil.		
	2. The name or kind of cannabidiol oil or THC-A oil and its strength.		
	3. The serial number assigned to the oil during production.		
	4. The date of dispensing the cannabidiol oil or THC-A oil;		
	5. The quantity of cannabidiol oil or THC-A oil dispensed, which cannot exceed 60 fluid ounces.		
	6. The name and registration number of the registered patient.		
	7. The name and registration number of the certifying practitioner.		
	8. Such directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner.		
	9. The name or initials of the dispensing pharmacist.		
	10. Name, address, and telephone number of the pharmaceutical processor;		
	11. Any cautionary statement as may be necessary.		
	12. A prominently printed expiration date based on the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.		
	The dispensed cannabidiol oil or THC-A oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).		
	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.		
	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.		
	A pharmacist shall document a registered patient's self-assessment of the effects of cannabidiol oil or THC-A oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof.		
	A pharmaceutical processor shall maintain such documentation in writing or electronically for two years from the date of dispensing and such documentation shall be made available in accordance with regulation.		
	A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, or legal guardian if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, or legal guardian may have negative health or safety consequences for the registered patient or the public.		
	Labeling of Dispensed CBD or THC-A Oil		**18 VAC 110-60-295**
	A pharmaceutical processor shall label each cannabidiol oil or THC-A oil product prior to dispensing by a pharmacist and shall securely affix to the package a label that states in legible English:		
	1. The brand name of the cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-20-285.		
	2. A serial number as assigned by the pharmaceutical processor.		
	3. The date of dispensing the cannabidiol oil or THC-A oil.		
	4. An appropriate expiration date, not to exceed six months.		
	5. The quantity of cannabidiol oil or THC-A oil contained therein.		
	6. A terpenes profile and a list of all active ingredients, including:		

		Result	Notes
	a. Tetrahydrocannabinol (THC).		
	b. Tetrahydrocannabinol acid (THC-A).		
	c. Cannabidiol (CBD).		
	7. A pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, and chemical residue analysis.		
	8. The name and registration number of the qualifying patient.		
	9. The name of the certifying practitioner.		
	10. Such directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner.		
	11. Name and address of the pharmaceutical processor.		
	12. Any cautionary statement as may be required by statute or regulation.		
	No person except a pharmacist or pharmacist technician under the direct supervision of a pharmacist at the pharmaceutical processor shall alter, deface, or remove any label so affixed.		
	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.		
	Quality Assurance Progarm		
	Dispensing Error Review, Reporting, Quality Assurance Program		**18 VAC 110-60-320**
	A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors.		
	A pharmaceutical processor shall distribute it to all pharmaceutical processor employees and shall make it readily available on the premises of the pharmaceutical processor.		
	Such policies and procedures shall include:		
	1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. Such communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient.		
	2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.		
	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.		
	4. Create a record of every quality assurance review. This record shall contain at least the following:		
	a. The date or dates of the quality assurance review and the names and titles of the persons performing the review.		

		Result	Notes
	b. The pertinent data and other information relating to the dispensing error reviewed.		
	c. Documentation of contact with the registered patient, parent, or legal guardian where applicable, and the practitioner who certified the patient.		
	d. The findings and determinations generated by the quality assurance review.		
	e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes, if any.		
	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.		
	Disposal		
	Disposal of CBD or THC-A Oil		**18 VAC 110-60-330**
	To mitigate the risk of diversion, a pharmaceutical processor, **an agent of the board, or the board's agent** shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by disposal in the presence of an agent of the board in such a manner as to render the cannabidiol oil or THC-A oil nonrecoverable.		
	The person disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:		
	1. The date and time of disposal;		
	2. The manner of disposal;		
	3. The name and quantity of cannabidiol oil or THC-A oil disposed of; and		
	4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil, the agent of the board, and any other persons present during the disposal.		
	The record of disposal shall be maintained at the pharmaceutical processor for **three** years from the date of disposal.		

The Virginia Board of Pharmacy
Inspection

Pharmacy Name		Pharmacy license number		Date	

The Virginia Board of Pharmacy
Inspection Summary

COMPLETE AND RETURN TO THE BOARD OFFICE WITHIN 14 DAYS OF THE INSPECTION.
SUBMIT BY U.S. MAIL, FAX (804-527-4472) OR EMAIL TO pharmbd@dhp.virginia.gov.
RETAIN A COPY FOR YOUR RECORDS.

Pharmacy Name		Pharmacy License Number		Date	

No	Law/Regulation	Deficiency
Corrective Steps Taken		

No	Law/Regulation	Deficiency
Corrective Steps Taken		

No	Law/Regulation	Deficiency
Corrective Steps Taken		

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Virginia Board of Pharmacy
Inspection Report
December 18, 2018

Licenses Issued

	6/1/17-8/31/17	9/1/17-11/30/17	12/1/17-2/28/18	3/1/18-5/31/18	6/1/18-8/31/18	9/1/18-11/30/18	License Count 12/1/2018
Business CSR	34	40	81	86	50	59	1,445
CE Courses	0	1	0	1	0	2	9
Limited Use Pharmacy Technician	0	1	0	0	0	1	18
Medical Equipment Supplier	3	3	2	5	4	1	239
Nonresident Manufacturer		13	92	20	4	7	135
Nonresident Medical Equipment Supplier		19	12	12	12	9	340
Non-resident Outsourcing Facility	17	3	1	9	1	2	33
Non-resident Pharmacy	4	38	32	35	33	27	774
Non-resident Wholesale Distributor	42	8	13	22	16	12	678
Non-restricted Manufacturer	10	0	1	0	0	1	29
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	1
Pharmacist	438	251	142	157	439	250	15,328
Pharmacist Volunteer Registration	4	1	0	0	2	0	0
Pharmacy	24	17	3	15	18	21	1,821
Pharmacy Intern	140	204	148	115	140	189	1,890
Pharmacy Technician	621	387	357	363	420	378	14,499
Pharmacy Technician Training Program	4	5	5	3	2	4	138
Physician Selling Controlled Substances	44	30	22	55	25	42	771
Physician Selling Drugs Location	5	5	1	10	10	4	167
Pilot Programs	2	0	2	0	1	0	17
Registered Physician For CBD/THC-A Oil					118	83	199
Repackaging Training Program	0	0	0	0	0	0	1
Restricted Manufacturer	0	1	0	0	0	0	54
Third Party Logistics Provider		2	3	1	0	1	5
Warehouser	1	0	39	3	10	7	101
Wholesale Distributor	3	5	1	0	**3**	**0**	81
Total	**1,396**	**1,034**	**957**	**912**	**1,308**	**1,100**	**38,773**

Virginia Board of Pharmacy
Inspection Report
December 18, 2018

Inspections Completed

	6/1/17-8/31/17	9/1/17-11/30/17	12/1/17-2/28/18	3/1/18-5/31/18	6/1/18-8/31/18	9/1/18-11/30/18
License Type						
Controlled Substances Registration	133	131	163	182	120	174
Medical Equipment Supplier	18	32	22	22	25	19
Non-restricted Manufacturer	1	1	1	0	0	3
Permitted Physician	0	0	0	0	0	0
Physician Selling Drugs Location	32	39	23	22	31	38
Restricted Manufacturer	1	3	0	2	0	0
Third Party Logistics Provider		2	1	1	0	2
Warehouse	3	6	11	11	14	12
Wholesale Distributor	20	13	6	3	7	7
Pharmacy	313	293	272	291	328	306
Pilot	2	1	0	1	0	1
Total	**523**	**521**	**499**	**535**	**525**	**562**

Pharmacy (0201) Inspections						
Change of Location	3	3	4	5	9	7
New	21	13	3	15	19	18
Reinspection	8	14	2	8	6	13
Remodel	45	55	31	43	31	42
Routine	232	206	232	218	242	222
Focus	4	0	0	2	1	4
Federal Agency	0	0	0	0	18	0
Compliance	0	2	0	0	2	0
Pilot	0	0	0	0	0	0
Total	**313**	**293**	**272**	**291**	**328**	**306**

Pharmacy Routine Inspections												
No Deficiency	52	23%	43	21%	77	33%	66	30%	93	38%	109	49%
Deficiency	100	43%	66	32%	77	33%	80	37%	75	31%	64	29%
Deficiency & IPHCO	80	34%	97	47%	78	34%	72	33%	74	31%	49	22%
Total	**232**	*	**206**		**232**		**218**		**242**		**222**	

* Corrected 12/11/17

Virginia Board of Pharmacy
December 18, 2018
Frequently Cited Deficiencies
June 2017 - November 2018

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	146
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)	59
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54
20. Pharmacist not checking and documenting repackaging or bulk packaging	39
12. Storage of prescription drugs not in the prescription department	38
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	37
18. Records of dispensing not maintained as required	37
7. Change of location or remodel of pharmacy without submitting application or Board approval	35
20a. Pharmacist not documenting final verification of non-sterile compounding	32
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	31
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)	193
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.	188
127. Repackaging records and labeling not kept as required or in compliance	156
130a. Compounded products not properly labeled	148
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	98
122. Engaging in alternate delivery not in compliance	91
124. Labels do not include all required information	88
108. Emergency access alarm code/key not maintained in compliance	87
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	48
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)	48

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
Routine Inspections Completed	**232**	**206**	**232**	**218**	**242**	**222**	**1352**	**Repeat**	**Repeat**
Total Deficiencies	**131**	**158**	**127**	**115**	**123**	**83**	**737**	**5**	**206**
Average Deficiencies per Inspection	**0.6**	**0.8**	**0.5**	**0.5**	**0.5**	**0.4**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	3	2	2	2	0	11		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	2	0	5	3	9	12	31		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	4	2	2	7	19		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	1	2	0	0	3		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	1	2	1	1	1	7		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	0	1	1		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	5	10	4	6	7	3	35		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	0	2	1	0	1	1	5		1
9. Alarm not operational or not being set	5	3	0	1	1	0	10		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	1	2	1	0	1	1	6		1

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	8	7	1	2	2	1	21		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	0	0	0	1	1	3		
12. Storage of prescription drugs not in the prescription department	5	7	12	8	5	1	38		9
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	0	1	0	1	5	0	7		3
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	2	6	0	5	2	0	15		2
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	15	8	6	5	16	9	59		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	25	29	31	17	24	20	146	1	95
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	7	9	6	7	6	2	37		3
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	0	2	0	2	2	0	6		
18. Records of dispensing not maintained as required	6	15	7	3	4	2	37		

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	2	7	2	0	1	0	12		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	9	10	5	7	4	4	39		15
20a. Pharmacist not documenting final verification of non-sterile compounding	8	7	6	5	3	3	32		3
20b. Pharmacist not documenting final verification of sterile compounding	5	4	6	2	5	3	25	1	10
21. No clean room	0	1	0	0	0	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	1	0	0	1	0	0	2		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	1	1	0	1	1	0	4		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	2	1	0	0	3		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	2	0	0	1	0	3		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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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	6	2	6	8	5	4	31	1	28
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	2	0	1	1	0	4		
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	1	2	3	2	3	0	11		
29. Unlawful compounding for further distribution by other entities	2	0	3	3	3	0	11		
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	8	12	10	14	4	6	54	2	14
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	1	1	0	0	0	0	2		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	0	0	1	3	1	1	6		1

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Deficiencies Above 100
(Formerly Minor Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
Routine Inspections Completed	**232**	**206**	**232**	**218**	**242**	**222**	**1352**	**Repeat**	**Repeat**
Total Deficiencies	**317**	**338**	**302**	**259**	**228**	**160**	**1444**	**7**	**255**
Average Deficiencies per Inspection	**1.4**	**1.6**	**1.3**	**1.2**	**0.9**	**0.7**	**1.1**		
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.	3	4	7	6	4	1	25		5
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	1	5	4	5	3	1	19		7
106. Prescription department substantially not clean and sanitary and in good repair	0	2	1	0	0	1	4		2
107. Current dispensing reference not maintained	1	6	4	1	3	1	16		10
108. Emergency access alarm code/key not maintained in compliance	13	16	18	17	15	8	87	1	16
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)	33	33	27	38	38	24	193	1	28
110. Storage of paraphernalia/Rx devices not in compliance	2	0	0	0	0	1	3		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	5	1	2	1	1	0	10		1
112. Biennial taken late but within 30 days	1	2	1	3	1	3	11		
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.	37	25	40	28	32	26	188	3	51

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Deficiencies Above 100
(Formerly Minor Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	5	9	10	4	7	2	37		
115. Other records of distributions not maintained as required	3	3	0	2	1	0	9		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	3	4	4	4	4	2	21		0
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	1	0	1	0	0	0	2		
119. Not properly documenting partial filling of prescriptions	5	6	10	8	4	4	37		24
120. Offer to counsel not made as required	7	2	2	0	0	0	11		
121. Prospective drug review not performed as required	0	1	0	0	0	1	2		
122. Engaging in alternate delivery not in compliance	19	18	14	15	16	9	91		6
123. Engaging in remote processing not in compliance	3	5	9	12	7	4	40		2
124. Labels do not include all required information	15	15	15	17	16	10	88		13
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	6	8	5	5	3	0	27		5
126. Special packaging not used or no documentation of request for non-special packaging	0	1	0	2	1	0	4		4
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	26	41	33	21	18	17	156		21
128. Unit dose procedures or records not in compliance	0	0	0	0	0	2	2		
129. Robotic pharmacy systems not in compliance	1	0	0	0	2	0	3		
130. Required compounding/dispensing/distribution records not complete and properly maintained	9	10	5	8	9	6	47		12
130a. Compounded products not properly labeled	60	42	18	9	10	9	148		8

Virginia Board of Pharmacy
Inspection Report
December 18, 2018

Deficiencies Above 100
(Formerly Minor Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	3	6	0	1	5	3	18		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	9	14	8	7	6	4	48		1
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	3	3	0	0	0	0	6		
Hospital specific or long-term care specific:							0		
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	0		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	1	0	1	2	1	1	6	1	1
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	0	0	1	0	1	4	6		
139. Emergency medical services procedures or records not in compliance	1	3	3	2	0	2	11	1	5
140. Emergency kit or stat-drug box procedures or records not in compliance	0	3	3	4	0	1	11		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	15	24	17	16	16	10	98		9
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	1	0	0	1	1	0	3		

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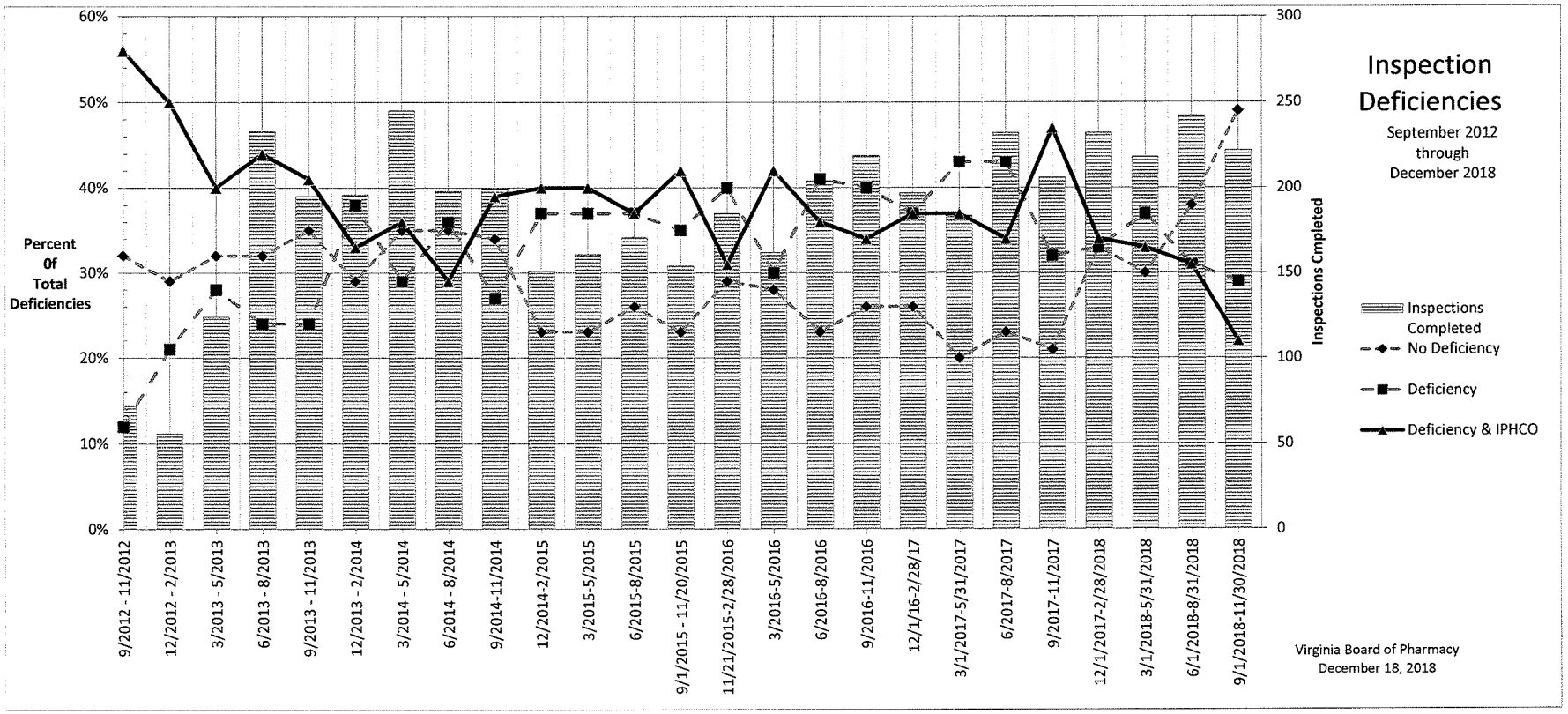
Deficiencies Above 100
(Formerly Minor Deficiency)

	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	9/18-11/18	Total	9/18-11/18	Cumulative
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	15	14	9	9	1	0	48		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	3	2	0	5	0	0	10		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	9	14	4	0	0	31		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	3	1	16	2	1	0	23		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)					**1**	**3**	4		3


Inspection Deficiencies
September 2012 through December 2018
Percent Of Total Deficiencies
Inspections Cmpleted
60%
50%
40%
30%
20%
10%
0%
300
250
200
150
100
50
0
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/1/2017-5/31/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/1/2018-5/31/2018
6/1/2018-8/31/2018
9/1/2018-11/30/2018
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Discipline Program Report

Staffing:
Ileita Redd and Rose DeMateo have been assisting in the absence of our Discipline Program Specialist.

Open Cases as of 11/15/18:

Patient Care Cases	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	34	15	59	5	18	1	132
Non-Patient Care Cases	92	5	20	1	28	11	157
							289

Notes:

1) Patient care cases:
    - We have thirty-four (34) patient care cases at Probable Cause as compared to 43 that were reported in September. Twenty-three of these cases are pending an IFC or FH.
    - Seven (7) patient care cases at Probable Cause exceed 250 work days (this is substantially below our 10% threshold for open cases).
2) Non-patient care cases (inspection cases or compliance related cases)
    - We are continuing to see a decrease in the number of inspection-related cases resulting in a PHCO.

Upcoming Disciplinary Proceedings:

January 9, 2019	Formal Hearings	
January 25, 2019	SCC-C	Cindy Warriner and Melvin Boone
February 27, 2019	Formal Hearings	
February 28, 2019	SCC-B	Ryan Logan and Kris Ratliff
March 26, 2019	Full Board Meeting/Formal Hearings	
March 28, 2019	SCC-A	Rafael Saenz and Patricia Richards-Spruill

Executive Director's Report – December 18, 2018

Recent Presentations/Meetings:

- October 2-3, 2018, NABP Interactive Executive Officer Forum
- October 12, 2018, RxPartnership
- October 18, 2018, NABP Executive Committee Conference Call
- October 24, 2018, VACDS presentation – O'Halloran and Yeatts
- October 29, 2018, Community Coalitions of Virginia State Summit presentation
- October 31-November 1, 2018 – NASCSA – O'Halloran
- November 9, 2018, Virginia Pharmacy Congress – Johnson and O'Halloran
- November 13-14, 2018, NABP Interim Planning/Budget & Finance Subcommittee
- November 19, 2018, Healthcare Information & Management Systems Society panelist
- November 27, 2018, NABP Executive Committee Meeting
- December 4, 2018, Food and Drug Law Institute panelist
- December 6, 2018, Virginia Press Association panelist
- December 7, 2018, RxPartnership

- Board E-newsletter published December 2018