COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearing and Full Board Meeting
September 25, 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:
  - June 20, 2018, Inspection Special Conference Committee 2-3
  - June 20, 2018, Ad Hoc Committee for Routine Pharmacy Inspection Process 4-7
  - June 21, 2018, Public Hearing to Schedule Certain Chemicals in Schedule I and to conform to DEA scheduling 8-10
  - June 21, 2018, Full Board Meeting 11-22
  - July 19, 2018, Special Conference Committee 23-26
  - August 14, 2018, Formal Hearings 27-32
  - August 15, 2018, Special Conference Committee 33-36
  - August 23, 2018, Public hearing to received comment on proposed regulations replacing emergency regulations for issuance of CSRs to community organizations to distribute naloxone and for tele-prescribing 37
  - September 4, 2018, Ad Hoc Committee for Pharmaceutical Processor Applications Handout

Call for Public Comment: The Board will receive public comment at this time, to include any comment on the pharmaceutical processor applications. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. Comments will be restricted to no more than 2 minutes per comment.

DHP Director's Report: David Brown, DC

Legislative/Regulatory/Guidance: Elaine Yeatts/Caroline D. Juran
- Regulatory Update – Chart of Regulatory Actions 38-39
- Adoption of exempt regulation to add certain chemicals to Schedule I 40-46
- Adoption of Proposed Regulations for Pharmaceutical Processors of CBD Oil and THC-A Oi 47-134
- Adoption of Final Regulations for Issuance of Controlled Substances Registration 135-144

- Request to Extend Emergency Regulations for Issuance of Controlled Substances Registration 145
- Consideration of Regulatory Action for White Bagging and Brown Bagging
- Summary of 2019 Legislative Proposals Submitted by DHP 146-170 171-181

New Business:

- Motion to Convene Closed Session pursuant to §2.2-3711(8) for consultation with legal counsel regarding specific legal matters requiring the provision of legal advice
- Motion to Reconvene into Open Session
- Evaluation of Applications and Determination of Criminal Background Check Process Confidential Handout

Reports:

- Chairman's Report – Rafael Saenz
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr. 182-193
- Report on Disciplinary Program – Ellen B. Shinaberry 194-203
- Executive Director's Report – Caroline D. Juran Handout

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

Adjourn

***The Board will determine after consultation with legal counsel if the evaluation of the pharmaceutical processor applications will occur in open or closed session. ***

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

Notice of Public Hearing
Placement of Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on September 25, 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 two (2) compounds for recommended inclusion into the Code of Virginia.

The following compound is classified as a powerful synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. **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.

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.

2. **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.

April 24, 2018

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, June 20, 2018
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 09:46 a.m.
PRESIDING:	Sheila Elliott, Committee Chair
MEMBERS PRESENT:	Jody Allen, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
JOHN RANDOLPH MEDICAL CENTER PHARMACY Permit No. 0201-001203	Kerri A. Johnson, Pharmacist-in-Charge, appeared on behalf of John Randolph Medical Center Pharmacy and was represented by Elizabeth A. Whalley Buono, Esquire to discuss allegations that John Randolph Medical Center Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the April 16, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 John Randolph Medical Center 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. Allen and duly seconded Ms. Elliott, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.

ADJOURNED: 10:20 a.m.

_____
Sheila Elliott, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE MEETING REGARDING ROUTINE PHARMACY INSPECTION PROCESS

June 20, 2018
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:05 pm

PRESIDING: Jody H. Allen, Chairman

MEMBERS PRESENT:
Cynthia Warriner
Melvin L. Boone, Sr.
Ryan K. Logan
Sheila K. W. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Ellen Shinaberry, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Melody Morton, Inspections Manager for Enforcement
Maria Damico, Pharmacy Inspector for Enforcement
Tim Reilly, Pharmacy Inspector for Enforcement

APPROVAL OF AGENDA:

MOTION: **The committee voted unanimously to approve the agenda as presented. (motion by Warriner, second by Logan)**

PUBLIC COMMENT: Christina Barrille, Executive Director for the Virginia Pharmacists Association thanked the Board for reviewing the inspection report and considering changes to the inspection deficiency guide. While overall the association approved of the proposed changes such as warnings for first time deficiencies, several members expressed a general concern with the inspection of USP <800> and requested clarity from the Board with regard to the inspection process for USP <800>.

- Overview of Revised Inspection Report: Ms. Juran provided an overview of why the ad hoc committee was convened. During the December 2017 full board meeting, it was agreed that an ad hoc committee should be formed to review the current inspection report and Guidance Document 110-9. It had been seven years since the current inspection program was implemented and Guidance Document 110-9 had become lengthy as more deficiencies were added throughout the years. Ms. Juran thanked Mr. Johnson and Melody Morton (Inspections Manager for Enforcement) for their hard work on

this project, along with Ms. Michelle Schmitz (Executive Director of Enforcement), and Pam Twombly (Deputy Executive Director of Enforcement). She shared that staff from the Board of Pharmacy and Enforcement, to include all pharmacy inspectors, met on April 26, 2018 to discuss the pros and cons with the current inspection process and report. Staff reached the following consensus regarding revisions to the current inspection reported: the report should remain as an Excel document; language from the former inspection report should be used in lieu of the current language; the report should be shortened to focus exclusively on items Virginia is interested in reviewing; and, the sterile compounding portion of the inspection report should be used for all pharmacies performing sterile compounding. Ms. Juran reminded the board that Virginia is a blueprint state for NABP and has agreed to use the sterile compounding portion of the universal inspection report for pharmacies that ship sterile compounded drugs into other states. Additionally she referenced the language on the revised inspection report regarding USP Chapter <800> that the inspectors will use when educating pharmacists on the new standards as requested by the board. She reminded the board that USP <800> cannot be enforced until the chapter has taken effect in December 2019 and that this portion of the inspection report is for educational purposes only.

Mr. Johnson stated that the report has been divided into multiple tabs. The inspector will only use the tabs relevant to the practice setting. He stated the length of the average pharmacy inspection report would likely be approximately 23 pages which is significantly shorter than the current version. When comparing the use of a shorter checklist inspection report format verses a lengthier format full of text referencing the relevant laws and regulations, there was consensus that the lengthier format assisted the inspectors and aided in educating the licensees more than the shorter checklist format. He then provided a detailed review of each section of the revised inspection report. Revisions and committee suggestions included:

- Removing areas of demographic information from the general inspection portion as well as the "areas reviewed";
- Adding "educational purposes only" or "deficiencies will not be cited" on the USP <800> portion;
- Removing "compounding of inordinate amounts" from page 21;
- Removing pages 27-37 within the non-sterile compounding portion as these items do not coincide with a Virginia deficiency listed in Guidance Document 110-9;
- Adding a heading to the sterile compounding portion;
- Rewording a few items to ensure the use of "compliant" or "non-compliant" clearly represents the issue;
- Clarify headings for the central or remote processing portion to distinguish between community/retail and hospital.

There was consensus that the inspectors should being using the revised inspection report on July 2, 2018 as presented and amended.

ACTION ITEMS:

Board staff will include on a subsequent meeting agenda: Consideration for renaming Guidance Document 110-36 since the current title is limited to compounding and yet USP Chapter <800> appears to be broader than just compounding; Adoption of guidance to clarify the requirement for a pharmacist-in-charge to be "fully engaged" at the pharmacy; and, Adoption of guidance to clarify what constitutes a remodel of a pharmacy for which a remodel application and fee must be submitted.

Review of Guidance Document 110-9

Mr. Johnson provided a review of the proposed changes to Guidance Document 110-9. Effective July 1, 2018, the proposed changes identify certain deficiencies for which the board would cite a deficiency on the inspection summary when a violation is observed during a routine inspection, but would not impose a monetary penalty through the issuance of a pre-hearing consent order for the first documented occurrence of the violation. If the same violation is observed during the next subsequent routine or focused inspection, then the board will cite the deficiency and impose the recommended monetary penalty. The committee was referred to the last page of Guidance Document 110-9 for examples further explaining the concept. The committee then reviewed each of the proposed changes to Guidance Document 110-9.

MOTION:

The committee voted unanimously to recommend to the full board to amend Guidance Document 110-9 as presented and amended as follows:

- **Change all draft references of "first citation" to "first documented occurrence";**
- **Deficiency 12: strike the draft language "first citation and no drug loss = no penalty; drug loss or repeat = $ penalty";**
- **Deficiency 12a: insert "of Schedule II" following "first documented occurrence and no drug loss";**
- **Deficiency 14: insert "per occurrence" as a condition for when it should be cited and strike the draft language "over 5 days late and first citation = no penalty; repeat = $ penalty";**
- **Deficiency 15: strike draft language "expired drugs not included and first citation = no penalty; repeat = $ penalty"; and,**
- **Deficiency 20b: strike draft language "1000 per compounded sterile product, up to maximum of 5000". (motion by S. Elliott, second by Boone).**

ADJOURN:

With all business concluded, the meeting adjourned at approximately 4:30 pm.

Jodi H. Allen, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS IN SCHEDULE I AND SCHEDULING/DE-SCHEDULING TO CONFORM TO FEDERAL ACTIONS

June 21, 2018
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:10a.m.

PRESIDING: Jodi H. Allen

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Cheryl H. Nelson
Rafael Saenz
Cynthia Warriner
Sheila K. W. Elliott

MEMBERS ABSENT:
Ryan K. Logan, Chairman
Michael Elliott, Vice Chairman
James L. Jenkins, Jr.
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Ellen Shinaberry, Deputy Executive Director
David E. Brown, D.C., Director for DHP
Barbara Allyson-Bryan, Chief Deputy Director for DHP
James Rutkowski, Assistant Attorney General

CALL FOR PUBLIC COMMENT: Ms. Allen called for comment to consider placement of the following chemical substances, identified by the Department of Forensic Science, into Schedule I:

- 2,5-dimethyoxy-4-chloroamphetamine (other name: DOC)
- N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamine (other name: Ocfentanil)
- N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: 4-methoxybutyrylfentanyl)
- N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: isobutyryl fentanyl)
- N-phenyl-N-[1-(2-pehnylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl)
- N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl)
- 1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-

3-carboxamide(other name: 4-cyano CUMYL-BUTINACA)
- Flualprazolam

Additionally, Ms. Allen noted that to conform the Drug Control Act to recent scheduling changes enacted by the Drug Enforcement Administration, the Board will consider:

- Adding MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;
- Adding Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; and
- Removing naldemedine from Schedule II.

If approved by the Board of Pharmacy, the placement of these substances in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation. The scheduling action for the substances identified by the Department of Forensic Science pursuant to §54.1-3443(D) would remain in effect for a period of 18 months. The chemicals would then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I. The scheduling action of the drugs to conform the Drug Control Act to recent scheduling changes enacted by the Drug Enforcement Administration pursuant to §54.1-3443(E) would remain in effect permanently, unless otherwise amended.

PULIC COMMENT:

M. Scott Maye, Chemical Program Manager at the Department of Forensic Science provided information regarding the 8 chemicals it has identified for the Board's consideration to place into Schedule I. One chemical is a research chemical, five chemicals are powerful synthetic opioids, one compound is a cannabimimetic agent, and one is a benzodiazepine that has no accepted medical use in the United States.

ADJOURN:

The public hearing adjourned at 9:13am.

Jodi H. Allen, Presiding

Date

Caroline D. Juran, Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 21, 2018
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15am

PRESIDING: Jody H. Allen (until 9:40am)
Ryan K. Logan, Chairman (arrived 9:40am)

MEMBERS PRESENT: Melvin L. Boone, Sr.
Cheryl H. Nelson
Sheila K. W. Elliott
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT: Rebecca Thornbury
Michael I. Elliott
James L. Jenkins, Jr.

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Beth O'Halloran, Deputy Executive Director (arrived 9:17am)
David E. Brown, Director, DHP (departed 9:27am)
Barbara Allyson-Bryan, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General

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

APPROVAL OF AGENDA: An amended agenda was provided as a handout that included an additional item under New Business, "Consultation with legal counsel pursuant to §2.2-3711(A)(7). Additionally, staff requested verbally that an additional item be added under New Business regarding an ADA accommodation request.

MOTION: **The Board voted unanimously to approve the agenda as requested and amended. (motion by Warriner, second by Boone)**

APPROVAL OF MINUTES: A handout of the draft minutes for the June 5, 2018 special conference committee meeting was provided for adoption.

MOTION: **The Board voted unanimously to adopt the minutes as presented for the meetings held between March 28, 2018 and June 5, 2018. (motion by Saenz, second by S. Elliott)**

PUBLIC COMMENTS: Lauren Berton Paul, Senior Director of CVS, provided comment in

support of the petition for rulemaking regarding labeling requirements for alternate delivery. Ms. Paul stated the ISMP recommended best practice for white space on a label makes this requirement very difficult and that listing two pharmacy names on a label can be confusing to a patient. Ms. Paul stated that since the patients request to have the drug sent from a specialty pharmacy to a local pharmacy, they are aware of the two pharmacies involved in the process.

Christina Barrille, Executive Director for VPhA, expressed appreciation for the professionalism in implementing the pharmaceutical processor request for application, encouraged the board to support the choosing of local Virginia businesses in the review of the pharmaceutical processor applications, and encouraged physician and pharmacist training. Ms. Barrille also encourages the Board to urge the Administration to pass pending regulatory changes that have been pending for several years in some cases, e.g., the prohibition of incentives to transfer prescriptions and the allowance for a pharmacist to dispense a larger quantity of Schedule VI drugs, taking refills into consideration. She also stated VPhA members remain concerned with PBMs. She stated the Board should recognize that payment issues do create patient access concerns and that VPhA encourages the regulating of PBMs and increased transparency. Lastly, she provided a handout to the Board reflecting a VPhA member's comments on the pharmaceutical processors.

Ms. Juran shared a written comment from former board member Robbie Rhodes. He expressed concern raised by others at a recent VPhA law rally that the proposed requirement for a pharmacy to perform daily temperature checks should apply to nonresident pharmacies as well, particularly mail order pharmacies. He further shared concern for delivered drugs being ruined when left in mailboxes unchecked.

Ms. Juran shared a second written comment received that expressed concern for PBM practices and encouraged the Board to regulate the PBMs. She reported that she informed the commenter that the 2016 PBM workgroup concluded that legislative action would be needed, not regulatory action.

DIRECTOR'S REPORT

Dr. Barbara Allyson-Bryan provided the director's report as Dr. Brown had to step out for another meeting. She reported that Dr. Hughes Melton was recently appointed as Director of the Department of Behavioral Health and Developmental Services. Dr. Marissa Levine, former Commissioner of the Department of Health has moved to Florida and the new Health Commissioner is Dr. Norman Oliver. Dr. Allyson-Bryan stated that a public comment period has opened on the regulations for the autonomous practice of nurse practitioners. She reported that community health workers will now need to certify or register, however, VDH is already registering these persons. This subject is under review. DHP has been asked to look at the implications of providing physicians with overdose information. DHP has also been asked to define conversion therapy for children. Lastly, she reported that the e-prescribing workgroup will be re-convened in August.

LEGISLATIVE/
REGULATORY/GUIDANCE:

Regulatory Update

Ms. Juran stated that Ms. Yeatts could not be present for the meeting. Ms. Juran reviewed with the Board the chart of regulatory actions provided in the agenda packet. She noted the following updates since the posting of the agenda packet:

- The controlled substance registration for naloxone and teleprescribing action was signed on 6/15/18 and there will be a public hearing on 8/23/18 at 9:30am. The public comment period will be open from 7/9/18 through 9/7/18.
- The increase in fees action has moved on to the next stage as the Department of Planning and Budget completed its review on 6/15/18.

Adoption of Exempt Regulation to Add Certain Schedule Chemicals to Schedule I and Scheduling/De-scheduling to Conform to Federal Actions

There was a public hearing conducted at 9:10am this morning pursuant to requirements of §54.1-3443(D and E) of the Drug Control Act.

MOTION:

The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 pursuant to §54.1-3443(D) as presented which strikes chemicals in subsections A-D since they have now been scheduled in law and places the following chemicals into Schedule I:

Classified as research chemical:

- **2,5-dimethyoxy-4-chloroamphetamine (other name: DOC)**

Classified as a cannabimimetic agent:

- **1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide(other name: 4-cyano CUMYL-BUTINACA)**

Classified as powerful synthetic opioids:

- **N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamine (other name: Ocfentanil)**
- **N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: 4-methoxybutyrylfentanyl)**
- **N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: isobutyryl fentanyl)**
- **N-phenyl-N-[1-(2-pehnylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl)**
- **N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl)**

Classified as a benzodiazepine with no accepted use in the US:

- **Flualprazolam.**

The Board further adopted 18VAC110-20-323 pursuant to §54.1-3443(E) which conforms State scheduling to the following federal scheduling actions:

- **Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;**
- **Adds Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II; and**
- **Removes naldemedine from Schedule II. (motion by Warriner, second by Boone)**

Report from Regulation Committee Meeting and Possible Action:

Review of Guidance Documents

Mr. Elliott, Chairman of the Regulation Committee, could not attend today's full board meeting, therefore, Ms. Juran reported the Regulation Committee's recommendations for re-adoption of Guidance Documents that had not been acted upon in several years. The committee requested staff to determine if Guidance Document 110-6 was in need of revisions. She reported that she conferred with Ralph Orr, Director of the PMP, and that staff recommends deletion of the guidance document as it has not been utilized in recent years and does not accurately reflect current processes. Ms. Juran reported that Rebecca Thornbury recommended the suggested edit for Guidance Document 110-16 as presented in the agenda packet. Staff recommended the deletion of Guidance Documents 110-13 and 110-14 as they represent Orders imposed in 1997 and are otherwise available as public information. Ms. Warriner shared with the Board that the Regulation Committee had thoroughly vetted the documents during its review process.

MOTION:

The Board voted unanimously to re-adopt Guidance Documents 110-10, 110-11, 110-19, 110-22, 110-24, and 110-25 (motion by Warriner, second by Saenz)

The Board voted unanimously to delete Guidance Documents 110-6, 110-13, and 110-14. (motion by Boone, second by Warriner)

The Board voted unanimously to amend Guidance Document 110-16 as presented. (motion by Warriner, second by Boone)

Petition for Rulemaking from Lavino/CVS Health regarding 18VAC110-20-275

It was reported that the Regulation Committee voted 3:2 in favor of recommending to the full board that it initiate rulemaking in response to the petition received from Lavino/CVS Health.

MOTION:

The Board voted 5:1 in favor of initiating rulemaking by publishing a Notice of Intended Regulatory Action in response to the petition received from Lavino/CVS Health. (motion Allen, second Saenz; Warriner opposed)

Adoption of Revised Emergency Regulations for Pharmaceutical

Processors

Because of successful 2018 legislation, the emergency regulations for pharmaceutical processors need to be revised to conform the emergency regulations to the new changes in law. It was reported that the Regulation Committee reviewed the proposed changes and asked staff to research the number of plants required to provide a 90-day supply as referenced in 18VAC110-60-240(A)(1). Ms. Juran stated that staff recommends 12 plants based on past discussions during the Regulatory Advisory Panel meetings that developed the recommended regulations for board consideration. It was further stated that the Regulation Committee recommends adoption of the revised emergency regulations. Ms. Juran also reported that the Board will need to adopt permanent replacement regulations at the September 2018 full board meeting and that a 30-day public comment period will be opened prior to the meeting. Information regarding the public comment period will be posted as a General Notice on the Regulatory Town Hall website.

MOTION:

The Board voted unanimously to adopt the revised emergency regulations for pharmaceutical processors as presented. (motion by Warriner, second by S. Elliott)

Adoption of Emergency Regulations Related to Delivery of Schedule VI Devices

Ms. Juran stated that HB878 and SB413 requires the board to promulgate regulations related to the delivery of Schedule VI devices within 280 days of their enactment. She provided a general overview of the draft language provided in the agenda packet and stated that the interested stakeholders who requested introduction of the legislation were supportive of the draft language.

MOTION:

The Board voted unanimously to adopt emergency regulations as drafted to become effective and filed on or after July 1, 2018 and to approve a Notice of Intended Regulatory Action to replace the emergency regulations. (motion by Saenz, second by Warriner)

Adoption of Exempt Regulations for Nonresident Warehousers and Nonresident Third Party Logistics Providers

HB 520 created two new licensing categories: nonresident warehousers and nonresident third party logistics providers. The Board must amend regulations to reference the new licensing categories.

MOTION:

The Board voted unanimously to amend sections of 18VAC110-50-10 et seq., as presented in the agenda packet. (motion by Warriner, second by Allen)

Adoption of Fast Track Regulation to Rescind Pharmacy Permit if Not Operational

Ms. Juran stated that board staff has noted recently there have been several instances in which a pharmacy permit was obtained, yet the pharmacy, after one year, has never opened. There have also been instances in which the pharmacy opens, however, no drugs are stocked. It is feared there may be fraudulent activity occurring in some instances and the board does not have the ability to rescind a permit once it is issued. During the periodic regulatory review, the Board adopted a proposed amendment to allow the board to rescind a pharmacy permit if the

pharmacy has not become operational within 90 days, unless there is good cause for the delay. The Board understood that at times there may be delay due to extraordinary circumstances. During the discussion, Mr. Johnson and Ms. O'Halloran noted that a change of ownership was not included in the draft language and yet they are aware of concerns involving pharmacies that do not resume operation after performing a change of ownership. There was discussion regarding how staff would know when to rescind a permit and acknowledgement that the Bylaws (Guidance Document 110-12) may need to be amended, if the regulation becomes effective, to outline a process for the executive director to coordinate with the board chairman during the decision-making process.

MOTION:

The Board voted unanimously to adopt the amendment of 18VAC110-20-140(F) as amended to read: "If the pharmacy is not fully operational within 90 days of issuance of a permit or change of ownership, the board may rescind such permit. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension". (motion by Allen, second by S. Elliott)

Mr. Logan, who had a flat tire this morning, arrived and began presiding over the meeting.

Report From the Ad Hoc Inspection Committee Meeting and Possible Action

Jody Allen, Chairman of the ad hoc committee that met on June 20, 2018, presented the committee's report. She stated that the inspection report was discussed at the committee meeting and suggested changes were reviewed. The committee also recommended the board adopt the amendments to Guidance Document 110-9 as presented in the handout, with the exception of one error in Deficiency #4 wherein "first citation" should read "documented occurrence".

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-9 as presented in the handout, with the exception of one error in Deficiency #4 wherein "first citation" should read "documented occurrence". (motion by Warriner, second by Boone)

OLD BUSINESS:

Request from Gates Healthcare Associates, Inc. Regarding cGMP Inspections

Denise Frank, Senior Associate with Gates Healthcare Associates, Inc. provided brief comment regarding their request to have their cGMP inspection reports accepted for licensure purposes of an outsourcing facility, in lieu of an FDA inspection, when an FDA inspection has not been performed in a timely manner for the applicant to comply with Virginia law. Ms. Juran informed the board that additional information, as requested by the board at the last board meeting, was received by staff, but that Gates requested that the inspection-related information not be shared publically. Ms. Juran stated that the law did not allow the board to review the information confidentially without sharing with the public. Ms. Frank indicated that she just sent via email a revised version that

could be shared with the board and public. Several questions were asked of Ms. Frank. She stated there is currently one trained inspector of cGMPs who formerly worked with the FDA, but that other inspectors could be trained as necessary. She stated that Gates is not currently performing cGMP inspections for any other states, but that Gates is currently engaged in conversations with several states and that Gates has assisted some facilities in responding to FDA observations. She also reported that there is no defined inspection report to share currently such as a checklist that boards are familiar with using in routine pharmacy inspections, but that Gates could develop such and reflect whatever information the Board desires.

Mr. Logan recommended and the Board agreed to defer the request to a later meeting for consideration after reviewing the additional information Ms. Frank has emailed to staff.

NEW BUSINESS:

Presentation of 2017 Pharmacist and Pharmacy Technician Workforce Reports

Dr. Elizabeth A. Carter, Director of DHP Healthcare Workforce Data Center, provided a summary presentation of the work the center has done in collecting and presenting the reports of pharmacist and pharmacy technician workforce. There was a 96-98% response rate during the 2017 survey. When providing a general overview of the reports, she noted that 56% of the licensees have a relationship with Virginia, either having been born in Virginia, currently residing in Virginia, or having attended school in Virginia. This is higher than other professions. Pharmacy technicians have a higher percentage rate from rural backgrounds. Dr. Carter also demonstrated the new interactive Virginia CareForce Snapshots and Regional CareForce Snapshots, along with the Trends in Healthcare Workforce Full Time Equivalency Units report available at www.dhp.virginia.gov/hwdc Additionally, she provided a handout representing the overall breakout of individual disease states selected by responders for the newly added survey question regarding collaborative practice agreements. Results indicate 30% of the survey respondents reported participating in a collaborative practice agreement for diabetes, 23% participate in hypercholesterolemia, 25% participate in hypertension, 15% participate in tobacco cessation, and 7% participate in travel medications. She also provided handouts regarding pharmacist and pharmacy technician labor market information from www.virginiaLMI.com The Board thanked Dr. Carter for the very informative report.

MOTION:

The Board voted unanimously to adopt the 2017 workforce data reports for pharmacists and pharmacy technicians. (motion by Warriner, second by Saenz)

Consideration for a Board Retreat

Ms. Juran asked if the Board would be interested in having a one-day retreat this fall, perhaps in October, that would allow the members and staff to receive education on topics such as production and use of CBD/THC-A oil, pharmaceutical processor oversight, current trends to move toward a standard of care approach in regulatory oversight, and

advances in pharmacy technology and security systems. Ms. Juran noted that the Governor will potentially appoint 5-6 new board members prior to the September board meeting. The education may assist the Board in future regulatory and enforcement actions. There was general support expressed by the Board for this retreat.

Elections for Chairman and Vice-Chairman

MOTION: **The board voted unanimously to elect Rafael Saenz as Chairman of the Board for the term July 1, 2018 through June 30, 2019. (motion by Boone, second by Warriner)**

MOTION: **The board voted unanimously to elect Cindy Warriner as Vice Chairman of the Board for the term July 1, 2018 through June 30, 2019. (motion by Allen, second by Boone)**

The Board decided to consider the ADA accommodation request after all reports were received since the request would require the Board to enter into a closed session.

Chairman's Report

Mr. Logan provided information on the NABP meeting held in May in Denver, Colorado where he served as the elected delegate for the Resolutions Committee representing District 2 and the voting delegate for the Virginia Board. Mr. Logan encouraged everyone to attend this national meeting as he finds the information provided very valuable. He expressed appreciation for the opportunity to serve as the Board Chairman during the past year.

Report on Board of Health Professions

Mr. Logan reported that the next Board of Health Professions meeting is scheduled for June 26, 2018.

Report on Licensure Program

Mr. Johnson reported the Board currently licenses 36,648 individuals and facilities. The Board issued 912 licenses and registrations for the period of March 1, 2018 through May 31, 2018. Inspectors conducted 535 facility inspections including 218 routine inspections of pharmacies: 66 (30%) resulted in no deficiency, 80 (37%) with deficiencies and 72 (33%) with deficiencies and a consent order. Beginning with the September board meeting, the report of inspections and deficiencies will be modified to capture the impact of the amendments the Board approved to Guidance Document 110-9.

Report on Disciplinary Program

Ms. Shinaberry stated that as of 6/7/18 there were 296 open pharmacy cases. There has been an increase in cases recently primarily due to the CE audit. The board has six possible summary suspension cases it is working. She reported that the Board has worked through most of the older cases and currently has only three probable cause cases exceeding 250 days.

Executive Director's Report

Ms. Juran provided comment on the report provided in the agenda packet.

As noted earlier in the morning, she welcomed Cheryl Nelson as a newly appointed board member who is filling the unexpired term, previously held by Ms. Shinaberry that is set to expire June 30, 2018. She reported that Mr. Jenkins could not attend this first board meeting due to an already scheduled vacation. She provided an update on the pharmaceutical processor Request for Application, the deadline of which was 2pm on June 8, 2018. She reported that 53 applications were received. Four were deemed incomplete. Of those four, two were later deemed complete after review by the Office of the Attorney General. Of those 51 complete application, 9 applications were received in health service area I, 8 were received in health service area II, 10 were received in health service area III, 9 were received in health service area IV, and 15 were received in health service area V. The 51 complete applications will be evaluated by the ad hoc committee appointed by the Board Chairman. The ad hoc committee will tentatively meet in-person on July 30 and 31, 2018. Ms. Juran additionally noted that Ms. Shinaberry provided an excellent presentation at the NABP annual meeting regarding use of PMP data in regulating. Lastly, she stated Ralph Orr asked that she inform the Board that SB226, effective July 1, 2018, requires a pharmacy dispensing a covered substance for an animal to report the dispensing to the PMP using the animal owner's name and date of birth. A reporting exemption exists in §54.1-2522 for veterinarians dispensing a course of treatment not to last longer than 7 days. Ms. Juran stated that it is important that veterinarians issue prescriptions in accordance with the longstanding requirement of §54.1-3409 that requires the prescription to bear the full name of the owner of the animal and to include the species of the animal. Equally important, pharmacists must label and dispense the drug in compliance with the longstanding requirement of §54.1-3410 which requires the label to bear the name of the owner of the animal and the species of the animal. Ms. Juran reported that if the information reported to the PMP does not accurately reflect the owner's name, e.g., it's reported in the name of the animal, then the information in the database will not appropriately align with the name of the owner and the effort loses value.

ACTION ITEM:

The Board requested that staff collaborate with the Board Chairman to draft an email to send to pharmacists and pharmacy technicians regarding suggestions for complying with the new PMP reporting requirement and reducing medication errors resulting from possible confusion between dispensed drugs intended for animals and owners. Guidance may include suggestions for pharmacies to use different caps on vials to distinguish between drugs intended for the animal verses the owner, use of auxiliary labels, or placing the animal's name in the directions field on the label to distinguish between multiple animals' drugs belonging to a single owner.

Consultation with Legal Counsel
Pursuant to §2.2-3711(A)(7)

Motion for Closed Meeting:

Upon a motion by Jody Allen, and duly seconded by Cindy Warriner, the Board voted unanimously to convene a closed meeting pursuant

to § 2.2-3711(A)(7) of the Code of Virginia ("Code"), for the purpose of consulting with legal counsel pertaining to actual or probable litigation, where such consultation or briefing in open meeting would adversely affect the negotiating or litigating posture of the public body. Additionally, she moved that Caroline Juran, Sammy Johnson, Beth O'Halloran, Ellen Shinaberry and Jim Rutkowski attend the closed meeting.

Motion to Certify the Purpose of the Closed Session:

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

Consideration for ADA Accommodation Request on Licensure Examinations

Motion for Closed Meeting:

Upon a motion by Jody Allen, and duly seconded by Cindy Warriner, the Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(16) of the Code of Virginia ("Code"), for the purpose of deliberation on the confidential handout to reach a decision regarding a request for an ADA accommodation for licensure examinations. Additionally, she moved that Caroline Juran, Sammy Johnson, Beth O'Halloran, Ellen Shinaberry and Jim Rutkowski attend the closed meeting.

Motion to Certify the Purpose of the Closed Session:

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

Decision:

The Board approved the applicant's request to extend the allotted amount of time for completing the MPJE and NAPLEX to an amount equal to double the normally allotted amount of time. (motion S. Elliott, second by Warriner)

Consideration of Summary Suspensions

Lindsey N. Brooks
Registration No.: 0230-022588

Julia Bennett, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a possible summary suspension. Mykl Egan, Adjudication Specialist, was also present.

MOTION:

Upon a motion by Jody Allen, and duly seconded by Cindy Warriner, the Board voted unanimously in favor of the motion that according to the evidence presented, the continued practice by Lindsey N. Brooks as a pharmacy technician poses a substantial danger to the public; and therefore, the registration for Ms. Brooks shall be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Brooks for the indefinite suspension of her

pharmacy technician registration for not less than two years.

Tammy Lea Thompson
Registration No.: 0230-002189

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a possible summary suspension. Mykl Egan, Adjudication Specialist, was also present.

MOTION:

Upon a motion by Cindy Warriner, and duly seconded by Sheila Elliott, the Board voted unanimously in favor of the motion that according to the evidence presented, the continued practice by Tammy Lea Thompson as a pharmacy technician poses a substantial danger to the public; and therefore, the registration for Ms. Thompson shall be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Thompson for the indefinite suspension of her pharmacy technician registration for not less than two years.

John Daniel Barnett
License No.: 0202-009362

James Schleissmann, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a possible summary suspension. Mykl Egan, Adjudication Specialist, was also present.

MOTION:

Upon a motion by Sheila Elliott, and duly seconded by Melvin Boone, the Board voted unanimously in favor of the motion that according to the evidence presented, the continued practice by John Daniel Barnett as a pharmacist poses a substantial danger to the public; and therefore, the license for Mr. Barnett shall be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Mr. Barnett for the indefinite suspension of his pharmacist license for not less than two years.

Consideration of Consent Orders for Reinstatement

MOTION FOR CLOSED MEETING:

Upon a motion by Jody Allen, and duly seconded by Cindy Warriner, the Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of presentation of evidence from Ellen Shinaberry, Deputy Executive Director, for consideration of three Consent Orders. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.

Motion to certify the purpose of the closed meeting:

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

DECISION:

Upon a motion by Cindy Warriner, and duly seconded by Jody Allen, the Board voted unanimously to accept the Consent Orders for:

- **reinstatement of the nonresident medical equipment supplier**

registration issued to Dependable Diabetic Supply, LLC (License No.: 0237000166);

- **reinstatement of the nonresident medical equipment supplier registration issued to US Healthcare, LLC (License No.: 0237000216);**
- **temporary voluntary suspension of Angela D. Dillard's registration to practice as a pharmacy technician (Registration No: 0230-007092).**

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:48pm.

Ryan K. Logan, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, July 19, 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 09:16 a.m.
PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Sheila Elliott, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
WALGREENS #09195 Permit No. 0201-004040	Rusty Maney, Regional Healthcare Director, and William Droppleman, Regional Healthcare Supervisor, appeared on behalf of Walgreens #09195 to discuss allegations that Walgreens #09195 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 10, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Elliott, 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 Walgreens #09195. 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. Elliott and duly seconded Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
WALGREENS #07644 Permit No. 0201-003973	Rusty Maney, Regional Healthcare Director, and William Droppleman, Regional Healthcare Supervisor, appeared on behalf of Walgreens #07644 to discuss allegations that Walgreens #07644 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 16, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Elliott, 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 Walgreens #07644. 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. Elliott and duly seconded Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
WALGREENS #04616 Permit No. 0201-003510	Rusty Maney, Regional Healthcare Director, and William Droppleman, Regional Healthcare Supervisor, appeared on behalf of Walgreens #04616 to discuss allegations that Walgreens #04616 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 16, 2018 Notice.

Closed Meeting:	Upon a motion by Ms. Elliott, 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 Walgreens #04616. 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. Elliott and duly seconded Mr. Saenz, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
VIRGINIA SUPPORTIVE HOUSING License No. 0220-000984	Christopher Link, Team Lead, and Corina Taylor-Soltus, Clinical Program Manager, appeared on behalf of Virginia Supportive Housing to discuss allegations that Virginia Supportive Housing may have violated certain laws and regulations governing the conduct of pharmacy as stated in the April 10, 2018 Notice.
Closed Meeting:	Upon a motion by Ms. Elliott, 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. Elliott, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to dismiss the case.
MARGARET REDMAN ALMARODE Registration No. 0230009826	This case was continued.
ADJOURNED:	2:29 p.m.

_____
Rafeal Saenz, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

August 14, 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 9:41 a.m.

PRESIDING: Cindy Warriner, Chair

MEMBERS PRESENT:
Patricia Richards-Spruill
Melvin Boone
Glenn Bolyard
Ryan Logan
Kristopher Ratliff
James Jenkins

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
James Schliessman, Senior Assistant Attorney General (arrives at 11:25 a.m.)
Julia Bennett, Senior Assistant Attorney General (arrives at 11:25 a.m.)
Mykl Egan, DHP Adjudication Specialist

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

LINDSEY BROOKS
Registration No. 0230-022588

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

Mykl Egan, DHP Adjudication Specialist, presented the case.

Ms. Brooks was not present.
Kelly D. Ashley, DHP Senior Investigator, testified in person on behalf of the Commonwealth.

CLOSED MEETING:	Upon a motion by Mr. Logan, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Lindsey Brooks. 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 Mr. Boone, and duly seconded by Ms. Patricia Richards-Spruill, the panel voted unaninously to accept the Findings and Fact and Conclusions of Law proposed by Mr. Egan. Upon a motion by Mr. Logan, and duly seconded by Mr. Jenkins, the panel voted unanimously to indefinitely suspend Ms. Brooks's right to renew her pharmacy technician registration for no less than two years.
TAMMY THOMSON Registration No. 0230-002189	A formal hearing was held in the matter of Tammy Thomson to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia. Mykl Egan, DHP Adjudication Specialist, presented the case. Ms. Thomson was not present. Sarah King, DHP Senior Investigator, and Christina Lotton, Giant Asset Protection Coordinator, testified in person on behalf of the Commonwealth and Judy Fulton, Giant Pharmacist in Charge, testified by telephone.

CLOSED MEETING:	Upon a motion by Mr. Logan, and duly seconded by Mr. Jenkins, the panel voted unanimously 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 Tammy Thomson. 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 Mr. Boone, and duly seconded by Ms. Richards-Spruill, 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 Mr. Logan, and duly seconded by Mr. Boone, the panel voted unanimously to indefinitely suspend Ms. Thomson's pharmacy technician registration for no less than two years.
QUORUM:	Ms. Warrier departed at 11:35 am. With six (6) board members in attendance a quorum was maintained.
PRESIDING:	Ryan Logan, Chair
	POSSIBLE SUMMARY SUSPENSION
MYCKIEALA COOPER License No. 0202-0026333	Julia Bennett, Senior Assistant Attorney General, presented a summary of the evidence in this case, assisted by Mr. Egan, Senior Adjudication Specialist.
CLOSED MEETING:	Upon a motion by Mr. Boone, and duly seconded by Mr. Bolyard, the panel voted unanimously, 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 Myckieala Cooper. 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 Mr. Jenkins and duly seconded by Mr. Ratliff, the Board unanimously voted that with the evidence presented, the practice as a pharmacist by Myckieala Cooper poses a substantial danger to the public; and therefore, the license of Ms. Cooper shall be summarily suspended. Further, with the Notice of Formal Hearing, a Consent Order shall be offered to Ms. Cooper for the revocation of her license in lieu of the Formal Hearing.

POSSIBLE SUMMARY SUSPENSION

AWAHNEE THOMAS
Registration No. 0230027492

James Schliessmann, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

CLOSED MEETING:

Upon a motion by Mr. Boone, and duly seconded by Mr. Bolyard, the panel voted unanimously, 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 Awahnee Thomas. 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 Mr. Boone, and duly seconded by Mr. Bolyard, the that with the evidence presented, the practice as a technician by Awahnee Thomas poses a substantial danger to the public; and therefore, the registration of Ms. Thomas shall be summarily

suspended. Further, with the Notice of Formal Hearing, a Consent Order shall be offered to Ms. Thomas for the revocation of her registration in lieu of the Formal Hearing.

PRESENTATION OF CONSENT ORDER

UNIVERSITY COMPOUNDING PHARMACY
Registration No. 0214-001335

Ms. Shinaberry presented a Consent Order for University Compounding Pharmacy for reinstatement of their non-resident pharmacy registration.

DECISION:

Upon a motion by Ms. Richards-Spruill and duly seconded by Mr. Boone, the Board voted 5-1 (Jenkins opposed) to accept the Consent Order.

ADAM JACQUES
Registration No. 0230-023668

A formal hearing was held in the matter of Adam Jacques 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. Jacques was not present.

Steve Keen, DHP Senior Investigator, and Virginia West, Culpeper Medical Center Pharmacy Manager, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Mr. Ratliff, and duly seconded by Mr. Jenkins, the panel voted unanimously, 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 Adam Jacques. 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 Mr. Bolyard, and duly seconded by Mr. Ratliff, the panel voted unanimously to accept the Findings and Fact and Conclusions of Law as proposed by Mr. Egan.

Upon a motion by Ms. Richards-Spruill, and duly seconded by Mr. Ratliff, the panel voted unanimously to revoke Mr. Jacques's right to renew his pharmacy technician registration.

ADJOURNED: With all business concluded, the meeting adjourned at 1:36 p.m.

Cindy Warriner, Chair
(Brooks, Thomson)

Caroline D. Juran
Executive Director

Date

Ryan Logan, Chair
(Summary Suspensions, Ratification of Consent Order, Jacques)

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, August 15, 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 10:03 a.m.
PRESIDING:	Cindy Warriner, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Anne Joseph, Acting Deputy Executive Director Claire Foley, DHP Adjudication Specialist Mykl D. Egan, DHP Adjudication Specialist
SOUTH RIVER COMPOUNDING WEST END Permit No. 0201-004172	Baylor Rice, Pharmacist-in-Charge, appeared on behalf of South River Compounding West End to discuss allegations that South River Compounding West End may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 24 , 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of South River Compounding West End. Additionally, he moved that Anne Joseph and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.
FALLS CHURCH PHARMACY Permit No. 0201-003833	Thu Bui, Pharmacist in Charge, appeared on behalf of Falls Church Pharmacy to discuss allegations that Falls Church Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the June 11, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Falls Church Pharmacy. Additionally, he moved that Anne Joseph and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order with terms to include Probation and assessment of a monetary penalty.
RX3 Permit No. 0201- 003164	Christopher Currin, Pharmacist in Charge, and Nathan Kottcamp, Esquire, appeared on behalf of RX3 to discuss allegations that RX3 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the June 29, 2018 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of

deliberation to reach a decision in the matter of RX3. Additionally, he moved that Anne Joseph and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

The case was dismissed.

HAGUE PHARMACY
License No. 0202-002286

Heather Paschal, former Pharmacist in Charge, and Dino Yambao, Pharmacist in Charge, appeared to discuss allegations that Hague Pharmacy may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 4, 2018 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Falls Church Pharmacy. Additionally, he moved that Anne Joseph and Ellen B. Shinaberry attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Boone and duly seconded Ms. Warriner, the Committee unanimously voted to enter an Order with terms to include the assessment of a monetary penalty.

ADJOURNED: 4:10 p.m.

Cindy Warriner, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING ON PROPOSED REGULATIONS FOR ISSUING CSRs TO COMMUNITY ORGANIZATIONS TO DISTRIBUTE NALOXONE AND FOR TELE-PRESCRIBING

August 23, 2018
Second Floor
Hearing Room 6

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The public hearing was called to order at 9:05a.m.
PRESIDING:	Caroline D. Juran, Executive Director
STAFF PRESENT:	Elaine Yeatts, DHP Senior Policy Analyst
PULIC COMMENT:	No public comment was offered.
ADJOURN:	The public hearing adjourned at 9:07am.

_____
Caroline D. Juran, Executive Director

_____
Date

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**
As of September 13, 2018

Board	Board of Pharmacy	
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* *Comment closed: 9/5/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *At Governor's Office for 48 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Proposed - *Register Date: 7/9/18* *Comment closed: 9/7/18*
[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 - *At Governor's Office for 113 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Proposed - *Register Date: 9/17/18* *Comment closes: 11/16/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *At Secretary's Office for 90 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Rescission of pharmacy permit [Action 5080] Fast-Track - *At Agency* [Stage 8328]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 113 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] Final - *Register Date: 10/1/18* *Effective: 10/31/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of drugs or chemicals [Action 5082] Final - *Register Date: 8/6/18* *Effective: 9/5/18*

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Emergency/NOIRA - *At Secretary's Office for 3 days*
[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 Attorney General's Office*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *At Governor's Office for 8 days*

Agenda Item: **Regulatory Action – Adoption of Final Regulations**

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

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

Amendments to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

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

Board action:

Adoption of final regulation in sections 322

Notice of Public Hearing
Placement of Chemicals in Schedule I

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on September 25, 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 two (2) compounds for recommended inclusion into the Code of Virginia.

The following compound is classified as a powerful synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. **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.

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.

2. **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.

April 24, 2018

Project 5660 - none

BOARD OF PHARMACY

Schedule I chemicals 9-18

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

Agenda Item: Adoption of Proposed Regulations for Pharmaceutical Processors of Cannabidioil and THC-A oil

Included in your agenda package are:

Timeline for promulgation of regulation for pharmaceutical processors

A copy of the General Notice request for comment

Copies of comment received from the General Notice

Copy of the proposed regulations as recommended by Staff
(Proposed regulations include revisions to the emergency regulations approved in June with additional revisions based on comment from the General Notice)

Board action:

Adoption of proposed regulations

Timeline for Promulgation of Emergency Regulations

- Passage of SB701 (Chapter 577 of the 2016 Acts of the Assembly) - Board promulgated regulations governing issuance of a permit for a pharmaceutical processor to manufacture and provide cannabidiol oil and THC-A oil to be used for the treatment of intractable epilepsy.

- In June of 2016, the Board adopted Emergency regulations and a Notice of Intended Regulatory Action (NOIRA) to replace emergency regulations with permanent regulations.

- Emergency regulations became effective on 8/7/17 with expiration on 2/9/19. Comment closed on NOIRA on 9/6/17.

- Passage of SB330 and 726 (Chapters 246 and 567 of the 2018 Acts of the Assembly - Board to amend its emergency regulations to address the Code changes for patients who may receive a certification from a physician to possess the oil, the type of physician who may issue a certification, the change from a 30-day to a 90-day supply for dispensing the oil and the number of plants allocated, criminal background checks for applicants, allowance for delivery of the oil after the initial dispensing, and requirements for registration and labeling of the product by brand name.

- Board adopted revised emergency regulations and a NOIRA – submitted for Executive Branch review on 7/9/18.

- A General Notice with request for comment was posted on 7/3/18 with an expiration of 8/22/18. Since the Board is adopting proposed regulations based on the 2017 NOIRA and the 2018 legislation, the General Notice was posted to give the public the opportunity to provide comment prior to the September Board meeting.

- Once approved by the OAG, DPB, SHHR, and the Governor, the proposed regulations adopted at the meeting on 9/25/18 will be open for a 60-day comment period and a public hearing.

- Emergency regulation expire on 2/9/19; the Board will have to request a 6-month extension in order to avoid a gap in regulation since it will not be possible to have permanent regulations in effect by that date.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

General Notice

Edit Notice

Emergency regulations for pharmaceutical processors of CBD or THC-A oil

Date Posted: 7/3/2018

Expiration Date: 8/22/2018

Submitted to Registrar for publication: YES

30 Day Comment Forum closed. Began on 7/23/2018 and ended 8/22/2018 [20 comments]

The Board of Pharmacy will be adopting proposed regulations to replace emergency regulations for pharmaceutical processors at its meeting on September 25, 2018. Prior to adoption, It is seeking comment on the regulations as amended by the Board at its meeting in June. Public comment may be posted on the Townhall or sent to the Executive Director of the Board.

The emergency regulations may be viewed by copying this address:

http://leg1.state.va.us/000/lst/r1456642.HTM

Contact Information

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

Commonwealth of Virginia

Yeatts, Elaine <elaine.yeatts@dhp.virginia.gov>

Fwd: CannaMed Group Comments Regarding 18VAC110 - 60-330

1 message

Caroline Juran <caroline.juran@dhp.virginia.gov> Thu, Aug 23, 2018 at 1:31 PM
To: Elaine Yeatts <elaine.yeatts@dhp.virginia.gov>

Comment.

---------- Forwarded message ---------
From: Kim Philippi <kimphilippi@yahoo.com>
Date: Wed, Aug 22, 2018 at 8:20 PM
Subject: CannaMed Group Comments Regarding 18VAC110 - 60-330
To: Caroline Juran <caroline.juran@dhp.virginia.gov>
CC: Martha Paschal <paschal.martha@gmail.com>

Dear Dr. Juran:

The CannaMed Group Incorporated would like to submit the following comments and requests for changes to the regulations that will replace the Emergency Regulations for Pharmaceutical Processors of CBD or THC-A Oil. The attached pdf is a signed copy of the comments below.

18VAC110-60-30. Requirements for practitioner issuing a certification.
We recommend the above section, and Virginia Code 54.1-3408.3, Certification for use of Cannabidiol oil or THC-A oil for Treatment, be amended to require that licensed medical providers have at least 2 to 4 hours of required medical cannabis CME training in order to register as a provider with the Board of Pharmacy.

This training should include information on: Virginia state law and legal ramifications of recommending cannabis; the endocannabinoid system and phytocannabinoids; cannabinoid-related pharmacology, metabolism, administration, dosing, contraindications, drug interactions, side effects, risks and benefits; as well as cannabis use disorder.

Most physicians have no previous experience or training in medical school regarding cannabis compounds, or education on the endocannabinoid system and how these compounds interact in the body. The state of Virginia should follow at least 10 other states that require providers to have 2 to 5 hours of required CME prior to registration in order to make appropriate cannabis recommendations for patients.

Additionally, if the state Board of Medicine requires providers to have at least 2 hours of CME on the use of controlled substances, opioid dependence and appropriate pain management, it is logical to require providers to have at least this baseline amount of training prior to making recommendations for medical cannabis; a plant product with psychoactive properties and potential for psychological dependence.

18VAC110-60-30. Requirements for practitioner issuing a certification, Section F.
A practitioner shall not issue certifications for cannabidiol oil or THC-A oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and Board of Medicine for an

increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

CannaMed Group estimates one physician seeing 8 new patients per day will reach a total of 600 patients in 3.5 months. In Michigan and Massachusetts, high volume providers average about 2,000 patients per provider. Most states with medical cannabis regulations have no limit on the number of patients one physician can see for medical marijuana.

If the Board of Pharmacy's goal is to prevent the establishment of cannabis recommendation centers that solely focus on certifying patients, then mandating specific medical evaluation and reporting requirements is the appropriate solution to prevent the development of patient "mills".

As written, this limiting regulation imposes an undue burden on physicians. We recommend that the 600 patient limitation be increased to an initial total of 2,000 patients, with continued ability to petition the Board of Pharmacy in order to increase that number.

18VAC110-60-40. Prohibited practices for practitioners, Section 4.B.
A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabidiol oil or THC-A oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

While CannaMed Group does not have an issue with the second part of this prohibited practice (i.e. processor providing compensation to the practitioner for steering a patient to a specific processor or product), the Group does have significant concerns regarding the limitations on practitioners, spouse, and family members having direct or indirect financial interest in pharmaceutical processors.

This language is concerning for the following reasons:

1. Preventing physicians, family, coworkers or employees from receiving any financial gain from the cannabis pharmaceutical processing business may be considered overly restrictive and possibly legally challenged. As an example, many ophthalmologists own, or have financial interest, in eyewear businesses associated with their practice. Additionally, many physicians have financial interests or investments in pharmaceutical companies that produce medications they may prescribe for patients. This is not prohibited as long as the physician discloses these relationships.

2. Physicians, in particular, may wish to become involved with the investigation and production of new cannabidiol oils or THC-A products, including specific terpenes or extracts that might have beneficial effects for medical cannabis patients. Prohibiting the pharmaceutical processor from compensating the physician or provider for these efforts discourages clinical research and new product development.

As a solution, the CannaMed Group would recommend that the regulation be amended as follows:
"If a practitioner who issues certifications, or such practitioner's coworker, employee, spouse, family member, parent, or child have direct or indirect financial interest in the pharmaceutical processor or other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabidiol oil or THC-A oil, then this financial relationship shall be declared to the State Board of Pharmacy and to the patient for full transparency and accountability."

If the wording of the regulation is left unchanged, we respectfully request clarification regarding practitioners who may be financially invested in a pharmaceutical processor and whether they should be restricted or excluded from evaluating and treating patients who may benefit from a recommendation of medical cannabis.

Thank you for considering our comments and requests on proposed changes to these regulations.

Sincerely,

Kim Philippi, Chairman
CannaMed Group Inc.

"You have not lived until you have done something for someone who can never repay you" - Anonymous
"Better to be guilty in the eyes of men than in the eyes of God" - Malagasy Proverb

--
Caroline D. Juran, RPh, DPh
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Virginia Board of Pharmacy
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CannaMed Group Comments Regarding 18VAC110 - 60-330.pdf
1060K

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McGUIREWOODS

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August 22, 2018

Caroline Juran
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Surterra Virginia Comments on Pharmaceutical Processor Emergency Regulations

Dear Ms. Juran,

Surterra Virginia LLC, is an applicant for 3 of the 5 pharmaceutical processor licenses available in Virginia. Surterra Holdings, the parent company of Surterra Virginia, owns vertically-integrated licenses in Florida and Texas. Surterra operates 10 Wellness Centers in Florida and will have more than 20 open by the end of 2018. As a leader in the manufacturing and sale of cannabidiol and THC-A products, Surterra would like to offer the following comments on the Board of Pharmacy's current emergency regulations for pharmaceutical processors.

I. Communications with Practitioners

18VAC110-60-40(A) prohibits practitioners from accepting anything of value from any person associated with a pharmaceutical processor. It is unclear whether "anything of value" includes educational materials on THC-A oil or cannabidiol products.

Because the regulations also require practitioners to explain proper administration and the potential benefits and risks of cannabidiol oil or THC-A oil to patients, education of practitioners is critical.[1] Pharmaceutical processors should be permitted to provide accurate information on their products and potential benefits or risks associated with such products to practitioners.

Information as a thing of value is also an issue in the alcoholic beverage industry. Until recently, information from distillers and wineries related to product history, quality and

[1] 18VAC110-60-30(B)(4).

tasting notes were considered things of value and prohibited from dispersal to retailers. This change in policy recognizes the value in conveying information about a product to the consuming public. This should be the same approach taken with regard to these products. In addition, reasonable and customary business expenses should be authorized in order to facilitate educational seminars and the attendance of physicians at those seminars in order to convey information about these products.

Surterra Virginia asks that the Board amend 18VAC110-60-40(A) to exclude educational materials from "anything of value" as follows:

A. A practitioner who issues certifications shall not:
1. Directly or indirectly accept, solicit, or receive anything of value, *excluding any information on products or educational materials on the benefits and risks of THC-A and cannabidiol oils and reasonable and customary business reimbursements associated with attendance at educational events* from any person associated with a pharmaceutical processor or provider of paraphernalia.

II. Denial of Registration Application

Under 18VAC110-60-60, the Board may deny an application or renewal of the registration of a qualifying patient if the applicant has a prior conviction of a violation of any law pertaining to controlled substances.[2]

The opioid epidemic has created a public health emergency throughout the Commonwealth.[3] THC-A and cannabidiol products may replace the use of many opioids and other substances. The law should not exclude those individuals who may be seeking alternatives to opioids or illegal drugs, even if there is a prior violation of the law. While there is justification for excluding some individuals with drug trafficking, distribution, or similar convictions, a blanket exclusion may not be necessary.

Similarly under 18VAC110-60-90, the Board may revoke registration if any patient, parent, or legal guardian violates *any* federal or state law or regulation.[4] This is overly broad. No patient should be denied access if their parent or guardian commits an offense unrelated to cannabidiol or THC-A oil.

The Board should amend 18VAC110-60-60 to read:

6. Has a prior conviction of a violation of any law pertaining to controlled substances. *Notwithstanding this authority, the Board shall not deny an application from a patient solely on the grounds basis of a criminal conviction related to controlled substances if*

[2] 18VAC110-60-60(A)(6).
[3] VDH Declaration of Public Health Emergency, http://www.vdh.virginia.gov/commissioner/opioid-addiction-in-virginia/declaration-of-public-health-emergency/.
[4] 18VAC110-60-90(10).

the conviction involves a substance for which CBD oil or THC-A oil may be an effective treatment.

The Board should amend 18VAC110-60-90 to read:

10. The patient, parent, or legal guardian violated any federal or state law or regulation *related to controlled substances, fraud or moral turpitude. However, no permit shall be revoked solely based upon the patient's conviction if related to addiction to a controlled substance for which CBD oil and THC-A oil may be an effective treatment.*

III. Definition of Agent

Background checks are required for all employees and agents of a pharmaceutical processor before a pharmaceutical processor permit may be issued.[5] Neither §54.-3442.6 nor the regulations clarify the definition of agent. The Board should consider providing clarifying language as to who qualifies as an "agent" of the pharmaceutical processor who would be subject to the background checks.

IV. Access to Pharmaceutical Processor

18VAC110-60-220(B) states, "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."[6] In order to be "properly secured", it is likely that security personnel must remain on site after closure or at the very least, respond to security threats on site when necessary. However, 18VAC110-60-170(H) states, "At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty."[7] These restrictions seems to prohibit security personnel from accessing the pharmaceutical processor after hours without a pharmacist on duty. Consequently, this restriction should be amended as follows:

H. At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty *except for such security personnel as are necessary to comply with an approved security protocol for the facility.*

Under 18VAC110-60-170(G), the pharmacist on duty must "have a process in place, approved by the Board that provides adequate supervision to protect the security of the Cannabis…."[8] The Board should provide clarifications as to whether "adequate supervision" must be administered by a pharmacist or whether a security plan approved

[5] 18VAC110-60-130(A)(2).
[6] 18VAC110-60-220(B).
[7] 18VAC110-60-170(H).
[8] 18VAC110-60-170(G).

by the Board without a pharmacist on duty after closure or when a pharmacist is not present is sufficient.

18VAC110-60-210(C) requires a pharmacist on duty to restrict access 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....[9]

Similarly, 18VAC110-60-220(F) restricts access to pharmaceutical processor employees, registered patients, parents, or legal guardians except for laboratory staff.[10] The Board may waive this prohibition on prior written request. In order to provide clarity for accessing a pharmaceutical processor, the Board should add language to 18VAC110-60-210(C) as follows:

C. 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.
> *3. Any person who has been granted access pursuant to 18VAC110-60-220(F).*

V. Duties of Pharmacist in Charge

The regulations currently require the Pharmacist in Charge (PIC) to "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."[11] This language could potentially extend to business decisions by the owner of the pharmaceutical processor unrelated to the operations under the control or duties of the PIC. For example, this language would give control to the PIC of compensation issues for all company employees.

The Board should consider amending 18VAC110-60-200(B) to clarify the duties of the PIC with the following language:

B. The PIC or the pharmacist on duty shall control all *regulated* aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or

[9] 18VAC110-60-220(C).
[10] 18VAC110-60-220(F).
[11] 18VAC110-60-200(B).

other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

VI. Light Resistant Containers

The Board should remove the requirement that all products be sold in light-resistant containers.[12] Light-resistant is an ambiguous term and without a definition or standard, there is no obvious method of compliance. Light-resistant containers often contain a residue spray that may not be appropriate for the packaging of a medical product.

Furthermore, pharmaceutical processors are already required to counsel registered patients or patient guardians on the proper storage of products.[13]

VII. Permissible Information on Website

The current regulations restrict the information that may be posted on a pharmaceutical processor's website.[14] It is important that patients understand the products and pricing of the cannabidiol and THC-A oil before coming to the pharmaceutical processor. As a newly available product in Virginia, it is likely many patients will look to a licensed pharmaceutical processor for product information and pricing. The Board regulations contemplate the registration of product brands which differ in their chemical makeup. It is imperative that the practitioner and patient understand the products that are available. The company's website is the best vehicle for conveying that information.

Surterra Holdings prides itself on providing accurate and transparent information to its current patients in Florida and Texas and hopes to continue to be a resource for patients in Virginia if awarded a license. Providing credible information directly from the source distributing the cannabidiol and THC-A oil is the best interest of patients. Restricting the entity who arguably knows the most about the product (having control over the product from cultivation to dispensing) from providing information is counterintuitive.

The Board should allow pharmaceutical processors to post product information and pricing on websites. 18VAC110-60-220(D) should be amended as follows:

D. A pharmaceutical processor shall not [market or] 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;

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[12] 18VAC110-60-210(A).
[13] 18VAC110-60-210(H).
[14] 18VAC110-60-220(D).

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.
6. Product Information
7. Product Pricing

VIII. Number of Cannabis Plants Allowed

Due to the recently expanded scope of cannabidiol and THC-A from epilepsy to the treatment of any diagnosed condition,[15] the Board appropriately expanded the number of plants allowed per patient from four to twelve.[16] However, because many plants are lost during the propagation and vegetable stages, the Board should clarify that a pharmaceutical processor may have 12 *flowering* plants per patient. This change would adequately allow for pharmaceutical processors to meet demand and avoid a potential shortage.

The Board should amend 18VAC-60-240(A) as follows:

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the first [three nine] months of operation. Thereafter, the processor shall:

1. Not maintain more than [four 12] *flowering* Cannabis plants per patient at any given time based on dispensing data from the previous [30 90] days;

IX. Reportable Events

Security is an important aspect of operation of a pharmaceutical processor. With the strict security measures outlined in the regulations, it is likely that inadvertent events could occur during normal operation which after inspection and confirmation, do not rise to the level of a reportable offense. So as to avoid an influx of unnecessary notices as required under the current regulations, the Board should amend 18VAC110-60-270(B) as follows:

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

[15] Virginia Code Ann. § 54.1-3408.3.
[16] 18VAC110-60-240.

X. Guidance on Use of Pesticides under 18VAC110-60-280

The regulations prohibit the use of pesticide chemicals or petroleum-based solvents for cannabidiol and THC-A oil, except the Board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of crops.[17] Pesticide chemical is not defined in the regulations. The Board should provide clarity in the regulations or issue a guidance document as to whether pesticides classified as safe for plants or human consumption are permissible.

Additionally, the Board should provide clarity as to whether a pharmaceutical processor may preemptively seek Board approval for pesticide use for known pests, or if there must be an actual infestation before seeking approval for pesticide use.

XI. Registration of Products

18VAC110-60-285 requires product brand name registration to include a list of all active ingredients including any active ingredient that constitutes at least 1% of the batch used in the product.[18] Additionally, the regulations only allow for a 3% variance between products under the same brand name, including any active ingredient that at least 1% of the batch.[19]

As a naturally occurring product containing over 70 identifiable cannabinoids, identification and measurement of potential active ingredients at trace levels and determining their presence within the range proposed in subsection B is impractical. The amount of cannabinoids in a batch can vary greatly, especially at a 1% threshold. This would result in many different product names, causing confusion among patients.

The Board should remove 18VAC110-60-285(A)(5) so as to not require trace cannabinoids to be on the label and should not subject these trace cannabinoids to the 3% variance requirement in subsection (B).

XII. Labeling Organic

Regulations allow products to be labeled as "organic" as long as the products are certified to be consistent with federal law.[20] Because the US Department of Agriculture (USDA) is a federal organization and cannabis is still illegal at the federal level, there is no USDA organic label for cannabis. Therefore, the Department should allow Pharmaceutical Processors to use "organic" if they obtain a seal of approval from a

[17] 18VAC110-60-280.
[18] 18VAC110-60-285(A)(5).
[19] 18VAC110-60-285(B).
[20] 18VAC110-60-295(C).

third-party regulator such as Organic Materials Review Institute (OMRI) or California's Organic Input Materials OIM Program.

Surterra Virginia thanks the Board of Pharmacy for their work on this important effort to offer new medicinal solutions to the citizens of the Commonwealth of Virginia. We are happy to serve as a resource as the Board considers amending the Emergency Regulations.

Sincerely,

Kassie Schroth

Kassie Schroth, McGuireWoods LLP

CC: Theodore F. Adams III, McGuireWoods LLP
Jake Bergmann, Founder and Chief Executive Officer, Surterra Wellness

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August 22, 2018

Caroline Juran
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

Surterra Virginia Comments on Pharmaceutical Processor Emergency Regulations

Dear Ms. Juran,

Surterra Virginia LLC, is an applicant for 3 of the 5 pharmaceutical processor licenses available in Virginia. Surterra Holdings, the parent company of Surterra Virginia, owns vertically-integrated licenses in Florida and Texas. Surterra operates 10 Wellness Centers in Florida and will have more than 20 open by the end of 2018. As a leader in the manufacturing and sale of cannabidiol and THC-A products, Surterra would like to offer the following comments on the Board of Pharmacy's current emergency regulations for pharmaceutical processors.

I. Communications with Practitioners

18VAC110-60-40(A) prohibits practitioners from accepting anything of value from any person associated with a pharmaceutical processor. It is unclear whether "anything of value" includes educational materials on THC-A oil or cannabidiol products.

Because the regulations also require practitioners to explain proper administration and the potential benefits and risks of cannabidiol oil or THC-A oil to patients, education of practitioners is critical.[1] Pharmaceutical processors should be permitted to provide accurate information on their products and potential benefits or risks associated with such products to practitioners.

Information as a thing of value is also an issue in the alcoholic beverage industry. Until recently, information from distillers and wineries related to product history, quality and

[1] 18VAC110-60-30(B)(4).

tasting notes were considered things of value and prohibited from dispersal to retailers. This change in policy recognizes the value in conveying information about a product to the consuming public. This should be the same approach taken with regard to these products. In addition, reasonable and customary business expenses should be authorized in order to facilitate educational seminars and the attendance of physicians at those seminars in order to convey information about these products.

Surterra Virginia asks that the Board amend 18VAC110-60-40(A) to exclude educational materials from "anything of value" as follows:

A. A practitioner who issues certifications shall not:
1. Directly or indirectly accept, solicit, or receive anything of value, *excluding any information on products or educational materials on the benefits and risks of THC-A and cannabidiol oils and reasonable and customary business reimbursements associated with attendance at educational events* from any person associated with a pharmaceutical processor or provider of paraphernalia.

II. Denial of Registration Application

Under 18VAC110-60-60, the Board may deny an application or renewal of the registration of a qualifying patient if the applicant has a prior conviction of a violation of any law pertaining to controlled substances.[2]

The opioid epidemic has created a public health emergency throughout the Commonwealth.[3] THC-A and cannabidiol products may replace the use of many opioids and other substances. The law should not exclude those individuals who may be seeking alternatives to opioids or illegal drugs, even if there is a prior violation of the law. While there is justification for excluding some individuals with drug trafficking, distribution, or similar convictions, a blanket exclusion may not be necessary.

Similarly under 18VAC110-60-90, the Board may revoke registration if any patient, parent, or legal guardian violates *any* federal or state law or regulation.[4] This is overly broad. No patient should be denied access if their parent or guardian commits an offense unrelated to cannabidiol or THC-A oil.

The Board should amend 18VAC110-60-60 to read:

6. Has a prior conviction of a violation of any law pertaining to controlled substances. *Notwithstanding this authority, the Board shall not deny an application from a patient solely on the grounds basis of a criminal conviction related to controlled substances if*

[2] 18VAC110-60-60(A)(6).
[3] VDH Declaration of Public Health Emergency, http://www.vdh.virginia.gov/commissioner/opioid-addiction-in-virginia/declaration-of-public-health-emergency/.
[4] 18VAC110-60-90(10).

the conviction involves a substance for which CBD oil or THC-A oil may be an effective treatment.

The Board should amend 18VAC110-60-90 to read:

10. The patient, parent, or legal guardian violated any federal or state law or regulation *related to controlled substances, fraud or moral turpitude. However, no permit shall be revoked solely based upon the patient's conviction if related to addiction to a controlled substance for which CBD oil and THC-A oil may be an effective treatment.*

III. Definition of Agent

Background checks are required for all employees and agents of a pharmaceutical processor before a pharmaceutical processor permit may be issued.[5] Neither §54.-3442.6 nor the regulations clarify the definition of agent. The Board should consider providing clarifying language as to who qualifies as an "agent" of the pharmaceutical processor who would be subject to the background checks.

IV. Access to Pharmaceutical Processor

18VAC110-60-220(B) states, "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."[6] In order to be "properly secured", it is likely that security personnel must remain on site after closure or at the very least, respond to security threats on site when necessary. However, 18VAC110-60-170(H) states, "At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty."[7] These restrictions seems to prohibit security personnel from accessing the pharmaceutical processor after hours without a pharmacist on duty. Consequently, this restriction should be amended as follows:

H. At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty *except for such security personnel as are necessary to comply with an approved security protocol for the facility.*

Under 18VAC110-60-170(G), the pharmacist on duty must "have a process in place, approved by the Board that provides adequate supervision to protect the security of the Cannabis...."[8] The Board should provide clarifications as to whether "adequate supervision" must be administered by a pharmacist or whether a security plan approved

[5] 18VAC110-60-130(A)(2).
[6] 18VAC110-60-220(B).
[7] 18VAC110-60-170(H).
[8] 18VAC110-60-170(G).

by the Board without a pharmacist on duty after closure or when a pharmacist is not present is sufficient.

18VAC110-60-210(C) requires a pharmacist on duty to restrict access 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....[9]

Similarly, 18VAC110-60-220(F) restricts access to pharmaceutical processor employees, registered patients, parents, or legal guardians except for laboratory staff.[10] The Board may waive this prohibition on prior written request. In order to provide clarity for accessing a pharmaceutical processor, the Board should add language to 18VAC110-60-210(C) as follows:

C. 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.
> *3. Any person who has been granted access pursuant to 18VAC110-60-220(F).*

V. Duties of Pharmacist in Charge

The regulations currently require the Pharmacist in Charge (PIC) to "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."[11] This language could potentially extend to business decisions by the owner of the pharmaceutical processor unrelated to the operations under the control or duties of the PIC. For example, this language would give control to the PIC of compensation issues for all company employees.

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The Board should allow pharmaceutical processors to post product information and pricing on websites. 18VAC110-60-220(D) should be amended as follows:

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

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[12] 18VAC110-60-210(A).
[13] 18VAC110-60-210(H).
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The Board should amend 18VAC-60-240(A) as follows:

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[15] Virginia Code Ann. § 54.1-3408.3.
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X. Guidance on Use of Pesticides under 18VAC110-60-280

The regulations prohibit the use of pesticide chemicals or petroleum-based solvents for cannabidiol and THC-A oil, except the Board may authorize the use of pesticide chemicals for purposes of addressing an infestation that could result in a catastrophic loss of crops.[17] Pesticide chemical is not defined in the regulations. The Board should provide clarity in the regulations or issue a guidance document as to whether pesticides classified as safe for plants or human consumption are permissible.

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third-party regulator such as Organic Materials Review Institute (OMRI) or California's Organic Input Materials OIM Program.

Surterra Virginia thanks the Board of Pharmacy for their work on this important effort to offer new medicinal solutions to the citizens of the Commonwealth of Virginia. We are happy to serve as a resource as the Board considers amending the Emergency Regulations.

Sincerely,

Kassie Schroth

Kassie Schroth, McGuireWoods LLP

CC: Theodore F. Adams III, McGuireWoods LLP
Jake Bergmann, Founder and Chief Executive Officer, Surterra Wellness

Virginia Pharmacists Association response to permanent adoption of Virginia Board of Pharmacy New Regulations Chapter 60:

We applaud the Commonwealth for establishing the Pharmaceutical Processors under the supervision of the Virginia Board of Pharmacy. Pharmacists are interictal members of a patient's health care team. Pharmacists are specifically educated with a focus and level of expertise on medication therapy that exceeds that of other health care providers. It's imperative that a Pharmacist-in-charge (PIC) remain part of Section 18VAC110-60-170. Additionally, it's in the best interest of patient care to retain all current language in Chapter 60 related to PIC oversight and responsibility.

Section 18VAC110-60-170.J must be removed. When a Pharmacists goes through the process to have their license reinstated, there is no preclusion from dispensing any medication, including controlled substances. Pharmacists that have had their licenses suspended or revoked should not be discriminated against or prevented from applying for employment with a Pharmaceutical Processor.

To encourage research and discovery that enhances patient care, Section 18VAC110-60-220. A.2 "Sell, deliver, transport or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility;" and A.4 "Provide cannabidiol oil or THC-A oil samples" should be revised to allow delivery and/or samples to qualified external laboratories for testing.

Pharmacy students are the New Practioners of tomorrow. Currently, pharmacy students are permitted to perform all the duties of a pharmacist if they are under a pharmacist's supervision. Sections regarding pharmacist-on-duty and pharmacist-in-charge should be edited to allow pharmacy students to work under the supervision of a pharmacist at all Pharmaceutical Processors.

Section 18VAC110-60.C, should clarify that continuing in-service training may be conducted by an external organization accredited by the American Council for Pharmacy Education.

Lastly, the name "CBD oil" is confusing to the pharmacy community and our patients. There are many versions of CBD oil, particularly hemp products, being sold online and in retail stores. To set the Pharmaceutical Processors products apart it is recommended that the term medical cannabis be adopted.

We thank the Board of Pharmacy for their dedication to our profession and the Commonwealth's patients.

8-20-18

Dear Board of Pharmacy,

Members of the Youth and Community Action Team (YCAT, https://www.ycatcoalition.com/) would like to comment about the new regulations Chapter 60, governing pharmaceutical processors. YCAT is a substance abuse prevention coalition in Virginia Beach. YCAT was started 10 years ago, is comprised of lay and professional community members, and works most closely with the VB Behavioral Health. YCAT is a member of the Community Coalitions of Virginia.

Outlined below are our concerns:

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.
2. The Virginia Board of Pharmacy is violating federal law by setting up marijuana growers and dispensaries. Virginia law nor the board's regulations preempt federal law.
3. CBD-THC-A-THC oils are not FDA approved medicines.
4. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
5. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.
6. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.
7. It is medical malpractice for physicians to provide written certification for the promotion and use of marijuana as a medicine in the form of CBD-THC-A-THC oil without FDA approval because there is insufficient scientific evidence of the benefits and effects on patient safety are unknown.
8. It is ethically inappropriate for pharmacists to grow and dispense CBD-THC-A-THC oil without sufficient research on dosage and interactions.
9. Attorney General Jeff Session has reversed the Cole Memo, now instructing federal law enforcement to enforce federal law with regard to marijuana manufacturing and possession.
10. Increased access to marijuana oils increases usage in 12-17 year olds. (The National Survey on Drug Use and Health reports, SAMHSA)
11. Marijuana usage, including oils, is linked to mental illness and opioid use.
12. If the Virginia Board of Pharmacy adopts these new permanent regulations, it will further open the door to marijuana legalization in Virginia. All states that have legalized marijuana began with medical marijuana.

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

If the Virginia Board of Pharmacy does pass these new regulations, the following changes should be made:

- On page 2, Registered Patient definition should be "to receive" not "for dispensing of."
- On page 3, Registration fees for practitioners should be higher than patients' fees.
- On page 11, B.2, should also include within 1,000 feet of a church.
- On page 24, 1., 12 plants per patients is too high. Other states that have medicinal marijuana laws or marijuana legalization have a limitation of 6 plants per patients.

Thank you for your leadership and efforts to prevent risks in Virginia.

Dr. Mary Crozier
YCAT, Chair
CCoVA, Chair
252-864-1478, mkcrozier@gmail.com

Michael Reiss, MPH
YCAT, Vice Chair
EVMS CINCH Committee

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VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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Commenter: Erica Wiley 7/30/18 12:32 pm

Emergency Regulations 18VAC110-60-10 et sec.

I. 18VAC110-60-285. Registration of products and 18VAC110-60-290. Labeling of batch of cannabidiol oil or THC-A oil products.

Support the deletion of naming of the "products" or "batches", however there is still concern with naming by "Brand" name if same brand also manufactures or sells cannabis for recreational use.

II. 18VAC110-60-110 through 130.

For safety and security of employees, the public and adjacent neighbors, the Emergency Regulations should **require** Permittees be be housed in free-standing buildings, not multi-tenanted buildings with shared demising walls and parking areas. Fire safety, noxious odors, personnel safety, facility security, are all compromised with shared tenancy.

To discourage promotion of recreational use, the Emergency Regulations should **require** that applicants should be isolated from residential development, much like the stipulated minimum distances from schools (1000'). Average families may not care to distinguish between medical and recreational use and may not wish to be exposed to traffic generated by medical cannabis users, security risks, etc...

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

The Regulations are not specific enough regarding acceptable methods of disposal (incineration, mulching/composting/disposal). Rather than run afoul of a subjective standard, Processors would appreciate further detail as to which methods of disposal are acceptable to the Board. Further, in the event disposal where time is of the essence, e.g., contamination of plant material, please stipulate availability of Agent of the Board.

IV. Preference to Virginia Applicants. The Emergency Regulations should stipulate a preference for applicants owned of 51% or greater Virginia residents. This should be an industry by Virginians for Virginians.

VI. Avoidance of Monopoly. Permittees should not have interest in more than one Processing Permitee, creates a monopoly and inhibits fair trade.

VII. Regulations should stipulate that Permits should be renewable automatically upon compliance with Regulations and payment of Fees. Permits should be renewable automatically upon the

payment of fees if inspections are obtained and in absence of infractions to Regulations. Significant investment in infrastructure requires objective renewal standard (vs. discretionary renewal.)

Commenter: Lee Olesen, NOVA Pharma Processors 8/7/18 3:29 pm

18VAC110-60-10

"Temperature and Humidity"

The proposed regulations state that the temperature for growing cannabis when the growing lights are on should be between 77-85 degrees. This is an appropriate temperature range for when the growing lights are on and the plants are growing. However, the proposed regulations do not mention the temperature for when the lights are off. For optimal plant health, the temperature for when the lights are off and the plants are sleeping is 10 degrees under what the set temperature was for when the plants are growing and lights are on. So if the daytime lights on growing phase is set at 81 degrees then the lights off night temperature should be at 71 degrees.

Commenter: Joseph T. DiPiro, Dean, VCU School of Pharmacy 8/16/18 5:10 pm

Regulations for Pharmaceutical Processors

Regulations regarding Pharmacist-in-charge (18VAC110-60-170) must be retained as they are essential to safe therapeutic use of medical cannabinoid products.

In 18VAC110-60-C, clarify that continuing inservice training may be conducted by an external organization accredited by the American Council for Pharmaceutical Education.

Section 18VAC110-60-220. A.2 "Sell, deliver, transport or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility;" and A.4 "Provide cannabidiol oil or THC-A oil samples" should be revised to allow delivery and/or samples to qualified external laboratories for testing.

Sections relating to pharmacist-on-duty and pharmacist-in-charge should be revised to allow a pharmacy student intern to work in the facility under the direction of the pharmacist.

Commenter: Robert DiCenzo, Dean, School of Pharmacy at Shenandoah University 8/17/18 9:40 am

Pharmaceutical Processor Permit

In order to ensure that all patients benefit from comprehensive medication management provided by a pharmacist who is part of a health care team, Pharmacist-in-charge must be part of Section 18VAC110-60-170.

To encourage research and discovery that enhances patient care, Section 18VAC110-60-220. A.2 and A.4 should support delivery to laboratories for use in research.

Currently, pharmacy students are allowed to perform all the duties of a pharmacist as long as they are under a pharmacist's supervision. We suggest you revise sections regarding pharmacist-on-duty and pharmacist-in-charge to allow pharmacy students to work under the supervision of a pharmacist at all facilities that have received a pharmaceutical processor permit.

Commenter: Matthew Halquist 8/20/18 8:59 am

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

In Accordance to section B, *"Immediately prior to producing any cannabidiol oil or THC-A oil product, a pharmaceutical processor shall segregate all harvested Cannabis into homogenized batches. A pharmaceutical processor shall make a sample available from each batch for a laboratory to test for microbiological contaminants, mycotoxins, heavy metals, and pesticide chemical residue, and for purposes of conducting an active ingredient analysis."*

I suggest that "samples" (i.e., more than one sample) be made available due to the need most likely for more than one laboratory to perform all tests. Secondly, the storage of a small sample size may require additional requirements beyond a secure, cool, dry place (i.e., humidity and temperature controlled environment) to ensure stability.

Commenter: Matthew Halquist, VCU School of Pharmacy 8/20/18 9:07 am

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

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

Suggest that Cannabis be specifically defined or add in "all cannabis products or materials".

Commenter: Matthew Halquist, VCU School of Pharmacy 8/20/18 9:19 am

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

Under section A, suggest adding the following requirements:

1) Laboratory must have at Schedule I Analytical Laboratory licensure throught the VA Board of Pharmacy and registration with the Drug Enforcement Agency.

2) Laboratory must utilize validated methods such as ICH guidelines for method validation, USP, or equivalent.

Commenter: Matthew Halquist, VCU School of Pharmacy 8/20/18 9:25 am

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

Under section A or B, all cannibis products (or materials) should have established stability and storage requirements prior to and under packaging conditions. Testing for microbiological and active ingredients should be considered.

Commenter: Gretchen Rhedmon 8/20/18 4:58 pm

54.1-3408.3

Suggest that "practitioner" include DVM.

Commenter: Gretchen Rhedmon 8/21/18 1:26 pm

18VAC110-60-280 B.

Current methods, or standardized methods do not yet exist however all extractors should be; a) professionally designed, b) peer reviewed, and c) closed loop hydrocarbon extractors, or other extractor deemed safe and acceptable in chapter 38 of NFPA 1.

Commenter: Regina Whitsett, Substance Abuse Free Environment, Inc. (SAFE) 8/21/18 2:21 pm

SAFE's Public Comment in Response to permanent adoption of VA BOP New Regulations Chapter 60

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

SAFE provides this public comment in response to permanent adoption of Virginia Board of Pharmacy New regulations Chapter 60, Regulations Governing Pharmaceutical Processors and states:

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.
2. The Virginia Board of Pharmacy is violating federal law by setting up marijuana growers and dispensaries. Virginia law nor the board's regulations preempt federal law.
3. CBD-THC-A-THC oils are not FDA approved medicines.
4. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
5. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.
6. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.
7. It is medical malpractice for physicians to provide written certification for the promotion and use of marijuana as a medicine in the form of CBD-THC-A-THC oils without FDA approval because there is not sufficient scientific evidence of the benefits and effects on patient safety are unknown.
8. It is ethically inappropriate for pharmacists to grow and dispense CBD-THC-A-THC oil without sufficient research on dosage and interactions.
9. United States Attorney General Jeff Session has reversed the Cole Memo, now instructing federal law enforcement to enforce federal law with regard to marijuana manufacturing and possession.
10. Increased access to marijuana oils may contribute to increased usage in 12-17 year olds. (The National Survey on Drug Use and Health reports, SAMHSA 2016)
11. Marijuana usage, including oils, is linked to mental illness and opioid use.
12. If the Virginia Board of Pharmacy adopts these new permanent regulations, it will further open the door to marijuana legalization in Virginia. All states that have legalized marijuana began with medical marijuana.
13. Revenues collected from marijuana do not outweigh the negative impacts on public safety,

public health, the workplace, academics, health, black market and natural resources.

If the Virginia Board of Pharmacy does pass these new regulations, the following changes should be made:

- On page 2, Registered Patient definition should be "to receive" not "for dispensing of".
- On page 3, Registration fees for practitioners should be higher than patients' fees.
- On page 11, B.2, should also include within 1,000 feet of a church.
- On page 24, 1., 12 plants per patients is too high. Other states that have medicinal marijuana laws or marijuana legalization have a limitation of 6 plants per patients.

Contact Information:

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

Commenter: Community Coalitions of Virginia (CCOVA) 8/21/18 3:03 pm

Public comment from CCOVA

Community Coalitions of Virginia (CCoVA) is a non-profit organization that consists of representation from substance abuse prevention coalitions across the state. CCoVA works collaboratively to prevent and reduce substance abuse and related risk factors in Virginia communities in ways that are measurable and improve quality of life.
www.communitycoalitionsofva.com

Community Coalitions of Virginia provides this public comment in response to permanent adoption of Virginia Board of Pharmacy New regulations Chapter 60, Regulations Governing Pharmaceutical Processors and states:

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.
2. The Virginia Board of Pharmacy is violating federal law by setting up marijuana growers and dispensaries.Virginia law nor the board's regulations preempt federal law.
3. CBD-THC-A-THC oils are not FDA approved medicines.
4. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
5. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.
6. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.
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8. It is ethically inappropriate for pharmacists to grow and dispense CBD-THC-A-THC oil without sufficient research on dosage and interactions.

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

10. Increased access to marijuana oils may contribute to increased usage in 12-17 year olds. (The National Survey on Drug Use and Health reports, SAMHSA 2016)

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If the Virginia Board of Pharmacy does pass these new regulations, the following changes should be made:

- On page 2, Registered Patient definition should be "to receive" not "for dispensing of".
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- On page 11, B.2, should also include within 1,000 feet of a church.
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Contact Information:

Mary Crozier, CCoVA Chair, 252-864-1478, mkcrozier@gmail.com

Keri Jones, CCoVA Legislative Chair, 540-332-3806, joneskd@ci.staunton.va.us

Keenan Caldwell, KC3 Consulting, LLC, 804-937-2673, kc3consulting@outlook.com

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

Commenter: Julia Whiting, MD 8/21/18 4:27 pm

patient and caregiver fees

The Board of Pharmacy has received over a half million dollars in application fees from potential pharmacies/dispensaries. I propose substantial lowering of registry fees from patients and caregivers. The burden is specifically very high on guardians of disabled adults, with a $50 fee proposed for the patient, plus each of the guardians. The burden of paying for the medicine (currently not covered by insurance), paying for a doctor to certify the patient (not covered by insurance), in the setting of typically significant disease/disability is too burdensome for patients to additionally assume large costs associated with registration with Board of Pharmacy. I propose, for disabled adults, that parents or guardians should be exempt from any registration fees (as they

are for parents of children, before age 18). I also propose waived fees for spouses or one or more family members of registered patients, as procurement/transport of this new class of medication is not without risk, and the logistics of obtaining this medication from just a few locations in the state, is already a large barrier to access, and need not be complicated by a fee for every registered caregiver.

Commenter: Julia Whiting, MD 8/21/18 4:31 pm

longer window to be registered

I also propose a 2 year long time frame for patients and caregivers to remain certified with the state. Physician licensure with the state lasts 2 years. Asking a patient or caregiver to keep up with yearly registration is more burdensome than necessary.

Commenter: Michelle Peace, VCU 8/21/18 10:34 pm

110-60-300. Laboratory requirements; testing.

1. The process is not clear as to how the BoP will assure that laboratories conduct appropriate analyses. Typically, laboratories must adhere to an accreditation expectation when responsible for analyses that impact public health and safety.

2. Paragraph 2: Qualifications for director level person. Suggest language change to be:

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, or related discipline, and a minimum of five ~~two~~ years of post-degree laboratory management experience or a bachelor's degree in chemical or biological sciences, or related discipline, and a minimum of eight ~~four~~ years of post-degree laboratory management experience.

Justification for these edits: The instrumentation required for quality assurance testing for cannabinoid products is sophisticated, high complexity testing as defined by CLIAA, requiring intensive maintenance and calibration experience across various instrument platforms. Secondly, the director should have experience in developing instrument methods, laboratory procedures and safety and security, and be able to successfully implement and oversee quality control and quality assurance. This requires significant experience beyond the degree and bench level analyst work, as the proposed language would conceivably allow.

Would also highly recommend educational requirements for lab personnel such as bench scientists and instrument technicians.

3. Paragraph 3: Homogeneity of samples paragraph. Suggest the following change to the requirement:

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, at minimum, 3 samples throughout a batch available from each batch to assure homogeneity *within* 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.

Justification for this comment: It is essential that quality throughout a batch is assured - requiring samples to be collected at the begining, middle, and end of a production. This would apply to both the plant batches and oil/resin product batches.

4. Once the plant product is deemed free of contaminants and a oil product is manufactured,

quality assurance and safety of those oils also needs to be verified by the same analytical process. Therefore, a minimum of 3-5 samples in a product batch needs to be evaluated for the same contaminants. This is critical since the processing of the plant material to create the oils will concentrate any potential contaminants not detected above acceptable limits in the initial analysis, which may result in concentrations above acceptable safe limits. Additionally, even if the plant samples taken for the original testing are below the acceptable limits for contaminants, the storage and/or processing of those plant materials may lead to contaminants that would be concentrated during product processing.

5. 110-60-300 Lab Regulations does not define or specify requirements for identifying and quantitating the pharmacologically active ingredients (THC, THC-A, CBD, CBDA, and other cannabinoids that are naturally present in cannabis plant material) or identification the terpenes as are required in 110-60-285 Registration of Products. Recommend adding this requirement to this section of the regulations. This would require a clarification of the legislation defining acceptable limits of CBD, THC-A, and THC in plants and products.

As defined in 110-60-285 Registration of Products, the analysis requires precise analytical work to ensure the 97%-103% range for product branding. Even for lab personnel experienced in analyzing and quantitating drugs, this precision and accuracy window is tight. This could lead to cost-prohibitive production and labelling of separate lots over conceivably insignificant analytical differences. The investment of personnel with experience and training and for material and methods to reduce error in the lab will also add exceptional cost. According to the U.S. Department of Health and Human Services FDA document entitled Guidance for Industry Q2B Validation of Analytical Procedures: Methodology, an assay for a drug substance or finished drug product is normally from 80-120% of the test concentration.

Commenter: Nichole Miller, Parent 8/22/18 9:37 am

Two concerns: cost and length of registration

The financial burdens incurred by families with disabilities is extraordinary and the costs associated with obtaining this medicine are already extreme. I request that you limit the fees to $50 per patient total. I would also like to request that the registration be good for the same amount of time as the physician licensure. Thank you for your consideration.

Commenter: Lisa Smith, Parent/Guardian 8/22/18 10:59 am

Cost of registration and duration

Raising a child with speical needs causes already an undue burden on a family. According to the U.S. Department of Agriculture in 2015, it will take roughly **$240,000** to raise a child from birth to age 18. For a special needs child, those expenses can **QUADRUPLE!** The families that will be acquiring this oil have already exhausted traditional pharmaceutical medications and will take on the burden of the cost of the oil with no assistance from insurance. For this operation to be successful in Virginia, you will need the individuals who fit this profile to purchase the oils. In Georgia, their registration is $25 for the patient or caregiver and their term is two years. I would hope Virginia would take into consideration what they have done. I believe that this would be much more affordable given the statistics cited by the US Dept. of Agriculture.

Commenter: Greater Augusta Prevention Partners (GAPP) 8/22/18 3:02 pm

GAPP public comment

Greater Augusta Prevention Partners, (GAPP)

Serving City of Staunton, City of Waynesboro and Augusta County

GAPP's mission is to create and implement intentional strategies to prevent youth from involvement in criminal gang activity, drug use, violence, and other risky behaviors to foster stronger and heathier community for our youth. http://www.valleyprevention.com/

Greater Augusta Prevention Partners provides this public comment in response to permanent adoption of Virginia Board of Pharmacy New regulations Chapter 60:

1. Marijuana and its extracts are dangerous and addictive illegal Schedule 1 drugs according to federal law and the DEA.
2. CBD-THC-A-THC oils are not FDA approved medicines.
3. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
4. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.
5. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.
6. Attorney General Jeff Session has reversed the Cole Memo, now instructing federal law enforcement to enforce federal law with regard to marijuana manufacturing and possession.
7. Increased access to marijuana oils may contribute to increased usage in 12-17 year olds. *(The National Survey on Drug Use and Health reports, SAMHSA 2016)*
8. If the Virginia Board of Pharmacy adopts these new permanent regulations, it will further open the door to marijuana legalization in Virginia.All states that have legalized marijuana began with medical marijuana.
9. Revenues collected from marijuana do not outweigh the negative impacts on public safety, public health, the workplace, academics, black market and natural resources.

If the Virginia Board of Pharmacy does pass these new regulations, GAPP suggests the following changes should be made:

- < >
  18VAC110-60-20. B. Parents of children with ongoing medical conditions under current treatment by a pediatrician should have their fee waived. (ie: cancer, epilepsy.....) Also applies to section 18VAC110-60-50
- 18VAC110-60-120. Conditional approval should also include within 1,000 feet of a church and within 1,000 feet of a residential dwelling.

Contact Information:

Keri Jones, GAPP Coalition Coordinator, 540-332-3806, joneskd@ci.staunton.va.u

Commenter: Kim 8/22/18 8:59 pm

Potential HSA Licensee's

When deciding to award the licenses, it should be to VA RESIDENTS ONLY, with the company controlled by members that are residents of VA, and not allow big known national companies from out of state, or partnering with VA Residents controlling 90% of partnership/company.

Commenter: Melanie Morris, Roanoke Prevention Alliance 8/22/18 9:45 pm

Roanoke Prevention Alliance Response to VA Pharmaceutical Board New Regualtions Ch 60

Commenter: Roanoke Prevention Alliance

RPA public comment

Roanoke Prevention Alliance, (RPA)

Serving City of Roanoke

RPA is devoted to preventing drug and alcohol abuse among teens and young adults in the City of Roanoke. www.roanokepreventionalliance.org

The Roanoke Prevention Alliance provides this public comment in response to permanent adoption of Virginia Board of Pharmacy New regulations Chapter 60:

1. CBD-THC-A-THC oils are not FDA approved medicines.
2. There are already FDA approved drugs (dronabinol and nabilone) available that contain THC and parallel the effects of marijuana.
3. Epidolex is now an FDA approved medication that is available to treat intractable epilepsy patients. Treatment options already exist for other illnesses covered in these regulations.
4. FDA approved drugs are the only way to ensure proper recommended dosage and patient safety through side effect and drug interaction warning labels.
5. Increased access to marijuana oils may contribute to increased usage in 12-17 year olds. *(The National Survey on Drug Use and Health reports, SAMHSA 2016)*
6. Marijuana usage, including oils, is linked to mental illness and opioid use.
7. Revenues collected from marijuana sales do not outweigh the negative impacts on public safety, public health, the workplace, academics, black market and natural resources.

Contact Information:

Melanie Morris RPA Director, 540-982-1427 ext 120, memorris@brbh.org

Project 4878 - Emergency/NOIRA

BOARD OF PHARMACY

New regulations

CHAPTER 60

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I

General Provisions

18VAC110-60-10. Definitions.

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

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

"Code" means the Code of Virginia.

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

1. Variation from the intended oil to be dispensed, including but not limited to:

a. Incorrect oil;

b. Incorrect oil strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of an oil to the incorrect patient.

4. An act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient an act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabidiol oil and THC-A oil are sold to a registered patient, parent, or legal guardian or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system

and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"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.

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

"PIC" means the pharmacist-in-charge.

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

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

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

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabidiol oil or THC-A oil to such patient.

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

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

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

18VAC110-60-20. Fees.

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

B. Registration of practitioner.

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

C. Registration by a qualifying patient or by a parent or legal guardian.

1. Initial registration of a patient	$50
2. Annual renewal of registration of a patient	$50
3. Initial registration of a parent or legal guardian	$25
4. Annual renewal of registration of a parent or guardian	$25
3. Replacement of registration for a qualifying patient or parent or legal guardian whose information has changed or whose original registration certificate has been lost, stolen, or destroyed	$25

D. Pharmaceutical processor permit.

1. Application	$10,000

2. Initial permit	$60,000
3. Annual renewal of permit	$10,000
4. Change of name of processor	$100
5. Change of PIC or any other information provided on the permit application	$100
6. Any acquisition, expansion, remodel, or change of location requiring an inspection	$1,000
7. Reinspection fee	$1,000
8. Registration of each cannabidiol oil or THC-A oil product	$25

Part II

Requirements for Practitioners and Patients

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

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

B. A practitioner issuing a certification shall:

1. Conduct an assessment and evaluation of the patient in order to develop a treatment plan for the patient, which shall include an examination of the patient and the patient's medical history, prescription history, and current medical condition, including an in-person physical examination;

2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabidiol oil or THC-A oil would likely outweigh the health risks of such use to the qualifying patient;

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

5. Be available or ensure that another practitioner, as defined in § 54.1-3408.3 of the Code, is available to provide follow-up care and treatment to the qualifying patient, including physical examinations, to determine the efficacy of cannabidiol oil or THC-A oil for treating the diagnosed condition or disease;

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

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

9. Access or direct his delegate to access the Virginia Prescription Monitoring Program for the purpose of determining which, if any, covered substances have been dispensed to the patient.

C. Patient care and evaluation shall not occur by telemedicine for at least the first year of certification. Thereafter, the practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation.

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

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

F. A practitioner shall not issue certifications for cannabidiol oil or THC-A oil to more than 600 patients at any given time. However, the practitioner may petition the Board of Pharmacy and

Board of Medicine for an increased number of patients for whom certifications may be issued, upon submission of evidence that the limitation represents potential patient harm.

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

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

A. A practitioner who issues certifications shall not:

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

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

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

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

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

certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

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

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

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

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

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

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

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

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

5. Payment of the appropriate fees; and

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

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

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

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

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

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

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

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

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

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

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

B. If the board denies an application or renewal of a qualifying patient applicant or parent or legal guardian applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Part III

Application and Approval Process for Pharmaceutical Processors

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

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

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

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

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

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

B. Submission of initial application.

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

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

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

c. Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income, and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the

production and dispensing of cannabidiol oil and THC-A oil pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

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

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

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

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

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

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

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

k. A blueprint of the proposed pharmaceutical processor, which shall show and identify the square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may

contain Cannabis plants, cannabidiol oil, or THC-A oil, showing the placement of walls, partitions, counters, and all areas of ingress and egress;

l. Documents related to any compassionate need program the pharmaceutical processor intends to offer;

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabidiol oil or THC-A oil and to safely dispense such products; and

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

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

3. The board shall conduct criminal background checks on applicants and may verify information contained in each application and accompanying documentation in order to assess the applicant's ability to operate a pharmaceutical processor.

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

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

18VAC110-60-120. Conditional approval.

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

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

1. The results of the criminal background checks required in 18VAC110-60-110 B 3 or any history of disciplinary action imposed by a state or federal regulatory agency;

2. The location for the proposed pharmaceutical processor, which shall not be within 1,000 feet of a school or daycare;

3. The applicant's ability to maintain adequate control against the diversion, theft, and loss of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, or THC-A oil;

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

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

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

B. The board may disqualify any applicant who:

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

2. Fails to submit an application by the published deadline;

3. Fails to pay all applicable fees; or

4. Fails to comply with all requirements for a pharmaceutical processor.

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

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

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

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

1. Designation of a PIC;

2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by the board or its agents.

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

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

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a

pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

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

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

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

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

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

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

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

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

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

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

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

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

1. Notify the board;

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

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

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

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

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

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

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

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

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

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

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued, or place such permit on probation, place conditions on such permit, or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabidiol oil or THC-A oil that is authorized under state law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii)

involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

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

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

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

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

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

Part IV

Requirements for Pharmaceutical Processor Personnel

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

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

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

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

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

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

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

4. The measuring of the oil to be dispensed;

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

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

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

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

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

E. 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.

F. 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.

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

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

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

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

18VAC110-60-180. Employee training.

A. All employees of a pharmaceutical processor shall complete training, prior to the employee commencing work at the pharmaceutical processor, at a minimum, in the following:

1. The proper use of security measures and controls that have been adopted for the prevention of diversion, theft, or loss of Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, cannabidiol oil, and THC-A oil;

2. Procedures and instructions for responding to an emergency;

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

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

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

C. The PIC shall assure the continued competency of all employees through continuing in-service training, provided at least annually and designed to supplement initial training, which shall include any guidance specified by the board.

D. The PIC shall be responsible for maintaining a written record documenting the initial and continuing training of all employees, 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.

E. When a change of pharmaceutical processor PIC occurs, the new PIC shall review the training record and sign it, indicating that the new PIC understands its contents.

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

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

A. The ratio of pharmacy technicians to pharmacists on-duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed four pharmacy technicians to one pharmacist.

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

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

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

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding 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.

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

A. 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.

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

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

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

2. All record retention requirements are met;

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

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

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

a. Pharmaceutical processor permit;

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

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

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

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

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

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

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

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

A. A pharmaceutical processor shall sell cannabidiol oil or THC-A oil only in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, or legal guardian, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

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

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

1. 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.

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

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

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

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

H. A pharmacist shall counsel registered patients, parents, and legal guardians regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil;

I. 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.

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. 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.

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

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

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

1. Name and location of the processor;

2. Contact information for the processor;

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

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

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

F. No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

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

1. An employee shall escort and monitor 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.

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

I. Notwithstanding the requirements of subsection F of this section, 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.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor, prior to commencing business, shall:

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

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

B. Upon commencing business, each pharmaceutical processor and production facility shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil in stock, which 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.

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

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

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

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

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

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabidiol oil or THC-A oil for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall:

1. Not maintain more than 12 Cannabis plants per patient at any given time based on dispensing data from the previous 90 days;

2. Not maintain cannabidiol oil or THC-A oil in excess of the quantity required for normal, efficient operation;

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

4. Store all cut parts of Cannabis plants, extracts, cannabidiol oil, or THC-A oil in an approved safe or approved vault within the pharmaceutical processor and 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; and

8. Not allow keys to be left in the locks or accessible to non-pharmacists.

B. The pharmaceutical processor shall have an adequate security system to prevent and detect diversion, theft, or loss of Cannabis seeds, plants, extracts, cannabidiol oil, or THC-A oil. A device for the detection of breaking and a back-up alarm system with an ability to remain operational during a power outage shall be installed in each pharmaceutical processor. The installation and the device shall be based on accepted alarm industry standards and 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; and

5. Access to the alarm system for the pharmaceutical processor shall be restricted to the pharmacists working at the pharmaceutical processor and the system shall be activated whenever the pharmaceutical processor is closed for business.

C. A pharmaceutical processor shall keep the outside perimeter of the premises well-lit. A processor shall have video cameras in all areas that may contain Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

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

2. The video system shall have:

a. A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the processor within five minutes of the failure, either by telephone, email, or text message;

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

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

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

3. All video recording shall allow for the exporting of still images in an industry standard image format. Exported video shall have the ability to be archived in a proprietary format that ensures authentication of the video and guarantees that no alteration of the recorded image has taken place. Exported video shall also have the ability to be saved in an industry standard file format that can be played on a standard computer operating system. A pharmaceutical processor shall erase all recordings prior to disposal or sale of the facility; and

4. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, 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.

D. The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested no less than two times per year.

E. A pharmaceutical processor shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor shall make available a current list of authorized employees and security system service

employees who have access to the surveillance room to the processor. The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

F. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

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

A. A pharmaceutical processor shall:

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

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

3. Be maintained in a clean, sanitary, and orderly condition; and

4. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. A processor shall compartmentalize all areas in the facility based on function and shall restrict access between compartments. The processor shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper cultivation of

Cannabis and production of cannabidiol oil or THC-A oil. These shall include policies and procedures that:

1. Restrict movement between compartments;

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

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

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

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

1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. 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.

D. The processor shall store all Cannabis, including seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, in the process of production, transfer, or analysis in such a manner as to prevent diversion, theft, or loss; shall make Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the aforementioned items to their secure location immediately after completion of the production, transfer, or analysis process or at the end of the scheduled business day. If a production process cannot be completed at the end of a working day, the pharmacist shall securely lock the processing area or tanks, vessels, bins, or bulk containers containing Cannabis, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, inside an area or building that affords adequate security.

18VAC110-60-260. Recordkeeping requirements.

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

1. Guarantees the confidentiality of the information contained 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; and

3. Is capable of being reconstructed in the event of a computer malfunction or accident resulting in the destruction of the data bank.

B. All records relating to the inventory, laboratory results, and dispensing shall be maintained for a period of three years and shall be made available to the board upon request.

18VAC110-60-270. Reportable events; security.

A. Upon becoming aware of 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.

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

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

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

2. A breach of security;

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

4. Corrective measures taken, if any.

D. A pharmacist or pharmaceutical processor shall immediately notify the board of an employee convicted of a felony or a violation referenced in 54.1-3442.6.

Part VI

Cultivation, Production, and Dispensing of Cannabidiol Oil or THC-A Oil

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

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

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

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

18VAC110-60-285. Registration of products.

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

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THCA);

3. Cannabidiols (CBD);

4. Cannabidiolic acid (CBDA); and

5. Any other active ingredient that constitutes at least 1% of the batch used in the product.

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

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

1. Is identical to, or confusingly similar to, the name of an existing commercially available product;

2. Is identical to, or confusingly similar to, the name of an unlawful product or substance;

3. Is confusingly similar to the name of a previously approved cannabidiol oil or THC-A oil product brand name;

4. Is obscene or indecent;

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

6. May encourage the use of cannabidiol oil or THC-A oil for a disease or condition other than the disease or condition for which the practitioner intended to treat;

7. Is customarily associated with persons under the age of 18; or

8. Is related to the benefits, safety or efficacy of the cannabidiol oil or THC-A oil product unless supported by substantial evidence or substantial clinical data.

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

Cannabidiol oil or THC-A oil produced as a batch 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; and

2. Labeled with:

a. The name and address of the pharmaceutical processor;

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

c. A unique serial number that 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); and

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 pesticide chemical residue analysis.

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

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

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

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

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

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

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

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

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

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

9. The name of the certifying practitioner;

10. 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; and

12. Any cautionary statement as may be required by statute or regulation.

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

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

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

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

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

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned, from a college or university accredited by a national or regional certifying authority, at least 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 chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

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

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

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

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

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

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:

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

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

Metal	Natural Health Products Acceptable Limits uG/KG BW/Day
Arsenic	<0.14
Cadmium	<0.09
Lead	<0.29
Mercury	<0.29

4. 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.

G. 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.

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

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

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

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

1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, or legal guardian. The pharmacist or pharmacy technician shall verify in the 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.

2. 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.

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

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

C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil 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 [~~20~~ 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; and

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.

D. 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).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. The destruction shall be witnessed by the PIC and an agent of the board or another pharmacist not employed by the pharmacy. The persons disposing of the cannabidiol oil or THC-A oil shall maintain and make available a separate record of each such disposal indicating:

1. The date and time of disposal;

2. The manner of disposal;

3. The name and quantity of cannabidiol oil or THC-A oil disposed of; and

4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil, ~~the agent of the board, and any other persons present during the disposal~~.

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

Agenda Item: Adoption of Final Regulations – Issuance of controlled substance registration (CSR)

Included in your agenda package are:

A copy of the Proposed regulations – identical to emergency regulations currently in effect

There were no comments on the proposed regulations.

Board action:

Adoption of final regulation as included in agenda package or adoption of different amended language

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Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Meeting: Public Hearing

Edit meeting

Meeting Details	
Date / Time	8/23/2018 9:30 am
Location	Perimeter Center, 9960 Mayland Drive, Suite 201, Hearing Room 6, Richmond, VA 23233
Board Website	http://www.dhp.virginia.gov
Agenda document	not available
Minutes document	not available

Disability Friendly? Yes **Deaf interpreter available upon request?** Yes

Purpose of the meeting

Public hearing to received comment on proposed regulations replacing emergency regulations for issuance of CSRs to community organizations to distribute naloxone and for tele-prescribing.

Meeting Scope

- [X] Public hearing to discuss a proposed change
- [ ] Discuss particular regulations / chapters
- [ ] General business

This meeting is a public hearing to discuss the following proposed change(s)

Controlled substances registration for naloxone and teleprescribing

Contact Information	
Name / Title:	Caroline D. Juran / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Henrico, 23233
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Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

Project 5048 - Proposed

BOARD OF PHARMACY

Controlled substances registration for naloxone and teleprescribing

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

A. A person or entity ~~which~~ that maintains or intends to maintain a supply of ~~Schedule~~ Schedules 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~~ that 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, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, 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, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that ~~Schedule~~ Schedules 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.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer 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~~ that 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 (i) 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; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; ~~or~~ (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation, or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. 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, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

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~~ that meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug ~~which~~ that 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~~ Schedules 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~~ that 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~~ that has a security device for the detection of breaking ~~which~~ that 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, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.

18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.

2. Invoices or other records showing receipts of naloxone shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of the person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect it from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

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

Agenda Item: **Request for extension of CSR Regulations**

Staff note:

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 15 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.

In order to avoid a gap in the authority to issue a CSR, a request must be filed to extend the emergency regulation for another six months to allow completion of the promulgation of replacement regulations.

Action:

Motion to approve the request to extend the emergency regulations for issuance of a CSR for six months beyond the expiration of November 7, 2018.

Agenda Item: **Regulatory Action/White Bagging and Brown Bagging**

Enclosed:

Copy of NOIRA background document

Copy of comments received on the NOIRA

Staff note:

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.

Board action:

Motion to refer the regulatory action on white bagging and brown bagging to the Regulation Committee.

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	White bagging/brown bagging
Date this document prepared	12/11/17

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 consider adopting a regulation to regulate brown bagging of drugs requiring reconstitution or compounding prior to administration and to set specific requirements for specialty pharmacies participating in white bagging. The intent of the regulatory action is public protection to ensure drugs are appropriately dispensed and administered.

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 address patient safety concerns relating to brown bagging and white bagging. information available to the Board will enhance its ability to protect the public health and safety.

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.

In the amended regulation, the Board will need to define "brown-bagging and white-bagging." At the 2016 annual meeting of the National Association of Boards of Pharmacy, a study resolution included these definitions: "*white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration.*"

In the addition to new definitions in the proposed regulations, the Board will consider regulations for:

- Brown bagging of drugs requiring special storage, reconstitution or compounding prior to administration;
- Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care;
- Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped.

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.

On March 4, 2016, a Pharmacy Benefit Manager Workgroup issued its report to the Secretary of Health and Human Resources on a number of issues relating to the practice of PBMs. It included a discussion of some issues relating to "brown bagging and white bagging." The consensus among Workgroup members was that the Board of Pharmacy should review the practices to address issues of concern for patient safety. There are no viable alternatives to achieve the essential purpose of safety and efficacy of prescription drugs.

The Board will review regulations adopted in other states, such as provisions from Oregon which allow for "white bagging" with certain safeguards in place for reconstitution, labeling and accountability.

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.

John M. Mueller, MD, FACP
Hematology/Oncology & Internal Medicine

Michael J. Strachan, MD
Rheumatology & Internal Medicine

E. Jody Crognale, MD
Internal Medicine

Mihail Moroianu, MD
Rheumatology

Tammy R. Spring, MD
Rheumatology

Olga O. Bailey, MD
Rheumatology

Laura E. Joyner, MSHA, CMPE
Administrator

September 5, 2018

Virginia Board of Pharmacy
Department of Health Professions
Attn: Elaine Yeatts
9960 Maryland Drive
Suite 300
Henrico, VA 23233

Re: NORIA on White bagging/brown bagging

On behalf of the physicians of Premier HealthCare Associates, Inc., a small independent medical practice of Rheumatologists and Internal Medicine, I am submitting comments regarding the Virginia Board of Pharmacy's Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the practice of Pharmacy regarding the practice of Brown Bagging and White Bagging.

Premier HealthCare Associates recognize the definition of "white bagging" and "brown bagging" as defined by the National Association of Boards of Pharmacy.

We strongly oppose Brown Bagging of drugs as a means of delivering injectable Rheumatology drugs to patients. With brown bagging, patients receive their injectable drug(s) from a pharmacy and then are required to transport the drug(s) to their physician for administration. The practice of Brown bagging puts a patient's health at risk, due to a number of reasons related to compromising the integrity of the drug(s), including:

- Improper handling of the drug(s);
- Improper storage of the drug(s); and
- Improper transport of the drug(s).

All of these scenarios delay the patient from receiving treatment which may adversely impact patient outcomes.

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Mihail Moroianu, MD
Rheumatology

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Rheumatology

Olga O. Bailey, MD
Rheumatology

Laura E. Joyner, MSHA, CMPE
Administrator

We strongly oppose White Bagging, as it has the same potential for patient harm. Many times a patient's dose and strength may change at time of administration, which is not possible when the drug is being shipped via white bagging ahead of time and prior to the patient's visit. This will create drug waste and increased costs.

Premier HealthCare Associates, position is that the preferred method for physician practices to administer Rheumatology drugs, including drugs that must be administered by injection at the site of care, is the time-tested model whereby the physician practice procures the drugs and inventories them at the site-of-care. The chain of custody is assured; drugs are transported and stored under the optimal, required conditions; and the treatment is tailored to the patient based on changing clinical parameters; and waste is minimized. Most importantly, each patient is given the right drug and on time.

Thank you for the opportunity to submit comments on this critically important issue.

Sincerely,

Laura E. Joyner

Laura Joyner, MSHA, CMPE
Administrator

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CVSHealth

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

September 4, 2018

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

Re: Notice of Intended Regulatory Action in regard to White Bagging and Brown Bagging

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 to the Notice of Intended Regulatory Action for white bagging and brown bagging. We would 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.

The NOIRA outlines that the Board will consider brown bagging requirements such as storage, reconstitution and administration along with white bagging notifications to the receiver of the patient specific medication which includes dates of estimated arrival, name of patient, and exact address where the product has shipped. In review of Board materials and discussions regarding this topic, it seems the intent is to restrict brown bagging and push for utilization of white bagging, which requires adoption by physician's offices, hospitals and clinics. With evaluation of 18VAC110-20-275 (delivery of dispensed prescriptions), it appears that white bagging is already regulated in Virginia and that much more than notification is already required. Section C of this regulation requires a written contract between a pharmacy and a practitioner for what appears to be synonymous with the process of white bagging, which limits the use of this model in Virginia. Brown bagging is also already regulated under the definition of the practice of pharmacy found in § 54.1-3300 which includes but is not limited to the art and science of compounding and dispensing along with proper safe storage and distribution with the responsibility of providing information concerning drugs.

National Association of Boards of Pharmacy (NABP) staff also convened a study to research the issue and provide findings to the Executive Meeting for consideration of any changes to the Model Act based on Resolution 112-1-16 passed at the NABP 112th Annual Meeting in May 2016. Proposed amendments to the Model Act were presented to the Executive Committee in 2017, who voted not to approve the changes, but instead requested that NABP staff convene a panel of experts and bring amended language back to the Executive Committee for review in early 2018. In April 2018, in lieu of any amendments to the Model Act, NABP released a white paper on the topic with two recommendations. The first recommendation was that no definition addition would be made to the model act for brown bagging as this is already addressed in the definition of the practice of pharmacy, similar to Virginia. Secondly, that the pharmacy is responsible for appropriate notification when dispensing occurs to an entity and not the patient via white bagging.

In light of NABP's recommendations being in line with statutory definitions and Virginia regulations already requiring more than a notification, we ask the Board to consider tabling this issue and not pursuing further adoption of regulations regarding white bagging and brown bagging purposes.

CVSHealth

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

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

Sincerely,

Lauren Paul, PharmD

Lauren Paul, PharmD.
Sr Director, Pharmacy Regulatory Affairs
CVS Health

COMMUNITY ONCOLOGY ALLIANCE
Innovating and Advocating for Community Cancer Care

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(202) 756-2258 | communityoncology.org

September 4, 2018

Virginia Board of Pharmacy
Department of Health Professions
Attn: Elaine Yeatts
9960 Mayland Drive
Suite 300
Henrico, VA 23233

Re: NOIRA on White bagging/brown bagging

Dear Ms. Yeatts:

On behalf of the Community Oncology Alliance ("COA"), and our Community Oncology Pharmacy Association ("COPA") network of community oncology practice pharmacy providers, I am submitting comments regarding the Virginia Board of Pharmacy's (the "Board") Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy regarding the practice of Brown Bagging and White Bagging of drugs.

COA is non-profit organization that represents community oncology practices and, most importantly, the patients they serve. COA is the only organization dedicated solely to independent, community oncology practices, where the majority of Americans with cancer are treated. The mission of COA is to ensure that cancer patients receive quality, affordable, and accessible cancer care in their own communities.

More than 1.5 million people in the United States are diagnosed with cancer each year and deaths from the disease have been steadily declining due to earlier detection, diagnosis, and treatment. With the majority of Americans battling cancer receiving treatment in the community setting, it is imperative that the vitality of the community cancer care delivery system be preserved. Studies have consistently shown that cancer care delivered in the community oncology setting is significantly less expensive than oncology care received in a hospital outpatient setting.

COA aims to help shape a future where all Americans have access to quality, affordable cancer care. Further, one of COA's critical aims is ensuring that cancer patients have access to appropriate cancer treatment at the time(s) when needed. This is why it is imperative that we submit our viewpoints on this issue to ensure that well intentioned Board proposals do not have an inadvertent impact on the balance of site of care vitality.

I. COA recognizes the definitions of "White Bagging" and "Brown Bagging" as Advanced by NABP.

According to the National Association of Boards of Pharmacy (NABP):

- "Brown Bagging" refers to the dispensing of a medication from a pharmacy (typically a specialty pharmacy) directly to a patient, who then transports the medication(s) to the physician's office for administration.

- "White Bagging" refers to the distribution of patient-specific medication from a pharmacy, typically a specialty pharmacy, to the physician's office, hospital, or clinic for administration. It is often used in oncology practices to obtain costly injectable or infusible medications that are distributed by specialty pharmacies and may not be available in all non-specialty pharmacies.

COA recognizes the use of the definitions of Brown Bagging and White Bagging advanced by NABP.

II. COA neither recognizes nor supports Brown Bagging due to patient safety concerns related to handling and storage of drug therapy.

In addition to the definitions of Brown Bagging and White Bagging, the Board is considering regulations for Brown Bagging of drugs requiring special storage, reconstitution, or compounding prior to administration.

Oncology drugs are highly sensitive and toxic. They typically require specific handling and storage requirements in order to preserve efficacy and ensure safety. These requirements can include refrigeration and protection from light. The majority of cancer drugs must not be exposed to high temperatures above room temperature for more than an extremely limited period of time. Failure to do so

COA does not recognize and strongly opposes Brown Bagging of drugs as a means of delivering injectable oncology drugs to patients. With Brown Bagging, patients receive their injectable drug(s) directly from a pharmacy and then are required to transport the drug(s) to their physician for administration. Brown Bagging puts a cancer patient's health at risk, due to a number of reasons relating to compromising the integrity of the drug(s), including:

- Improper handling of the drug(s);
- Improper storage of the drug(s); and
- Improper transport of the drug(s).

For example, an oncology drug may be improperly handled by a patient after receiving the drug(s) from their pharmacy, such as storing them at the wrong or dangerous temperature. The potential also exists for the patient to misplace the drug(s) before transporting the drug(s)

to their physician. This not only creates waste but also calls into question the patient's liability in misplacing the drug(s). Perhaps most importantly, all of these scenarios also delay the patient from receiving treatment during his/her scheduled interval. Delayed cancer treatment may adversely impact patient outcomes, cause unnecessary complications and hospitalizations, and/or potentially shorten life expectancy.

Given the number of high temperature days in Virginia, there are significant and very real problems with patients transporting their cancer drugs to their physicians for administration that threaten to compromise the efficacy and safety of these typically highly toxic drugs.

Patients administered drugs that are not efficacious puts patients' health status at risk for worsening conditions and/or further complications. For example, if a cancer patient picks up his/her drug(s) from the pharmacy and then transports the drug(s) in their car without air conditioning on a hot Virginia summer day – or worse yet mistakenly leaves the drug(s) in their car – the drug(s) is at risk for being damaged or even destroyed. This means it can have reduced efficacy, which can then endanger the patient's health status. The same holds true for the patient who forgets to bring the drug(s) to their appointment when the drug(s) is scheduled to be administered. Very significantly, if the patient stores the drug(s) at home after picking up the drug(s) from the pharmacy, there is a risk that others in the household, including children, may have access to the drug(s), which in any cases are highly toxic.

III. COA neither recognizes nor supports White Bagging due to patient safety concerns related to handling and storage of cancer drug(s).

COA notes that the Board is considering regulations related to White Bagging that require the following:

1) the specialty pharmacy participating in White Bagging must notify the receiving pharmacy of the drug(s) shipment to ensure appropriate coordination of patient care; and
2) the specialty pharmacy provides to the receiving pharmacy an estimated arrival date, the name of the patient to whom the drug(s) will be administered, and the exact address of the physician to where the drug(s) has been shipped.

COA does not recognize and strongly opposes White Bagging. White Bagging has the same potential for patient harm based on the experiences community oncology practices have previously had with it. White Bagging also can put patient safety and health at risk, adversely impacting treatment outcomes, causing unnecessary complications and hospitalizations, and/or potentially shorten life expectancy.

COA reminds the Board that the specialty pharmacy dispensing the drug(s) under a White Bagging distribution arrangement may be shipping or delivering the drug(s) to a physician

practice, and not another receiving pharmacy. This is especially true in the case of cancer drugs that need to be administered by trained oncology nurses at the point of care.

With White Bagging, the pharmacy must take adequate care, steps, and precautions to ensure that the drug(s) arrives at the physician's destination not only in a manner that maintains the integrity of the drug, but also in a timeframe that meets both the patient and physician practices' treatment plans.

Oncology drug regimens are specifically structured and scheduled to optimize therapy effectiveness, and any deviations from the schedule may result in decreased therapy efficacy for the patient. For instance, if the drug(s) does not arrive in time for scheduled patient administration, the patient's set treatment schedule is disrupted. A disruption in the patient's scheduled infusion may require the patient to re-schedule his/her treatment, which creates both patient inconvenience but also risks that the patient unable to return, potentially adversely impacting the patient's treatment. As discussed above, disrupting cancer treatments has the potential to result in worse patient outcomes, cause unnecessary complications and hospitalizations, and/or potentially shorten life expectancy.

Another problem associated with White Bagging is waste, which can occur when a drug(s) has been dispensed for the patient but a physician decides to change the drug(s), dosage(s) or otherwise adjust the treatment plan. Cancer drugs are often discontinued and switched based on how well the drug(s) is being tolerated by the patient. The same holds true of switch drug(s) dosage and strength. The reality of cancer treatment is such that community oncology practices have experienced a large amount of waste of very expensive cancer drugs from both White Bagging and Brown Bagging.

We also note that that controlled substances cannot be administered or dispensed via the route of White Bagging. The Federal Controlled Substance Act prevents the dispensing of controlled substances to anyone other than the patient or a member of the patient's immediate household. Thus, if a patient's cancer treatment regimen contains a controlled substance, this drug would not be able to be delivered to the patient under White Bagging, which may lead to patient confusion, adherence issues, or inadequate pain control.

Finally, entities employing White Bagging to deliver cancer drugs do not help patients with their financial assistance and typically do not send the drug on behalf of the patient until the entity receives payment in full from the patient for any copayment due under their insurance plan. This can also result in delayed treatment or even worse, termination of the patient's treatment. Community Oncology practices work closely with, and on behalf of, patients to obtain any necessary financial assistance so that any delays in treatment are avoided.

COA is very concerned with White Bagging and the potential for patient harm based on the experiences community oncology practices have had with it. Simply put, White Bagging puts patient safety and health at risk, potentially leading to shorter life expectancy for cancer patients.

IV. COA emphasizes an alternative method for patient accessibility to cancer drugs.

COA's position is that the preferred method for physician practices administering cancer drugs, including drugs that must be administered by injection at the site of care, is the time-tested model whereby the physician practice procures the drugs and inventories them at the site-of-care.

By purchasing cancer drugs from the major specialty drug distributors, the chain of custody is assured; drugs are transported and stored under the optimal, required conditions; treatment is tailored to each patient based on changing clinical parameters; and waste is minimized. Most importantly, each patient is given the right drug and on time.

Conclusion

COA supports the Virginia Board of Pharmacy's consideration of these regulations but strongly opposes both Brown Bagging and White Bagging and believes that neither has a place in a cancer care system that values patient safety and outcomes.

Thank you for the opportunity to submit comments on this critically important issue. We welcome the opportunity to serve as a resource to you if you have any further questions as you proceed further in your rulemaking process.

Sincerely,

Ricky Newton on behalf of COA
Director of Financial Services & Operations
Community Oncology Alliance
760 Lynnhaven Parkway, Suite 150
Virginia Beach, VA 23451

VIRGINIA ASSOCIATION OF HEMATOLOGISTS AND ONCOLOGISTS

September 5, 2018

Virginia Board of Pharmacy
Department of Health Professions
Attn: Elaine Yeatts
9960 Mayland Drive
Suite 300
Henrico, VA 23233

BY ELECTRONIC DELIVERY

Re: NOIRA on White Bagging/Brown Bagging

Dear Ms. Yeatts:

The Virginia Association of Hematology and Oncology (VAHO) appreciates this opportunity to comment on the Virginia Board of Pharmacy's (the "Board") Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO represents over 150 oncology physicians and other oncology healthcare professionals practicing in Virginia. VAHO seeks to improve the quality of oncology care available to the people of Virginia. VAHO members are committed to ensuring that safe, evidenced-based practices for the prevention, diagnosis and treatment of cancer are available to all Virginians.

Under the definition of the National Associations of Boards of Pharmacies (NABP), VAHO recognizes "white bagging" and "brown bagging" as the following:

- "Brown Bagging" – Under this practice, a pharmacy dispenses a medication directly to a patient, who then transports the medication themselves for administration at their physician's office. Often, this practice occurs at specialty pharmacies.

- "White Bagging" – Under this practice, the pharmacy dispenses a patient's medication to the physician's office for administration. This practice is often used for oncology patients to obtain medications that are not available at all non-specialty pharmacies.

Administration of drugs for cancer patients requires a great deal of care and sensitivity to ensure safety for the patient and their provider. Due to the imperative needs of oncology drugs to be treated with certain handling, storage, and transportation requirements, VAHO is deeply concerned and opposes brown bagging to deliver injectable oncolytics to cancer patients in the state of Virginia. Both white bagging and brown bagging have the potential to put the patient and their provider at risk, as well as significantly impact a patient's treatment outcomes, and for that reason, VAHO stands in opposition of the NAIRO notice. Oncology drugs are delivered to patients specifically with adequate safety measures in mind, especially during administration.

Tel 301 984 9466
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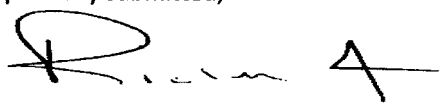
1801 Rockville Pike Ste 400
Rockville MD 20852

VAHO would like to voice concern over a waste issue that can arise with "white bagging" if a physician needs to make a timely decision to update a patient's dosage or adjustment of a patient's treatment. Administration of oncolytics for a patient can change rapidly, and "white bagging" has been proven to increase waste of expensive oncolytics for cancer patients and their providers across the country.

Thank you for this opportunity to share the oncology provider perspective on your proposals in the Virginia Board of Pharmacy's Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO supports continued consideration of these regulations but is in strong opposition to "white bagging" and "brown bagging." Please feel free to contact Dr. Richard Ingram, VAHO President, RIngram@usoncology.com, if you have any questions or need any additional information. We look forward to working with you on this critical issue for oncology patients and their providers in the state of Virginia. Thank you again for your attention to this very important matter.

Respectfully submitted,



Richard Ingram, MD
VAHO President

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action	**Brown bagging and white bagging**
Stage	**NOIRA**
Comment Period	Ends 9/5/2018

All comments for this forum

Back to List of Comments

Commenter: Cynthia Williams, Riverside Health System 8/23/18 7:12 am

Comment on NOIRA for brown bagging/white bagging

I am in overall support of the NOIRA related to brown bagging and white bagging of medications. I support the use of the NABP definitions as presented. I am in overall support of the proposed regulations, but would like to submit some additional comments for considerations:

1. The brown bagging of drugs requiring special storage, reconstituion or compounding prior to administration should not be allowed from a patient safety and administering organization liability perspective. There is no method to ensure that the medication has been maintained at appropriate temperature and conditions prior to administration. Even if kept in a refrigerator at the patient home, the is no confirmation that the medication was maintained between 36-46 as required by standard. For RT medications, there is no confirmation that the medication was maintained at controlled room temperature. This not only puts the patient at risk, but puts the organization administering the medication at risk. For the most part, this practice is being driven soley for the financial benefit of insurance vendors, not for the benefit lor safety) of the patient or healthcare provider.

2. There are similar concerns related to storage for white bag medications. There is not the same assurance of integrity as if the organization had provided the medication and stored the medication as required by board of pharmacy regulation and requirements of other accrediting organizations (The Joint Commission, DNV, etc). Even with special packaging, there is not assurance of maintenance of temperature, putting the patient and administering organization at risk. Again, this practice is being driven soley for the financial benefit of insurance vendors.

3. Coordination of care with medications provided through a "white bag" process is challenging for both the healthcare provider and the patient, resulting in delays in care in many cases. The burden is put back on the patient and administering organization, while the financial benefit resides with the insurance vendor and out-of-state dispensing pharmacy. At a minimum, the burden should be placed back on the dispensing pharmacy to take ownership of coordination of shipping and receiving of medication. Ideally, regulations that pertain to any willing provider and other limitations of provision of services by payers (e.g. site of service limitations) could be strengthened to allow health systems to provide medications through normal procurement and distribution systmes.

Thank you in advance for your intent to draft regulation to control a process that lacks control and oversight today, and to improve the care and safety for our patients.

Commenter: Jamin Engel

8/31/18 11:29 am

Comments to Proposed "White" and "Brown" Bagging Regulations

Thank you for the Board's consideration in adopting regulations to regulate "brown" and "white" bagging within the State of Virginia. I am in support of these efforts, and appreciate the opportunity to submit further comments for consideration by the Board.

Overall, "brown" and "white" bagging through the utilization of specialty pharmacies has placed a significant burden on sites of care and patients. There is confusion on the differences between these two practices and the proper method of conducting business and treatment of patients. In addition, patients are becoming frustrated at a process that seems convoluted, impersonal, and a burden to receiving safe and effective care within established patient-provider locations. These established locations, if they choose to continue treatment for a patient forced to utilize a specialty pharmacy, are accepting the burden of risk for treatment with a medication procured outside traditional channels, and are spending significant resources in coordination of care.

Thank you for your consideration of the following comments:

1. Brown bagging should not be allowed. These medications require special storage and handling considerations and there is no validated method to ensure it is a safe to administer. This places an organization at high risk of liability, and the patient at high risk for adverse outcomes. Many organizations have already restricted use of brown bagging within their sites of care due to the safety risks.

2. I am in support of proposals to improve communication and chain of custody of white bagging. Often product is sent without any notification, and there are significant resources that are spent on determining who the medication is for, and when the administration is due. This results in patients showing up for administrations prior to the medication being procured, or the medication is sent to the wrong site of care.

3. Please consider modification or inclusion of 18VAC110-20-275, which requires a written contract or agreement for delivery of a filled prescription to another pharmacy for patient pickup. Specialty pharmacies has refused to sign these agreements in the past. In addition, please consider the implications of this practice on DSCSA Federal Regulations.

4. Consider the impact of white bagging on patients. In rural settings, we have patients that are driving past infusion centers for which they receive other medications. They are driving over an hour in some cases to an infusion center located in a "strip" mall, because that location has a contract with their specific insurance company. Patients do not understand why they cannot receive their medications in established, and in their opinion, safe sites of care. They are often apprehensive about the locations of these infusion centers. This practice is degrading trust in safe medication management, and reducing sites and access of care for patients.

5. Access to care may also continue to decrease as some infusion sites are receiving no reimbursement for resources and supplies used to administer these medications to patients. As specialty pharmacy continues to grow, the economic burden will continue to increase, and thus decisions will be made to discontinue treatment of these patients at previous sites of care. Organizations may also deem it too high of liability to continue.

6. Please consider language to remove restrictions to the pharmacies that patients may obtain these specialty medications. The pharmacies that serve current infusion centers, procure the same products through safe and validated supply channels. It also allows pharmacies that already take care of patients to continue to make safe decisions on care as they have access to the full patient medical record.

Thank you again for your time and consideration!

Commenter: Elizabeth Early 9/4/18 12:28 pm

White/Brown bagging

I believe that brown bagging should not be allowed for the simple reason of that the pharmacy has to control of the medication to ensure the appropriate storage and integrity of the medication. We cannot delegate this responsibility, not even to the patient.

As for white bagging, I also do not support the use of white bagging for a facility that is capable of providing the medication for their patients. The reasons for not supporting this practice based on a variety of quality and patient safety issues. My concerns are:

- Patients receive a call from a pharmacy that is unknown to them and may be asked to provide credit card information to a company not associated with facility providing the care (difficult to differentiate from a phone scam). This may cause a delay in treatment.
- Before a shipment is sent out, the mail order pharmacy requires the approval and full copay remittance from the patient: no monthly payments or bills after the treatment as you would find at a healthcare facility. Due to the high cost and co-pays for these medications, this may cause a significant financial burden and/or result in a delay in treatment.
- The patient's next treatment becomes dependent on a delivery, not an established schedule. Coordinating ordering, receipt and administration drains a facility's resources and may test the staff's (and the patient's) patience.
- The mail order pharmacy will not have the entire medical record for the patient which may lead to issues with continuity of care between the ordering provider, the pharmacy and the facility infusing the medication.
- The patient's condition may change before the shipment is received. The patient may have to pay for another medication (in addition to the one that was sent originally). Because the drug arrives at the facility, but is the property of the patient, the pharmacy cannot use the drug on another patient and is now responsible for disposal of a hazardous product.
- Most mail order pharmacies are not willing to sign alternate site delivery contracts as required by Virginia law.
- The origin of drugs cannot be traced further back than the mail-order company. Where, when and from whom were the drugs purchased?
- Mail order pharmacies may take longer to fill backorders causing delays and cancelling treatments that may be perceived by the patient as a facility issue.
- A delivery may sit for hours in extreme heat or cold conditions. So, a box full of sensitive drugs sitting outside for hours may result in compromised contents....how does the facility ensure that it was handled appropriately and safely at all times if they are not controlling the supply chain?
- Is the facility legally responsible for any product injected into the patient even when they have lost control of the process? Will malpractice insurance cover such claims? Whose fault is it in the case of a negative outcome?
- The pharmacy preparing the drug receives no reimbursement for their time and supplies used to get the drug ready for administration. In addition, the facility may not be able to get reimbursement/denied reimbursement for the administration if there is no drug charge on the bill.

Commenter: Marci Cali, Virginia Association of Hematology and Oncology 9/5/18 2:51 pm

Re: NOIRA on White Bagging/Brown Bagging

Dear Ms. Yeatts:

The Virginia Association of Hematology and Oncology (VAHO) appreciates this opportunity to comment on the Virginia Board of Pharmacy's (the "Board") Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO represents over 150 oncology physicians and other oncology healthcare professionals practicing in Virginia. VAHO seeks to improve the quality of oncology care available to the people of Virginia. VAHO members are committed to ensuring that safe, evidenced-based practices for the prevention, diagnosis and treatment of cancer are available to all Virginians.

Under the definition of the National Associations of Boards of Pharmacies (NABP), VAHO recognizes "white bagging" and "brown bagging" as the following:

- "Brown Bagging" – Under this practice, a pharmacy dispenses a medication directly to a patient, who then transports the medication themselves for administration at their physician's office. Often, this practice occurs at specialty pharmacies.
- "White Bagging" – Under this practice, the pharmacy dispenses a patient's medication to the physician's office for administration. This practice is often used for oncology patients to obtain medications that are not available at all non-specialty pharmacies.

Administration of drugs for cancer patients requires a great deal of care and sensitivity to ensure safety for the patient and provider. Due to the imperative needs of oncology drugs to be treated with certain handling, storage, and transportation requirements, VAHO is deeply concerned and opposes brown bagging to deliver injectable oncolytics to cancer patients in the state of Virginia. Both white bagging and brown bagging have the potential to put the patient and their provider at risk, as well as significantly impact a patient's treatment outcomes, and for that reason, VAHO stands in opposition of the NAIRO notice. Oncology drugs are delivered to patients specifically with adequate safety measures in mind, especially during administration.

VAHO would like to voice concern over a waste issue that can arise with "white bagging" if a physician needs to make a timely decision to update a patient's dosage or adjustment of a patient's treatment. Administration of oncolytics for a patient can change rapidly, and "white bagging" has been proven to increase waster of expensive oncolytics for cancer patients and their providers across the country.

Thank you for this opportunity to share the oncology provider perspective on your proposals in the Virginia Board of Pharmacy's Notice of Intended Regulatory Action to amend 18VAC110-20, Regulations Governing the Practice of Pharmacy, regarding the "white bagging" and "brown bagging" of drugs. VAHO supports continued consideration of these regulations but is in strong opposition to "white bagging" and "brown bagging." Please feel free to contact Dr. Richard Ingram, VAHO President, if you have any questions or need any additional information. We look forward to working with you on this critical issue for oncology patients and their providers in the state of Virginia. Thank you again for your attention to this very important matter.

Respectfully Submitted,

Richard Ingram, MD

VAHO President

Commenter: Tracie Chambers, Community Health Systems 9/5/18 3:28 pm

White-bagging

My company owns 3 sites in Virginia. We are committed to helping each of sites provide the best care to all patients' while meeting all rules and regulations. Recently, during a Board visit, one site who had received a refrigerated med from a specialty pharmacy for a patient scheduled in the next day was asked if they had a written contract with this pharmacy to do business. Of course the answer was No, as this is viewed as a patient's own med and having it sent directly from the other pharmacy to the hospital pharmacy helps assure the integrity of the product prior to use versus having the med sent to the patient at home where proper storage requirements cannot be verified. The time of notification that the patient was coming in for a refrigerated, injectable med and time of receipt was approximately one week which would not allow the hospital enough time to set up a contract or written agreement with the specialty pharmacy. I would hate to have to turn this patient population away but given the quick turnaround times, there is no way to be compliant with the current guideline for contracting. I want each of our sites to be able to care for Virginia residents so would appreciate your consideration to grant exceptions for these patients' that require a refrigerated medication that insurance dictates must be purchased through a specialty pharmay and allow them to be viewed as patients' own meds just temporarily stored in the hospital pharmacy until day of administration similar to inpatients' that must use their own med if it is not available on the hospital formulary.

Commenter: Natalie Nguyen, Virginia Society of Health System Pharmacists 9/5/18 6:14 pm

Comments on Behalf of the Virginia Society of Health-System Pharmacists

VSHP is in overall support of regulation to regulate brown bagging of drugs requiring reconstitution or compounding prior to administration and the establishment of specific requirements for specialty pharmacies participating in white bagging, with the overall intent of public protection.

VSHP supports the use of definitions of brown bagging and white bagging as established by NABP.

In addition to the regulations under consideration as defined in the NOIRA, VSHP suggests expansion of regulations under consideration to include:

1. Not allowing brown bagging of medications that require special storage, reconstitution or compounding prior to administration due to the risk to the patient and the organization providing administration of the medication.

2. Leverage current "Any Willing Provider" legislation to allow health systems that have specialty pharmacy/retail pharmacy capability to provide the needed medications for patients receiving care at health system owned locations. Alternatively, include provisions that would allow health systems to provide medications through normal procurement process versus through external specialty pharmacy providers. This would allow more robust coordination, reduce the risk of medication errors and patient harm, limit risk of improper storage of medications, and minimize delays in patient care.

3. Inclusion of requirement for coordination of shipment and arrival date to include physician-based practices and other locations of care since often the transfer is not pharmacy to pharmacy.

In addition, VSHP members have inquired about whether proposed regulations will impact the following scenarios, and we look forward to providing further comment:

- Patient Assistance Programs and Manufacturer Consignment Programs
- Patient request of provider administration of non-reconstituted, non-compounded medications (such as ready to inject syringes) brown bag medications due to concerns with self-administration at home
- Exclusions for emergent situations. Example: Patients with hemophilia admitted to emergency departments requiring emergent blood factor treatment that requires reconstitution that is not carried by pharmacy. These patients usually bring their own blood factor products to the Emergency Department as a result.

Commonwealth of Virginia

Yeatts, Elaine <elaine.yeatts@dhp.virginia.gov>

comments

1 message

Lubkowski, John <JLubkowski@augustahealth.com> Fri, Aug 24, 2018 at 2:22 PM
To: "elaine.yeatts@dhp.virginia.gov" <elaine.yeatts@dhp.virginia.gov>
Cc: "Juran, Caroline (DHP)" <Caroline.Juran@dhp.virginia.gov>

Good Morning Ms. Yeatts. I wanted to provide some input regarding the Brown Bag/White Bag NOIRA.

I fully support guidance regarding, and regulation of, the practices of White Bagging and Brown Bagging by the Board of Pharmacy. There are potential negative implications of these practices on patient care, including delays in treatment, improper storage, and non-compliance with existing Board of Pharmacy regulations on alternate delivery sites.

I support the definitions of these two practices as presented.

I generally agree with a regulation restricting brown bagging of drugs requiring reconstitution or compounding prior to administration, however there should be an allowance for drugs that are emergently needed in life threatening situations. In my practice we occasionally see patients in our Emergency Department that are traveling through our area who are hemophiliacs. These patients carry their own blood factors that may not be stocked at my facility. If they arrive in an emergent situation the Provider may elect to treat them with their own "Brown Bag" blood factor. These products do require reconstitution prior to administration and I feel that this should be allowed.

I support the establishment of specific requirements for specialty pharmacies that participate in white bagging, with the end goal of patient protection. This includes requiring appropriate notification to the receiving facility of shipments to ensure appropriate coordination of patient care. I also feel this should include physician based practices and other site of care locations, as the transfer is not always pharmacy to pharmacy.

Finally, I would also like to suggest the application of current "Any Willing Provider" regulations to allow health systems that have retail pharmacy capability to provide the needed medications for patients receiving care at health system owned locations. Alternatively, requiring availability of medications through normal procurement process rather than specialty pharmacy providers would allow more robust coordination, limit risk of improper storage of medications, and minimize delays in patient care.

I sincerely appreciate the Board of Pharmacy taking action on these practices, to limit patient risks. Thank you.

John Lubkowski, RPh, MBA

Director of Pharmacy

Augusta Health

78 Medical Center Drive | Fishersville, VA 22939

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Summary of Legislative Proposals Submitted by DHP
(14 proposals in no particular order)

E-prescribing implementation (bill attached)

The proposal will: 1) set out 10 exceptions to the requirement for an electronic prescription for a drug containing an opiate; 2) require licensing boards to promulgate emergency regulations for a temporary waiver based on hardship; 3) authorize a pharmacy to dispense a valid prescription transmitted by other means; and 4) require the convening of a workgroup to identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances by November 1, 2022.

Process for placement of drugs under seal or seizure by Board or law enforcement (bill attached)

The proposal will clarify the authority of the Board of Pharmacy or law enforcement to seize drugs and the process to be followed if drugs are placed under seal, forfeited and destroyed.

Correction of circular mandatory suspensions and inconsistency in the Code (bill attached)

The proposal will amend section of Code relating to mandatory suspension to avoid issues that arise when another state suspends a license based on an earlier suspension in Virginia, triggering another action to suspend in Virginia even if the licensee has subsequently been reinstated. It will also amend a provision in the Pharmacy law on the time frame for holding a hearing after a mandatory suspension that is inconsistent with the law for all boards and is unrealistic.

Flexibility in terms of board members to re-balance expiration dates and fill certain vacancies

The proposal will amend sections of the Code to: 1) allow the Governor to extend the four-year term of a member on a health regulatory board for an additional one or two years for the purpose of staggering the expiration of terms and maintaining valuable board experience and knowledge; and 2) re-designate membership on the Boards of Nursing and Psychology.

Practice by dental hygienists under remote supervision; authority to administer certain topical drugs

The legislation will expand the topical medications dental hygienists are authorized to administer to include topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, as well as any other Schedule VI topical drug approved by the Board of Dentistry. It will also eliminate the current restriction on administration of topical fluoride varnish by dental hygienists, which limits its use to children aged six months to three years.

DRAFT Legislation

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3408.02 and 54.1-3410 of the Code of Virginia relating to electronic prescribing of a controlled substance containing an opiate.

Be it enacted by the General Assembly of Virginia:

1. **That § 54.1-3408.02 and 54.1-3410 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-3408.02. (Effective July 1, 2020) Transmission of prescriptions.

A. Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy as an electronic prescription or by facsimile machine and shall be treated as valid original prescriptions.

B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription with the following exceptions:

1. A prescriber who dispenses the opiate directly to the patient or patient's agent;

2. A prescription for a controlled substance containing an opiate for a person residing in a hospital, assisted living facility, nursing home, or residential healthcare facility or receiving services from a hospice provider or outpatient dialysis facility, or;

3. A prescriber who experiences temporary technological or electrical failure or other temporary extenuating circumstance that prevents the prescription from being transmitted electronically, provided the prescriber documents the reason for this exception in the patient's medical record;

4. A prescriber who writes a prescription to be dispensed by a pharmacy located on federal property, provided the prescriber documents the reason for this exception in the patient's medical record;

5. A prescriber who writes a low volume of prescriptions, defined as less than 25 prescriptions during the most recent twelve-month period with a maximum of a seven-day supply for each prescription;

6. A prescription issued by a veterinarian;

7. A prescription for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing,

such as a drug with risk evaluation and mitigation strategies that include elements to assure safe use;

8. A prescription issued for an opiate under a research protocol;

9. A prescription issued in accordance with an Executive Order of the Governor for a declared emergency; and

10. A prescription that cannot be issued electronically in a timely manner and the patient's condition is at risk, provided the prescriber documents the reason for this exception in the patient's medical record.

C. In accordance with regulations adopted by the licensing board for a prescriber, a waiver may be granted for a period not to exceed one year of the requirement that any prescription for a controlled substance that contains an opiate be issued as an electronic prescription due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstance demonstrated by the prescriber.

§ 54.1-3410. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom,

or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § 54.1-3411.
If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

E. (Effective July 1, 2020) ~~No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription.~~ A dispenser is not required to verify that a prescriber properly falls under one of the exceptions specified in § 54.1-3408.02 for electronic prescribing prior to dispensing a controlled substance containing an opiate. A dispenser may continue to dispense a controlled substance containing an opiate from valid written, oral, or facsimile prescriptions that are otherwise consistent with applicable laws.

2. That the Boards of Medicine, Nursing, Dentistry, and Optometry shall promulgate regulations for issuing or renewing a temporary waiver for a prescriber within 280 days of enactment of this Act.

3. That the Secretary of Health and Human Resources shall convene a work group within two years of the effective date of this Act of interested stakeholders, including the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, the Virginia Dental Association, the Virginia Association of Health Plans, and the Virginia Pharmacists Association to evaluate the implementation of this Act and shall make a report to the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by November 1, 2022. The workgroup's evaluation shall identify successes and challenges with the mandate, and offer possible recommendations for increasing the electronic prescribing of controlled substances.

Department of Health Professions

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-2408.1, 54.1-3424, and 54.1-3434 relating to authority for the Board of Pharmacy or law enforcement to place drugs under seal or seize drugs under certain circumstances.

Be it enacted by the General Assembly of Virginia:

1. **That §§ 54.1-2408.1, 54.1-3424 and 54.1-3434 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-2408.1. Summary action against licenses, certificates, registrations, or multistate licensure privilege; allegations to be in writing.

A. Any health regulatory board may suspend the license, certificate, registration, permit, or multistate licensure privilege of any person holding a license, certificate, registration, permit, or licensure privilege issued by it without a hearing simultaneously with the institution of proceedings for a hearing, if the relevant board finds that there is a substantial danger to the public health or safety which warrants this action. A board may meet by telephone conference call when summarily suspending a license, certificate, registration, permit, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension.

B. Any health regulatory board may restrict the license, certificate, registration, permit, or multistate licensure privilege of any person holding a license, certificate, registration, permit, or licensure privilege issued by it without proceeding simultaneously with notification of an informal conference pursuant to §§ 2.2-4019 and 54.1-2400, if the relevant board finds that there is a substantial danger to the public health or safety that warrants this action. A board may meet by telephone conference call when summarily restricting a license, certificate, registration, permit, or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. The informal conference shall be scheduled within a reasonable time of the date of the summary restriction.

C. A substantial danger to the public health or safety may include evidence that the registration issued by the Drug Enforcement Administration to a licensee, certificate holder, registrant, permittee, or person holding a multistate licensure privilege has been suspended or voluntarily surrendered in lieu of disciplinary action.

~~C.~~D. Allegations of violations of this title shall be made in writing to the relevant health regulatory board.

§ 54.1-3424. Suspension or revocation of registration, license, ~~or~~ permit or certificate; limitation to particular controlled substance; controlled substances and devices placed under seal; ~~sale of perishables~~ disposition, ~~and~~ forfeiture, and seizure; notification to DEA.

A. A registration, license, permit, or certificate to manufacture, distribute, or dispense a controlled substance or device may be suspended or revoked by the Board upon a finding that the registrant, licensee, permittee, or certificate holder:

1. Has furnished false or fraudulent material information in an application filed under this chapter;

2. Has been convicted of a felony under any state or federal law relating to any controlled substance;

3. Has had his federal registration to manufacture, distribute or dispense controlled substances suspended or revoked;

4. Has violated or cooperated with others in violating any provision of this chapter or regulations of the Board relating to the manufacture, distribution or dispensing of controlled substances.

B. The Board may limit revocation or suspension of a registration to the particular controlled substance with respect to which grounds for revocation or suspension exist.

~~C. If the Board suspends or revokes a registration, or if the license or permit of a person possessing controlled substances under an exemption in § 54.1-3422 A is suspended or revoked by the issuing board, all controlled substances owned or possessed by the registrant, licensee or permittee at the time of suspension or the effective date of the revocation order may be placed under seal. No disposition may be made of substances under seal until the time for taking an appeal has elapsed or until all appeals have been concluded unless a court orders the sale of perishable substances and the deposit of the proceeds of the sale with the court. Upon a revocation order becoming final, all controlled substances shall be forfeited to the Commonwealth.~~

If the Board summarily suspends, suspends or revokes a registration, license, permit, or certificate, all controlled substances and prescription devices owned or possessed pursuant to the registration, license, permit, or certificate may be placed under seal by the Board or an authorized agent of the Board as of the effective date of the order of summary suspension, suspension or revocation. An inventory of the controlled substances and devices placed under seal shall be performed by the Board or an authorized agent of the Board. The controlled substances and devices placed under seal shall remain in a secured manner on the premises at the address of the registration, license, permit, or certificate where the Board had previously authorized controlled substances and prescription devices to be possessed. No one may access or relocate the controlled substances and devices without authorization from the Board. The registrant, licensee, permittee, or certificate

holder shall ensure the controlled substances and devices remain securely under seal at all times with no unauthorized access or relocation.

Following the elapsed time for filing an appeal or at the conclusion of all appeals, the controlled substances and devices are subject to forfeiture. The Board shall direct the owner to appropriately transfer or dispose of the sealed controlled substances or devices under the supervision of an authorized agent, or the controlled substances and devices shall be forfeited, seized and destroyed by the Board, an authorized agent of the Board, or any law enforcement officer. Costs associated with the storage and the destruction of the seized drugs and devices shall be at the expense of the owner.

Prior to forfeiture, nothing shall preclude the owner of the controlled substances and devices from requesting and obtaining permission from the Board to transfer the sealed controlled substances and devices, at the owner's expense and under the supervision of an authorized agent, to an entity authorized to possess or destroy the controlled substances and devices.

D. Controlled substances and prescription devices that have been abandoned and are stored at a location that is not authorized for the storage of such drugs or devices shall be considered contraband and may be seized and destroyed by any law enforcement officer or an authorized agent of the Board. Costs associated with the storage and destruction of the controlled substances and devices shall be at the expense of the owner, if known.

~~D.~~E. The Board shall promptly notify the DEA of all orders suspending or revoking registration and all forfeitures of controlled substances.

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

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

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

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

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

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

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

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

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

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

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

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

Department of Health Professions

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-2409 and 54.1-3434.3 relating to mandatory suspension and reinstatement of licenses for health professionals.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2409 and 54.1-3434.3 of the *Code of Virginia* are amended and reenacted as follows:

§ 54.1-2409. Mandatory suspension or revocation; reinstatement; hearing for reinstatement.

A. Upon receipt of documentation by any court or government agency that a person licensed, certified, or registered by a board within the Department of Health Professions has had his license, certificate, or registration to practice the same profession or occupation revoked or suspended for reasons other than nonrenewal or accepted for surrender in lieu of disciplinary action in another jurisdiction and has not had his license, certificate, or registration to so practice reinstated within that jurisdiction, or has been convicted of a felony or has been adjudged incapacitated, the Director of the Department shall immediately suspend, without a hearing, the license, certificate, or registration of any person so disciplined, convicted or adjudged, unless the action taken by the other jurisdiction was solely based on the disciplinary action of a board within the Department. The Director shall notify such person or his legal guardian, conservator, trustee, committee, or other representative of the suspension in writing to his address on record with the Department. Such notice shall include a copy of the documentation from such court or agency, certified by the Director as the documentation received from such court or agency. Such person shall not have the right to practice within this Commonwealth until his license, certificate, or registration has been reinstated by the Board.

B. The clerk of any court in which a conviction of a felony or an adjudication of incapacity is made, who has knowledge that a person licensed, certified, or registered by a board within the Department has been convicted or found incapacitated, shall have a duty to report these findings promptly to the Director.

C. When a conviction has not become final, the Director may decline to suspend the license, certificate, or registration until the conviction becomes final if there is a likelihood of injury or damage to the public if the person's services are not available.

D. Any person whose license, certificate, or registration has been suspended as provided in this section may apply to the board for reinstatement of his license, certificate, or registration. Such person shall be entitled to a hearing not later than the next regular meeting of the board after the

expiration of 60 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify in his behalf. The Board may consider other information concerning possible violations of Virginia law at such hearing, if reasonable notice is given to such person of the information.

The reinstatement of the applicant's license, certificate, or registration shall require the affirmative vote of three-fourths of the members of the board at the hearing. The board may order such reinstatement without further examination of the applicant, or reinstate the license, certificate, or registration upon such terms and conditions as it deems appropriate.

E. Pursuant to the authority of the Board of Nursing provided in Chapter 30 (§ 54.1-3000 et seq.) of this title, the provisions of this section shall apply, mutatis mutandis, to persons holding a multistate licensure privilege to practice nursing.

§ 54.1-3434.3. Denial, revocation, suspension of registration, summary proceedings.

The Board may deny, revoke, suspend, or take other disciplinary actions against a nonresident pharmacy registration as provided for in § 54.1-3316.

The Board shall immediately suspend, without a hearing, the registration of any nonresident pharmacy upon receipt of documentation by the licensing agency in the jurisdiction where a nonresident pharmacy registered with the Board is located, that the nonresident pharmacy has had its license, certificate, permit, or registration as a pharmacy revoked or suspended by that agency and has not been reinstated, or if the Board has received notification from the licensing agency that the pharmacy in the resident state no longer holds a valid unexpired license, permit, certificate, or registration as a pharmacy. The Board shall provide written notice of the suspension to the nonresident pharmacy at the address of record on file with the Board and to the resident-state licensing agency. The nonresident pharmacy may apply for reinstatement of the registration only after it has been reinstated by and holds a current and unrestricted license, certificate, permit, or registration as a pharmacy from the licensing agency in the jurisdiction where it is located. Such nonresident pharmacy shall be entitled to a hearing not later than the next regular meeting of the Board after the expiration of ~~30~~ 60 days from the receipt of such application, and shall have the right to be represented by counsel and to summon witnesses to testify on its behalf.

The Board may summarily suspend the registration of any nonresident pharmacy without a hearing, simultaneously with the institution of proceedings for a hearing, if it finds that there is a substantial danger to the public health or safety that warrants such action. The Board may meet by telephone conference call when summarily suspending the registration if a good faith effort to assemble a quorum of the Board has failed and, in the judgment of a majority of the members of the Board, the continued dispensing by the nonresident pharmacy constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension. The Board may consider other information concerning possible violations of Virginia law at a hearing, if reasonable notice is given to such nonresident pharmacy of the information.

A nonresident pharmacy with a suspended registration shall not ship, mail, or deliver any Schedule II through VI drugs into the Commonwealth unless reinstated by the Board.

The Board may refer complaints concerning nonresident pharmacies to the regulatory or licensing agency in the jurisdiction where the pharmacy is located. The Board may take other disciplinary action against a nonresident pharmacy in accordance with §§ 54.1-2400 and 54.1-3316 following notice and the opportunity for a hearing.

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Licenses Issued

	3/1/17-5/31/17	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	License Count 9/10/2018
Business CSR	38	34	40	81	86	50	1,388
CE Courses	1	0	1	0	1	0	9
Limited Use Pharmacy Technician	0	0	1	0	0	0	17
Medical Equipment Supplier	9	3	3	2	5	4	238
Nonresident Manufacturer			13	92	20	4	128
Nonresident Medical Equipment Supplier			19	12	12	12	332
Non-resident Outsourcing Facility	40	17	3	1	9	1	32
Non-resident Pharmacy	9	4	38	32	35	33	764
Non-resident Wholesale Distributor	40	42	8	13	22	16	671
Non-restricted Manufacturer	18	10	0	1	0	0	28
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	1
Pharmacist	166	438	251	142	157	439	15,091
Pharmacist Volunteer Registration	0	4	1	0	0	2	0
Pharmacy	18	24	17	3	15	18	1,820
Pharmacy Intern	107	140	204	148	115	140	1,765
Pharmacy Technician	513	621	387	357	363	420	14,119
Pharmacy Technician Training Program	5	4	5	5	3	2	138
Physician Selling Controlled Substances	26	44	30	22	55	25	731
Physician Selling Drugs Location	5	5	5	1	10	10	160
Pilot Programs	0	2	0	2	0	1	16
Registered Physician For CBD/THC-A Oil						118	126
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	1	0	0	0	54
Third Party Logistics Provider			2	3	1	0	5
Warehouser	1	1	0	39	3	10	97
Wholesale Distributor	2	3	5	1	0	3	80
Total	**998**	**1,396**	**1,034**	**957**	**912**	**1,308**	**37,812**

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Inspections Completed

	3/1/17-5/31/17		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	
License Type												
Controlled Substances Registration	149		133		131		163		182		120	
Medical Equipment Supplier	25		18		32		22		22		25	
Non-restricted Manufacturer	2		1		1		1		0		0	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	18		32		39		23		22		31	
Restricted Manufacturer	1		1		3		0		2		0	
Third Party Logistics Provider					2		1		1		0	
Warehouse	5		3		6		11		11		14	
Wholesale Distributor	12		20		13		6		3		7	
Pharmacy	281		313		293		272		291		328	
Pilot	1		2		1		0		1		0	
Total	**494**		**523**		**521**		**499**		**535**		**525**	
Pharmacy (0201) Inspections												
Change of Location	4		3		3		4		5		9	
New	17		21		13		3		15		19	
Reinspection	9		8		14		2		8		6	
Remodel	48		45		55		31		43		31	
Routine	184		232		206		232		218		242	
Focus	3		4		0		0		2		1	
Federal Agency	15		0		0		0		0		18	
Compliance	1		0		2		0		0		2	
Pilot	0		0		0		0		0		0	
Total	**281**		**313**		**293**		**272**		**291**		**328**	
Pharmacy Routine Inspections												
No Deficiency	37	20%	52	23%	43	21%	77	33%	66	30%	93	38%
Deficiency	79	43%	100	43%	66	32%	77	33%	80	37%	75	31%
Deficiency & IPHCO	68	37%	80	34%	97	47%	78	34%	72	33%	74	31%
Total	**184**		**232**	*	**206**		**232**		**218**		**242**	

* Corrected 12/11/17

Virginia Board of Pharmacy
September 25, 2018
Frequently Cited Deficiencies
March 2017 - August 2018

Deficiencies Numbered Less Than 100	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is requirec	154
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	62
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)	60
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	41
12. Storage of prescription drugs not in the prescription department	40
20. Pharmacist not checking and documenting repackaging or bulk packaging	39
18. Records of dispensing not maintained as required	36
20a. Pharmacist not documenting final verification of non-sterile compounding	36
7. Change of location or remodel of pharmacy without submitting application or Board approval	35
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	34
Deficiencies Numbered Greater Than 100	**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)	204
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
130a. Compounded products not properly labeled	169
127. Repackaging records and labeling not kept as required or in compliance	157
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	110
124. Labels do not include all required information	94
122. Engaging in alternate delivery not in compliance	91
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	59
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)	54

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
Routine Inspections Completed	**184**	**232**	**206**	**232**	**218**	**218**	**1290**	**Repeat**	**Repeat**
Total Deficiencies	**117**	**131**	**158**	**127**	**115**	**123**	**771**	**9**	**201**
Average Deficiencies per Inspection	**0.6**	**0.6**	**0.8**	**0.5**	**0.5**	**0.6**	**0.6**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	0	2	3	2	2	2	11		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	2	2	0	5	3	9	21		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	0	2	2	4	2	2	12		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	0	1	2	0	3		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	3	1	1	2	1	1	9		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	0	0	0		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	3	5	10	4	6	7	35		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	2	0	2	1	0	1	6		1
9. Alarm not operational or not being set	1	5	3	0	1	1	11		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	0	1	2	1	0	1	5		1

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	1	8	7	1	2	2	21		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	1	0	0	0	1	3		
12. Storage of prescription drugs not in the prescription department	3	5	7	12	8	5	40		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)	4	0	1	0	1	5	11		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)	3	2	6	0	5	2	18		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)	10	15	8	6	5	16	60		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	28	25	29	31	17	24	154	1	94
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	6	7	9	6	7	6	41		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	0	2	0	2	2	6		
18. Records of dispensing not maintained as required	1	6	15	7	3	4	36		

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	1	2	7	2	0	1	13		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	4	9	10	5	7	4	39		15
20a. Pharmacist not documenting final verification of non-sterile compounding	7	8	7	6	5	3	36		3
20b. Pharmacist not documenting final verification of sterile compounding	5	5	4	6	2	5	27	2	9
21. No clean room	0	0	1	0	0	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	3	0	0	0	0	0	3		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	0	1	0	0	1	0	2		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	1	1	1	0	1	1	5		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	2	1	0	3		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	2	0	0	1	3	1	2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	0	0	0	0	0		1

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	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.	7	6	2	6	8	5	34	1	27
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	2	0	2	0	1	1	6		
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	1	1	2	3	2	3	12		
29. Unlawful compounding for further distribution by other entities	1	2	0	3	3	3	12		
30. Security of after-hours stock not in compliance	0	0	0	0	0	0	0		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	14	8	12	10	14	4	62	4	12
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	1	1	1	0	0	0	3		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	2	0	0	1	3	1	7		1

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
Routine Inspections Completed	184	232	206	232	218	218	1290	Repeat	Repeat
Total Deficiencies	275	317	338	302	259	228	1491	13	248
Average Deficiencies per Inspection	1.5	1.4	1.6	1.3	1.2	1.0	1.2		
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	1	0	0	0	0	0	1		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	4	3	4	7	6	4	28		5
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	9	1	5	4	5	3	27		7
106. Prescription department substantially not clean and sanitary and in good repair	2	0	2	1	0	0	5		2
107. Current dispensing reference not maintained	6	1	6	4	1	3	21	1	10
108. Emergency access alarm code/key not maintained in compliance	8	13	16	18	17	15	87	1	15
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)	35	33	33	27	38	38	204		27
110. Storage of paraphernalia/Rx devices not in compliance	0	2	0	0	0	0	2		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	1	5	1	2	1	1	11		1
112. Biennial taken late but within 30 days	0	1	2	1	3	1	8		
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.	26	37	25	40	28	32	188	5	48

Virginia Board of Pharmacy
Inspection Report
September 25, 2018

Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	3	5	9	10	4	7	38		
115. Other records of distributions not maintained as required	3	3	3	0	2	1	12		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	5	3	4	4	4	4	24		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	0	1	0	1	0	0	2		
119. Not properly documenting partial filling of prescriptions	5	5	6	10	8	4	38		24
120. Offer to counsel not made as required	7	7	2	2	0	0	18		
121. Prospective drug review not performed as required	1	0	1	0	0	0	2		
122. Engaging in alternate delivery not in compliance	9	19	18	14	15	16	91	2	6
123. Engaging in remote processing not in compliance	10	3	5	9	12	7	46		2
124. Labels do not include all required information	16	15	15	15	17	16	94	2	13
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	4	6	8	5	5	3	31		5
126. Special packaging not used or no documentation of request for non-special packaging	2	0	1	0	2	1	6		4
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	18	26	41	33	21	18	157	1	21
128. Unit dose procedures or records not in compliance	0	0	0	0	0	0	0		
129. Robotic pharmacy systems not in compliance	0	1	0	0	0	2	3		
130. Required compounding/dispensing/distribution records not complete and properly maintained	6	9	10	5	8	9	47	1	12
130a. Compounded products not properly labeled	30	60	42	18	9	10	169		8

Virginia Board of Pharmacy
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Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	3	3	6	0	1	5	18		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	15	9	14	8	7	6	59		1
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	3	3	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	0	1	0	1	2	1	5		
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	2	0	0	1	0	1	4		
139. Emergency medical services procedures or records not in compliance	3	1	3	3	2	0	12		4
140. Emergency kit or stat-drug box procedures or records not in compliance	0	0	3	3	4	0	10		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	22	15	24	17	16	16	110		9
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	1	1	0	0	1	1	4		

Virginia Board of Pharmacy
Inspection Report
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Deficiencies

	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	3/18-5/18	6/18-8/18	Total	6/18-8/18	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)	6	15	14	9	9	1	54		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	3	2	0	5	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	4	9	14	4	0	35		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	8	3	1	16	2	1	31		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)						1	1		3

Inspection Deficiencies
September 2012 through August 2018
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Virginia Board of Pharmacy
September 25, 2018
Inspections Completed
300
250
200
150
100
50
0
60%
50%
40%
30%
20%
10%
0%
Percent Of Total Deficiencies
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

Discipline Program Report

Staffing:
Ileita Redd and Rose DeMateo have been assisting in the absence of Kennia Butler, Discipline Program Specialist. We also utilized overtime assistance from Donna Lee with the Board of Dentistry.

Open Cases as of 8/24/18:

Patient Care Cases	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
	43	9	61	6	11	0	130
Non-Patient Care Cases	117	4	29	0	1	16	167
							297

Notes:

1) We have 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.
2) Five patient care cases exceed 250 work days (this is substantially below our 10% threshold for open cases).
3) 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.
4) Possible summary suspension cases have tapered down to a more normal volume.

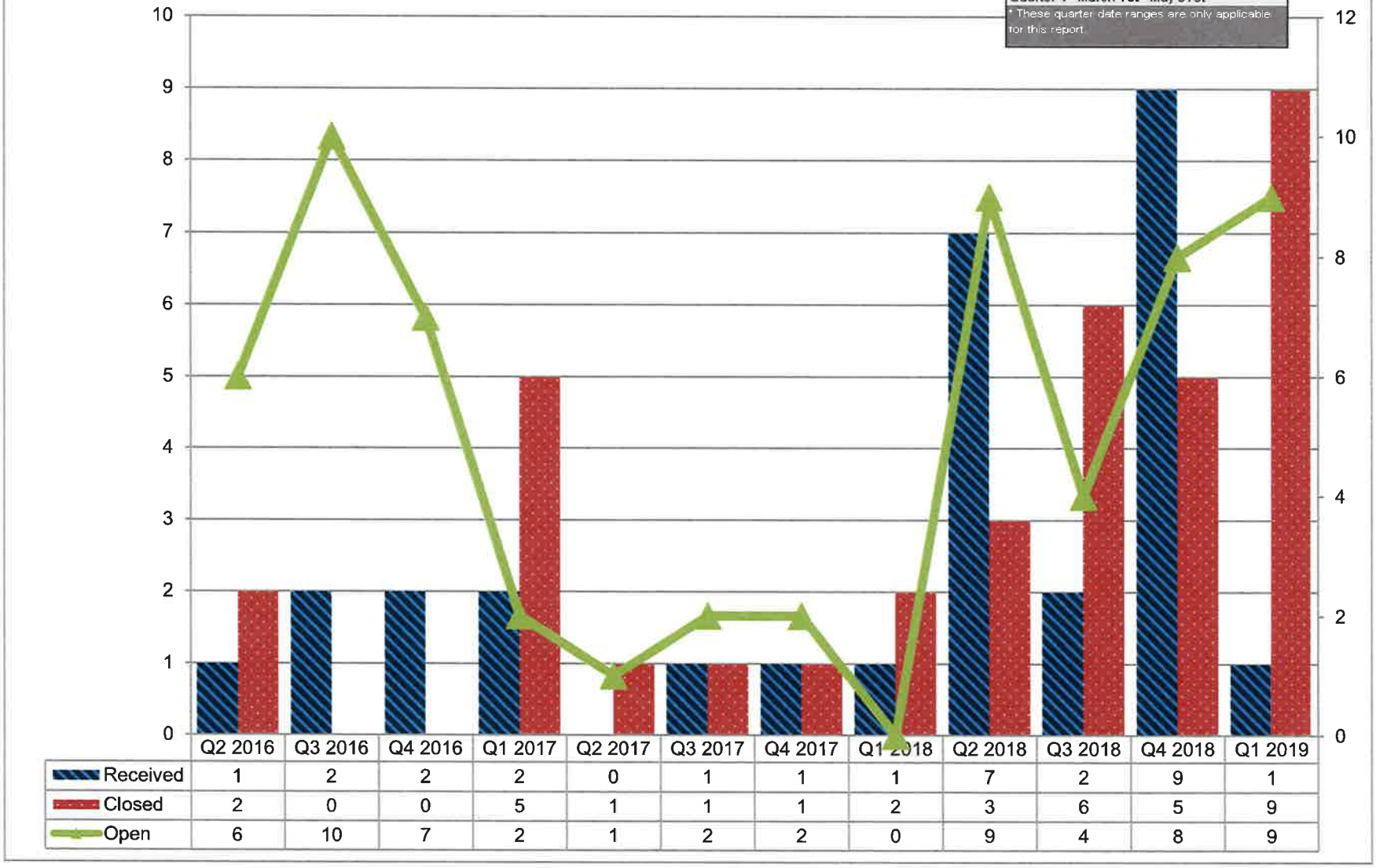
Upcoming Disciplinary Proceedings:

October 17, 2018	SCC-A	Rafael Saenz and Patricia Richards-Spruill
October 25, 2018	Formal Hearings	
November 27, 2018	SCC-C	Cindy Warriner and Melvin Boone
November 28, 2018	Formal Hearings	
December 12, 2018	SCC-B	Ryan Logan and Kris Ratliff
December 17, 2018	SCC-A	Rafael Saenz and Patricia Richards-Spruill
December 18, 2018	Formal Hearings	

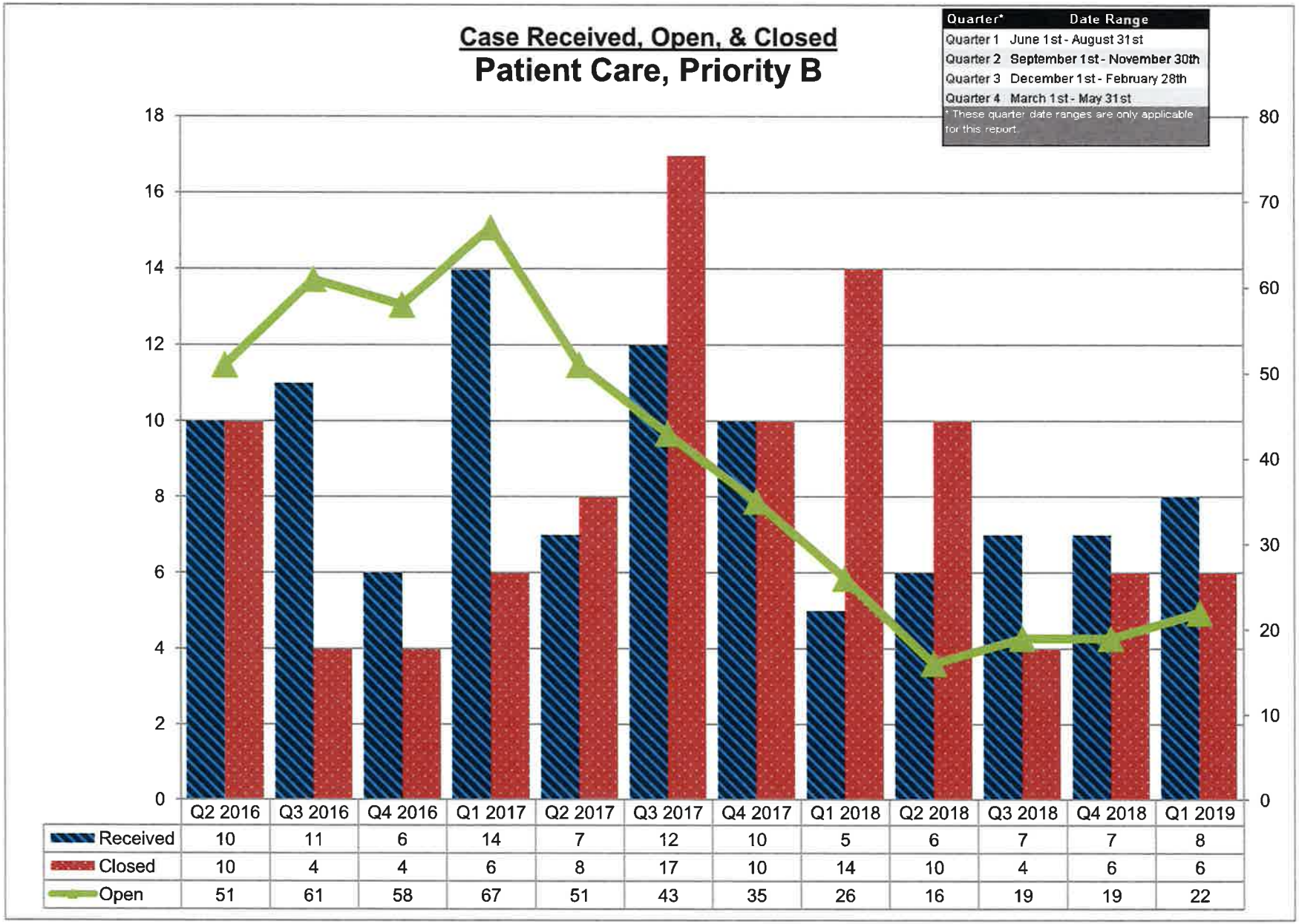
Case Received, Open, & Closed
Patient Care, Priority A

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

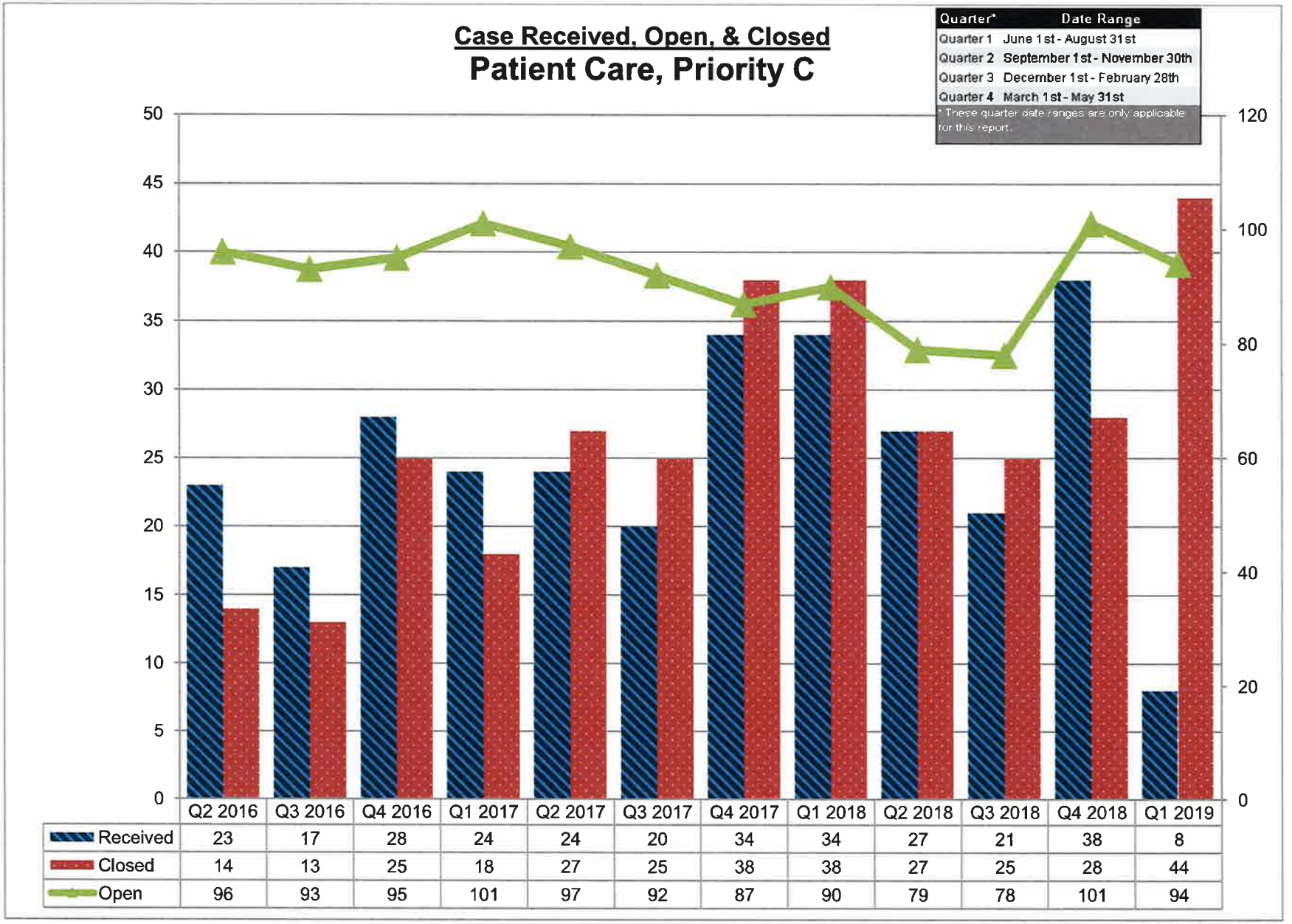
* These quarter date ranges are only applicable for this report.



	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	1	2	2	2	0	1	1	1	7	2	9	1
Closed	2	0	0	5	1	1	1	2	3	6	5	9
Open	6	10	7	2	1	2	2	0	9	4	8	9



	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	10	11	6	14	7	12	10	5	6	7	7	8
Closed	10	4	4	6	8	17	10	14	10	4	6	6
Open	51	61	58	67	51	43	35	26	16	19	19	22

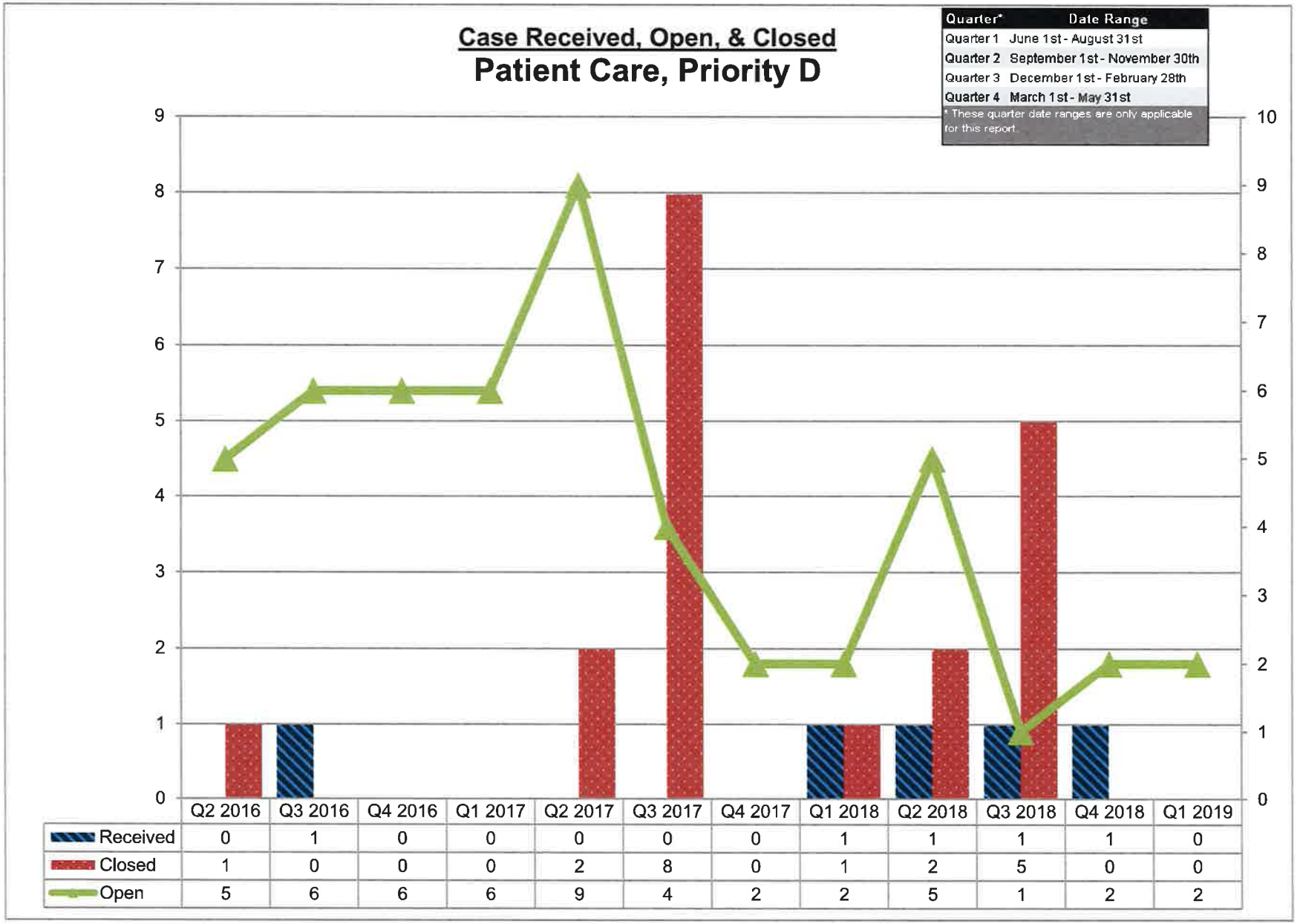


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	23	17	28	24	24	20	34	34	27	21	38	8
Closed	14	13	25	18	27	25	38	38	27	25	28	44
Open	96	93	95	101	97	92	87	90	79	78	101	94

Case Received, Open, & Closed
Patient Care, Priority D

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report.

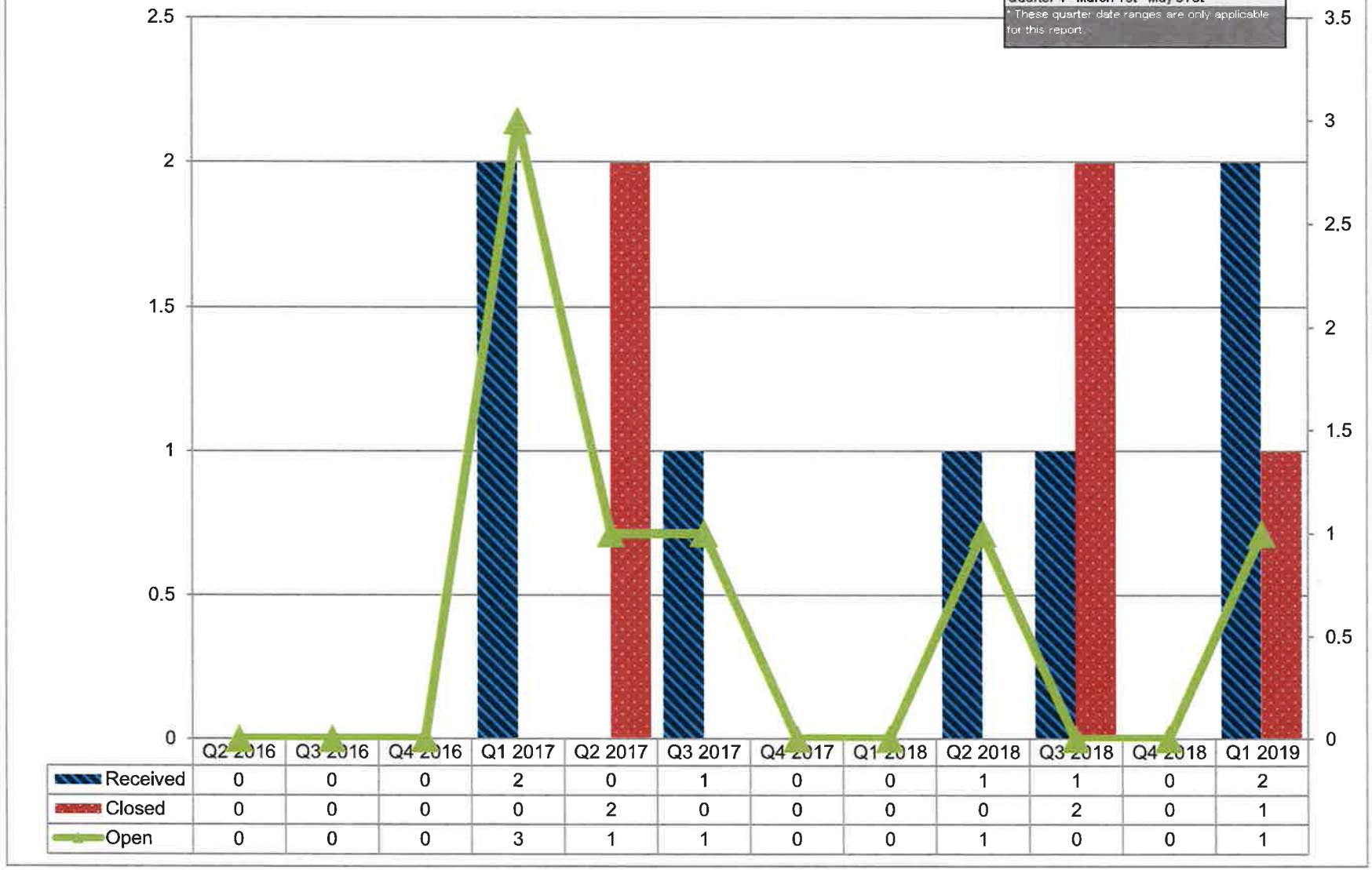


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	0	1	0	0	0	0	0	1	1	1	1	0
Closed	1	0	0	0	2	8	0	1	2	5	0	0
Open	5	6	6	6	9	4	2	2	5	1	2	2

Case Received, Open, & Closed
Non-Patient Care, Priority A

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report.

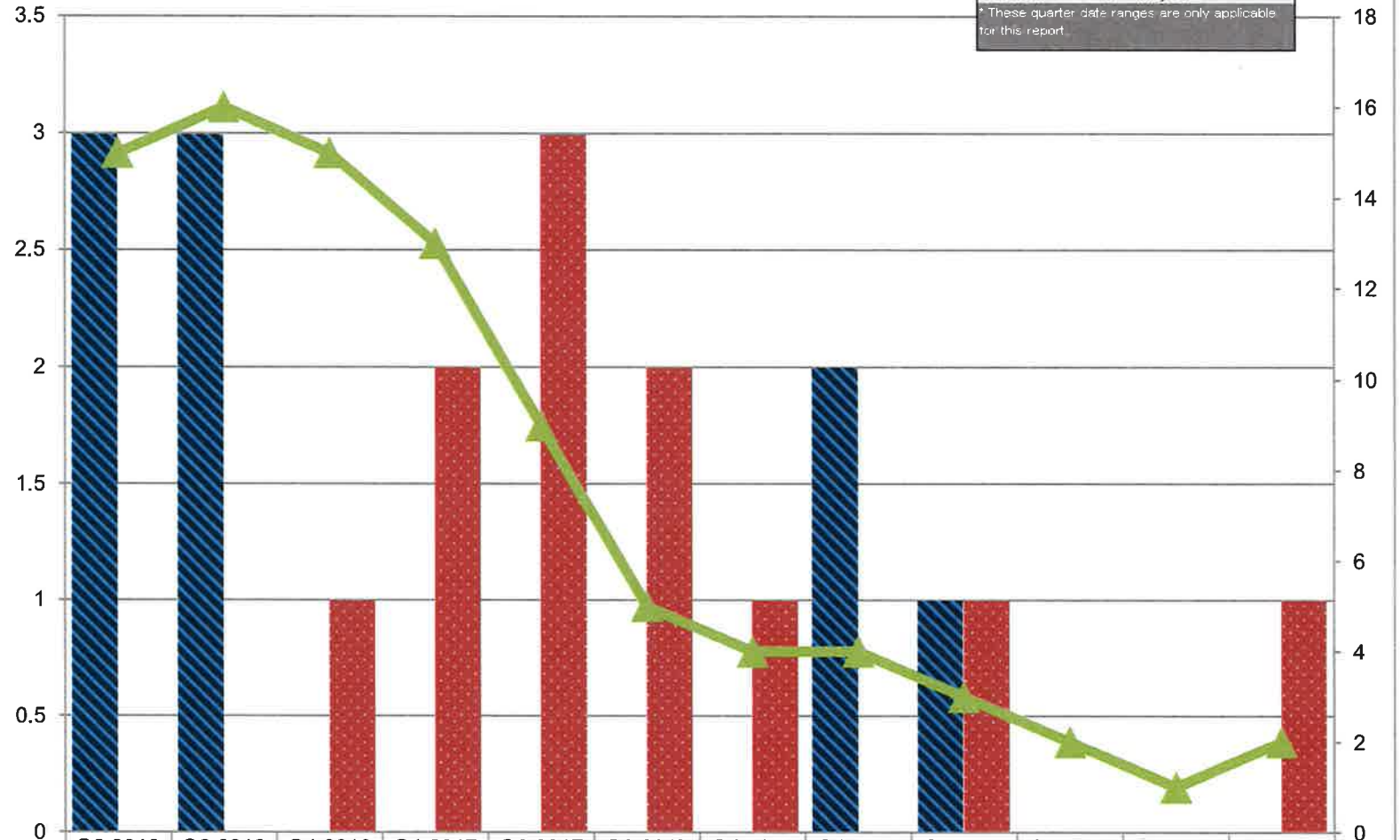


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	0	0	0	2	0	1	0	0	1	1	0	2
Closed	0	0	0	0	2	0	0	0	0	2	0	1
Open	0	0	0	3	1	1	0	0	1	0	0	1

Case Received, Open, & Closed
Non-Patient Care, Priority B

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report.

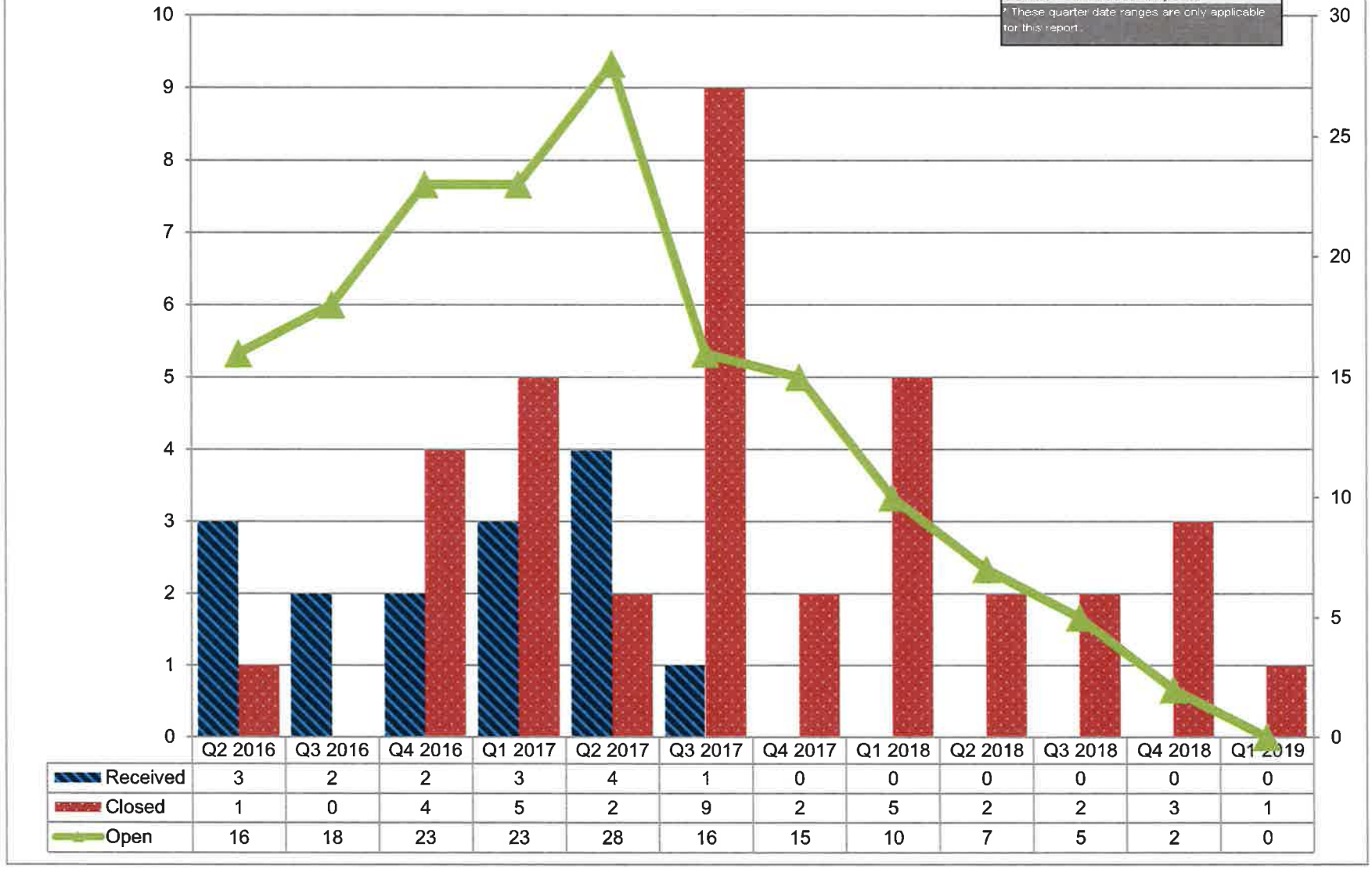


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	3	3	0	0	0	0	0	2	1	0	0	0
Closed	0	0	1	2	3	2	1	0	1	0	0	1
Open	15	16	15	13	9	5	4	4	3	2	1	2

Case Received, Open, & Closed
Non-Patient Care, Priority C

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report.

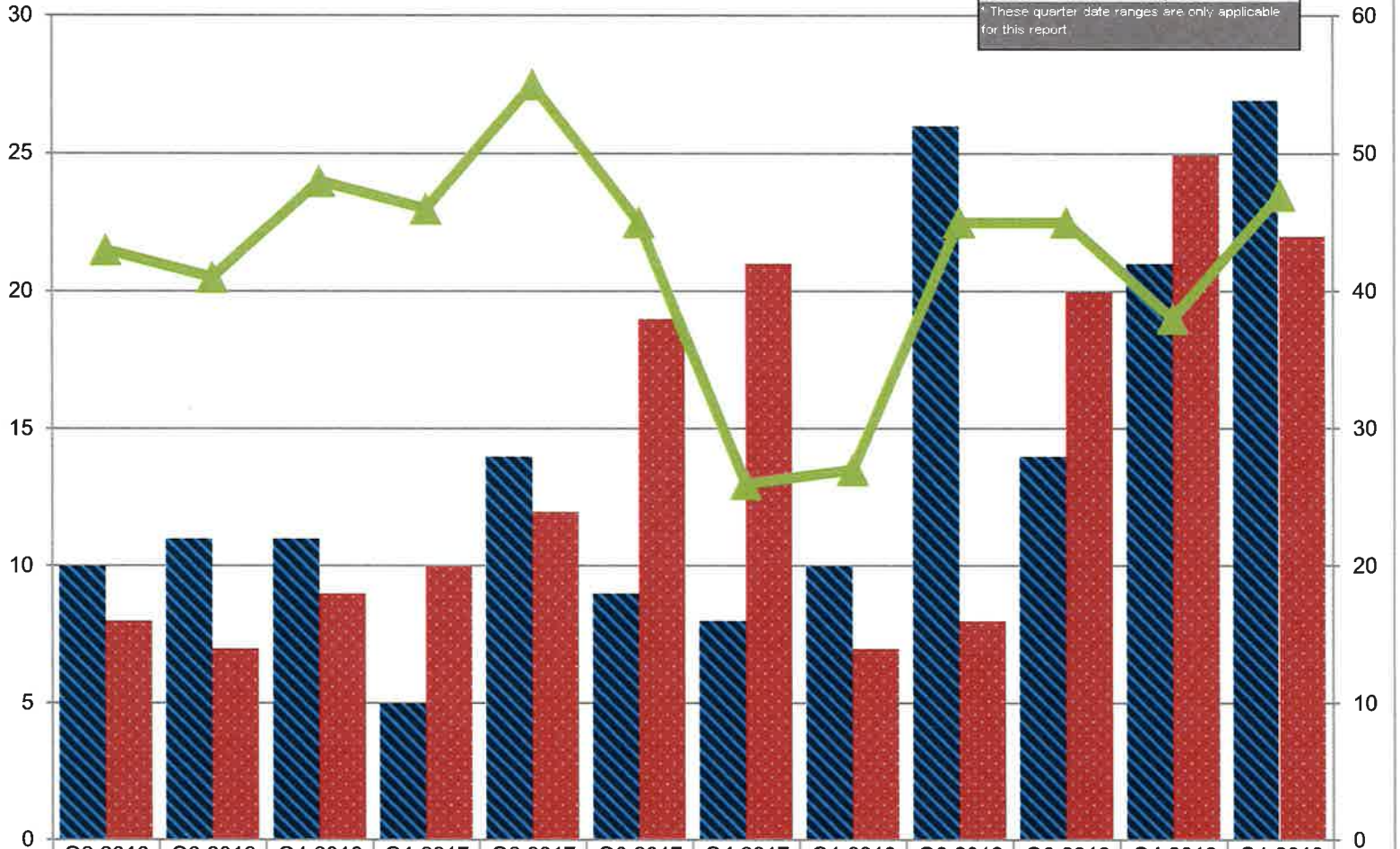


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	3	2	2	3	4	1	0	0	0	0	0	0
Closed	1	0	4	5	2	9	2	5	2	2	3	1
Open	16	18	23	23	28	16	15	10	7	5	2	0

Case Received, Open, & Closed
Non-Patient Care, Priority D

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report

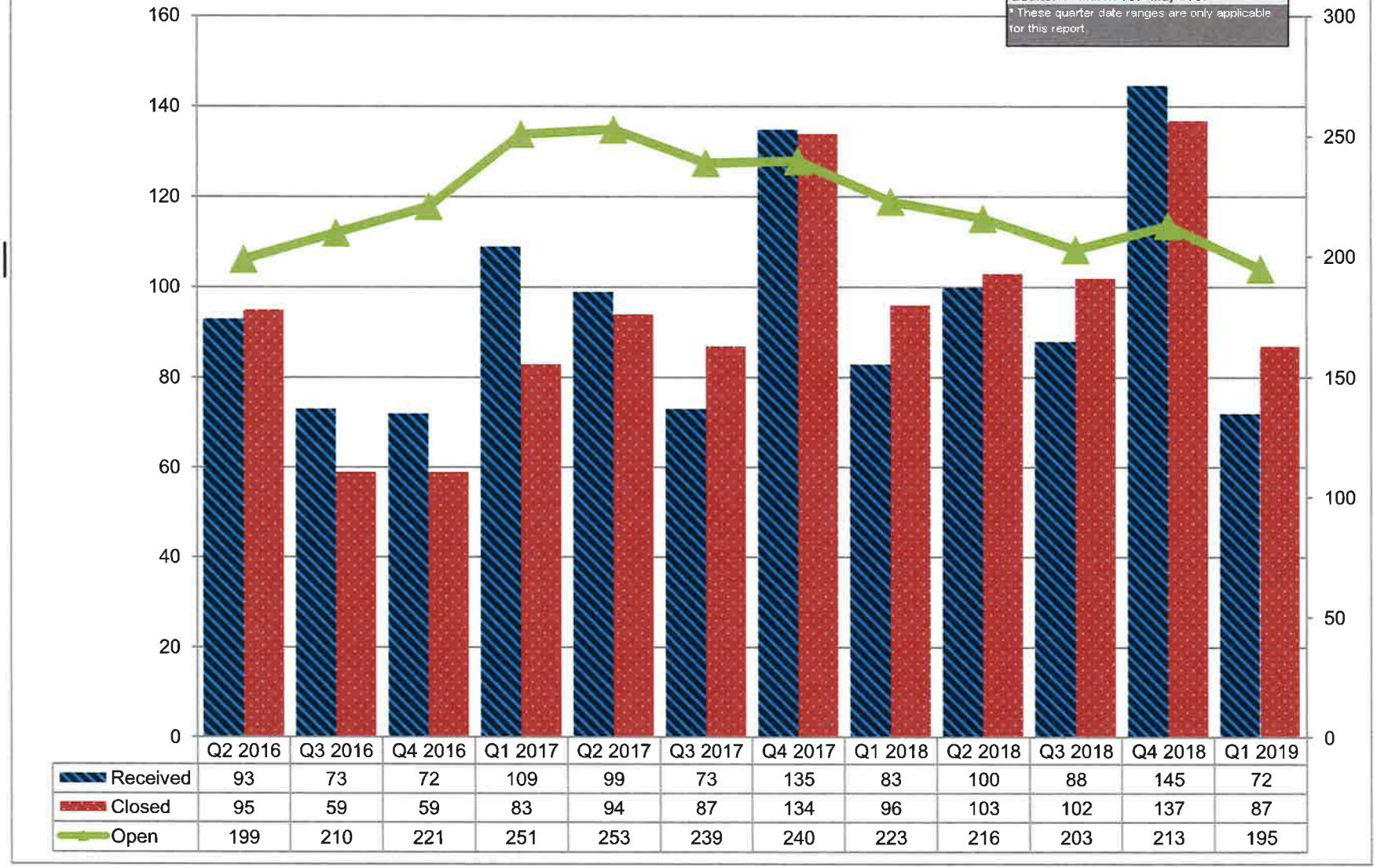


	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	10	11	11	5	14	9	8	10	26	14	21	27
Closed	8	7	9	10	12	19	21	7	8	20	25	22
Open	43	41	48	46	55	45	26	27	45	45	38	47

Case Received, Open, & Closed
Non-Patient Care, No Priority

Quarter*	Date Range
Quarter 1	June 1st - August 31st
Quarter 2	September 1st - November 30th
Quarter 3	December 1st - February 28th
Quarter 4	March 1st - May 31st

* These quarter date ranges are only applicable for this report



	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019
Received	93	73	72	109	99	73	135	83	100	88	145	72
Closed	95	59	59	83	94	87	134	96	103	102	137	87
Open	199	210	221	251	253	239	240	223	216	203	213	195