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 Regulation Committee Meeting

May 3, 2019

9AM

TOPIC	**PAGES**
Call to Order: Cindy Warriner, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Update on Regulatory/Policy Actions	1-4
• Recommendation on Proposed Regulations for Labeling Dispensed Prescriptions	5-13
• Recommendations on Final Regulations for Pharmaceutical Processors	14-73
• Recommendation on Number of Patients associated with Registered Agent – Emergency/Exempt Actions – Regulations for Pharmaceutical Processors	74-79
• Consideration of Possible 2020 Legislative Proposals	
o Pharmacy Technician Education Standards	80-100
o Compounding of Essentially Copies	101-104
o Telepharmacy	105-120
o White Bagging/Brown Bagging	121-124
• Consideration of Comments Received during Periodic Regulatory Review that Exceeded the Scope of the NOIRA	125-127
Adjourn	

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

Board of Pharmacy
Regulatory/Policy Actions – 2019 General Assembly

EMERGENCY REGULATIONS:

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

EXEMPT REGULATORY ACTIONS

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

NON-REGULATORY ACTIONS

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

HOUSE JOINT RESOLUTION NO. 662

Directing the Joint Commission on Health Care to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements, standing orders, and statewide protocols in the Commonwealth. Report.

Agreed to by the House of Delegates, February 21, 2019
Agreed to by the Senate, February 20, 2019

WHEREAS, a pharmacist practicing in the Commonwealth may only dispense drugs or devices pursuant to a valid prescription issued by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine licensed by the Board of Medicine; a physician assistant licensed by the Board of Medicine who has entered into a practice agreement with a licensed physician or podiatrist; a nurse practitioner licensed jointly by the Boards of Medicine and Nursing who has entered into a practice agreement with a patient care team physician or who meets the requirements for practice without a practice agreement; or a TPA-certified optometrist, or pursuant to a standing order or protocol or in accordance with a collaborative practice agreement; and

WHEREAS, the roles and responsibilities of pharmacists vary depending on the authority pursuant to which they dispense drugs or devices; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Joint Commission on Health Care be directed to study the dispensing of drugs and devices pursuant to prescriptions, pharmacy collaborative practice agreements, standing orders, and statewide protocols in the Commonwealth. In conducting its study, the Joint Commission on Health Care shall (i) review and evaluate laws and regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth, including the prescribing, dispensing, and administration of drugs and devices pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols; (ii) review the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in accordance with laws and regulations, including the roles and responsibilities of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols; such review shall include evaluation of the roles and responsibilities of pharmacists authorized to practice pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols conducting patient assessments and identifying appropriate drugs or devices for dispensing or administration; (iii) determine the legal liability of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices in the Commonwealth in accordance with laws and regulations, including the legal liability of pharmacists and other health care providers prescribing, dispensing, and administering drugs and devices pursuant to pharmacy collaborative practice, agreements, standing orders, and statewide protocols; (iv) identify any changes to such laws or regulations governing the prescribing, dispensing, and administration of drugs and devices in the Commonwealth, including the prescribing, dispensing, and administration of drugs and devices by pharmacists and other health care providers pursuant to pharmacy collaborative practice agreements, standing orders, and statewide protocols, that would enhance patient access to health care in the Commonwealth; and (v) develop specific proposals to implement changes identified, including proposed amendments to laws and regulations necessary to implement such changes. In conducting its study, the Joint Commission on Health Care shall provide for stakeholder input from the Department of Health, the Department of Health Professions, the Medical Society of Virginia, and the Virginia Pharmacists Association.

Technical assistance shall be provided to the Joint Commission on Health Care by the Board of Pharmacy. All agencies of the Commonwealth shall provide assistance to the Joint Commission on Health Care for this study, upon request.

The Joint Commission on Health Care shall complete its meetings for the first year by November 30, 2019, and the chairman shall submit to the Division of Legislative Automated Systems an executive summary of its findings and recommendations no later than the first day of the 2020 Regular Session of the General Assembly. The executive summary shall state whether the Joint Commission on Health Care intends to submit to the General Assembly and the Governor a report of its findings and recommendations for publication as a House or Senate document. The executive summary and report shall be submitted as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents and reports and shall be posted on the General Assembly's website.

Board of Pharmacy

Chart of Regulatory Actions as of April 26, 2019

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] NOIRA - *Register Date: 10/29/18* [Stage 8346] Committee to review 5/3/19
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Proposed - *At Governor's Office for 152 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *AT Attorney General's Office* [Stage 8585]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for pharmacy to be operational within 90 days [Action 5080] Fast-Track - *At Secretary's Office for 39 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Amending definition of "cold" [Action 5210] Fast-Track - *At Governor's Office for 12 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 338 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] Final - *At Governor's Office for 12 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling chemicals in Schedule I [Action 5211] Final - *Register Date: 3/4/19* *Effective: April 3, 2019*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling chemicals in Schedule I [Action 5261] Final - *AT Attorney General's Office* [Stage 8587]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 15 and 21 [Action 4538] Final - *At DPB* [Stage 8597]

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *AT Attorney General's Office* [Stage 8584]
[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 - *Register Date: 2/4/19 Effective: 3/22/19*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Proposed - *Register Date: 3/18/19* Comment from: 3/18/19 to 5/17/19

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

Enclosed:

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

Copy of comment on NOIRA

Draft proposed amendment to section 275

Excerpt from Board meeting on 12/18/18

Committee action:

1) Recommend draft proposed amendment; or
2) Revise proposed amendment for recommendation to Board.

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Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action: Delivery of dispensed prescriptions; labeling

Notice of Intended Regulatory Action (NOIRA)

Action 5093 / Stage 8346

Edit Stage | Withdraw Stage | Go to RIS Project

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

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

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
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Project 5715 - NOIRA

BOARD OF PHARMACY

Delivery of dispensed prescriptions; labeling

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

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

B. Delivery to another pharmacy.

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

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

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

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

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

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

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

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

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

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

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

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

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed

practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

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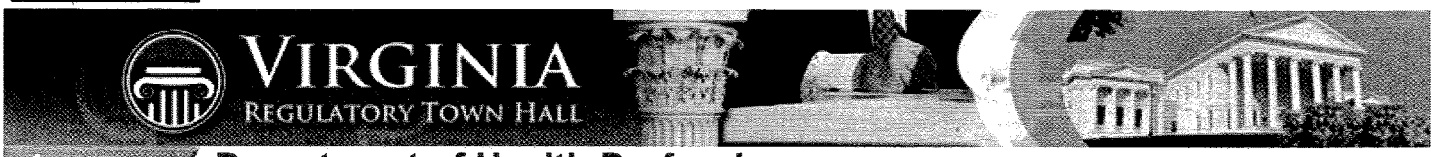

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

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

Back to List of Comments

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

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

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

effect until (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act." (motion by Warriner, second by Thornbury)

Amend 18VAC110-20-10, Storage Temperature Definition Reference to Freezer

USP has revised the allowable temperature range for drug storage in a freezer, therefore, the Board should consider amending regulation to conform to this standard. Historically, USP's definition for storage temperature in a freezer was between 20 and 10 degrees Celsius. The definition now is a "controlled temperature between 25 and 10 degrees Celsius" and that in "some instances articles may have a recommended storage condition below 20 degrees Celsius. In such cases, the temperature of the storage location should be controlled to +/- 10 degrees."

MOTION:

The Board voted unanimously to adopt a fast-track action to amend the meaning of "cold" within the definition of "storage temperature" in 18VAC110-20-10 by striking "maintained thermostatically between -20° and -10°C (-4° and 14°F)" following the phrase "A freezer is a cold place in which the temperature is" and replacing with "controlled between −25° and −10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20° C (-4°F), the temperature of the storage location should be controlled to +/-10°". (motion by Warriner, second by Jenkins)

Adoption of Final Regulations for E-Profile Requirement

Ms. Yeatts provided background on the proposed regulations and indicated that no public comment was received. The final regulations for consideration are identical to the proposed regulations. Applicants as well as renewal applicants would be required to provide the board with their e-profile ID number issued by NABP. Ms. Juran confirmed that most applicants already have an e-profile ID and there is no cost for obtaining the ID. Use of the e-profile ID will assist board staff in securely and efficiently communicating with NABP on licensure or disciplinary-related matters.

MOTION:

The Board voted unanimously to adopt final regulations to require pharmacists, pharmacy technicians and pharmacy interns to provide an e-profile ID number when applying for a new license or registration or renewing their license or registration. (motion by Nelson, second by Bolyard)

Adoption of Proposed Regulations for Labeling of Dispensed Medications

Ms. Yeatts reminded the Board that a petition for rulemaking was received on this subject and that the Board had adopted a NOIRA. She reported that comments received on the NOIRA generally favored rulemaking. One commenter did not support the petitioner's request for rulemaking. The Board now needed to consider the adoption of proposed regulations on the subject. The draft proposed regulations provided in the agenda packet amended 18VAC110-25-275(B) to clarify requirements for the policies and procedure manual when a pharmacy delivers a dispensed drug to another pharmacy. Additionally, it stated that the identity of the pharmacy solely involved in the holding of a prescription for pick-up or further delivery is not required on the prescription label, or may be included in a unique identifier, when that

pharmacy has not shared in other filling or dispensing functions. Ms. Warriner expressed concern for patients and other caregivers potentially not being able to identify both pharmacies on the prescription label. Ms. Thornbury agreed with Ms. Warriner's comments. It was stated that it may be confusing to the patient to have two phone numbers listed on the label and that it may be more appropriate to list only the number of the pharmacy that was involved in the dispensing of the drug. Ms. Yeatts reminded the Board that the action is still at the proposed stage so there will be an additional 60-day comment period for the public to provide comment on the proposed regulations.

MOTION:

The Board voted unanimously to refer the matter to the Regulation Committee for further consideration of the draft proposed regulatory language. (motion by Logan, second by Richards-Spruill)

Adoption of Fast-Track Regulation for Pharmacy Permit Recession

The Board previously adopted a proposed regulatory action to authorize the Board to rescind a pharmacy permit if the pharmacy did not become operational within a defined period. Counsel subsequently advised that the action was not consistent with statutory authority and needed to be revised. Ms. Juran reminded the Board that this action was intended to address concerns with what appears to be suspicious fraudulent activity. The revised language indicates that once a pharmacy permit is issued, a pharmacy must be operational within 90 days of issuance. The Board may grant an extension for good cause shown. If not operational and no extension is granted, the pharmacy would be subject to possible disciplinary action for violating the regulatory requirement.

MOTION:

The Board voted unanimously to adopt a fast track regulatory action to amend 18VAC110-20-140 by inserting a new subsection F that reads:

- **"Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension." (motion by Warriner, second by Nelson)**

Review of Guidance Documents

The Board completed its review of guidance documents that have not been reviewed or re-adopted in the past 4 years. Ms. Juran indicated that Guidance Document 110-43 should be amended to accurately reflect the current edition of the FDA's Orange Book.

MOTION:

The Board voted unanimously to amend sentences within the first paragraph of Guidance Document 110-43 in accordance with the underlined additions and strikethroughs listed below:

- **"However, according to the preface of the ~~32nd~~ 38th edition of the FDA's Orange Book, ~~page vii,~~ "Any drug product in the ~~List~~ Orange Book repackaged and/or distributed by other than the ~~application holder~~ applicant is considered to be therapeutically equivalent to the**

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

Enclosed:

Copy of Townhall notice

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

Proposed regulations as published

DRAFT changes recommended by staff

Staff note:

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

Comments on proposed regulations may be received until 5/17/19, so any comment received after the meeting of the Regulation Committee will go to full Board for its consideration.

Committee action:

1) Recommend draft proposed amendments; or
2) Revise proposed amendments for recommendation to Board.

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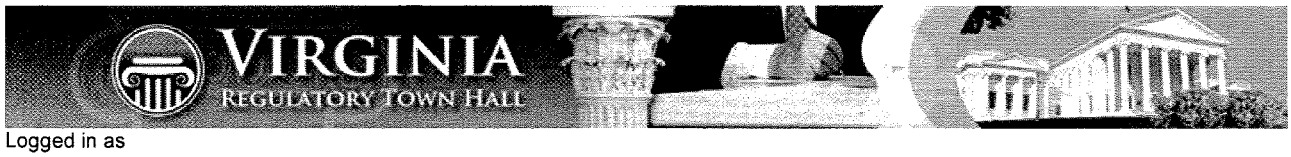

Logged in as
Elaine J. Yeatts

Agency Department of Health Professions

Board Board of Pharmacy

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

Action: New regulations

Proposed Stage

Action 4695 / Stage 8484

Edit Stage | Withdraw Stage | Go to RIS Project

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

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

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

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

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

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

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

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

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT: James L. Jenkins, Jr.

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

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

A powerful synthetic opioid:

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

Research chemicals:

- alpha-pyrrolidinoisohexiophenone (other name: alpha-

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

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

PULIC COMMENT:

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

No other comment on this subject was provided.

CALL FOR PUBLIC COMMENT:

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

PUBLIC COMMENT:

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

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

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

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

ADJOURN:

The public hearing adjourned at 9:25am.

Project 4878 - Proposed

BOARD OF PHARMACY

New regulations

CHAPTER 60

REGULATIONS GOVERNING PHARMACEUTICAL PROCESSORS

Part I

General Provisions

18VAC110-60-10. Definitions.

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

"90-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients, which cannot exceed 60 fluid ounces.

"Board" means the Board of Pharmacy.

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

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

1. Variation from the intended oil to be dispensed, including:

a. Incorrect oil;

b. Incorrect oil strength;

c. Incorrect dosage form;

d. Incorrect patient; or

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

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

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

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

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

3. Delivery of an oil to the incorrect patient.

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

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

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

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

"PIC" means the pharmacist-in-charge.

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

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

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

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

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

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

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

18VAC110-60-20. Fees.

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

B. Registration of practitioner.

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

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

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

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000
4. Change of name of processor.	$100

5. Change of PIC or any other information provided on the permit application.	$100
6. 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 a practitioner issuing a certification.

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

B. A practitioner issuing a certification shall:

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

2. Diagnose the patient;

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

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

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

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

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

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

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

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

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

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

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

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

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

A. A practitioner who issues certifications shall not:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5. Payment of the appropriate fees; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Part III

Application and Approval Process for Pharmaceutical Processors

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

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

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

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

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

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

B. Submission of initial application.

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

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

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

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

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

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

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

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

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

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

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

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

k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and oils; (iii) the location of all areas that may contain

Cannabis plants, cannabidiol oil, or THC-A oil; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;

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

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

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

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

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

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

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

18VAC110-60-120. Conditional approval.

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

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

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

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

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

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

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

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

C. The board may disqualify any applicant who:

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

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

3. Fails to pay all applicable fees; or

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

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

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

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

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

1. Designation of a PIC;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Notify the board;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Part IV

Requirements for Pharmaceutical Processor Personnel

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

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

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

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

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

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

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

4. The measuring of the oil to be dispensed;

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

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

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

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

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

E. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience

cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

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

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

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

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

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

18VAC110-60-180. Employee training.

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

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

2. Procedures and instructions for responding to an emergency;

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

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

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

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

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

1. The name of the person receiving the training;

2. The dates of the training;

3. A general description of the topics covered;

4. The name of the person supervising the training; and

5. The signatures of the person receiving the training and the PIC.

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

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

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

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

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

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

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

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent or legal guardian regarding (i) cannabidiol oil, THC-A oil, or other drugs either before or after cannabidiol oil or THC-A oil has been dispensed or (ii) any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking;

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

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

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

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

A. No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.

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

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

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

2. All record retention requirements are met;

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

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

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

a. Pharmaceutical processor permit;

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

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

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

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

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

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

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

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

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

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

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

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

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

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

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

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

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

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

I. The pharmaceutical processor shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

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

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

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

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

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

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

1. Name and location of the processor;

2. Contact information for the processor;

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

4. Laboratory results;

5. Product information and pricing; and

6. Directions to the processor facility.

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

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

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

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

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

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

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

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

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

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor prior to commencing business shall:

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

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

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

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

THC-A oil was sold; the kind and quantity of cannabidiol oil or THC-A oil sold or disposed of; and the method of disposal.

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

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

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

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

18VAC110-60-240. Security requirements.

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

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

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

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

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

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

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

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

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

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

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

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

3. The device shall fully protect the entire processor facility and shall be capable of detecting breaking by any means when activated;

4. The device shall include a duress alarm, a panic alarm, and an automatic voice dialer; and

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

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

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

2. The video system shall have:

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

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

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

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

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

4. The processor shall make 24-hour recordings from all video cameras available for immediate viewing by the board or the board's agent upon request and shall retain the recordings for at least 30 days. If a processor is aware of a pending criminal, civil, or administrative investigation or legal proceeding for which a recording may contain relevant information, the processor shall retain an unaltered copy of the recording until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the pharmaceutical processor PIC that it is not necessary to retain the recording.

D. The processor shall maintain all security system equipment and recordings in a secure location so as to prevent theft, loss, destruction, or alterations. All security equipment shall be maintained in good working order and shall be tested at least every six months.

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

processor shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor. The pharmaceutical processor shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

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

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

A. A pharmaceutical processor shall:

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

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

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

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

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

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

1. Restrict movement between compartments;

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

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

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

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

1. Handling mandatory and voluntary recalls of cannabidiol oil or THC-A oil. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor to (i) remove defective or potentially defective cannabidiol oil or THC-A oil from the market or (ii) promote public health and safety by replacing existing cannabidiol oil or THC-A oil with improved products or packaging;

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

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

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

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

18VAC110-60-260. Recordkeeping requirements.

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

1. Guarantees the confidentiality of the information contained in the system;

2. Is capable of providing safeguards against erasures and unauthorized changes in data after the information has been entered and verified by the pharmacist; and

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

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

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

A. Upon becoming aware of (i) diversion, theft, loss, or discrepancies identified during inventory; (ii) unauthorized destruction of any cannabidiol oil or THC-A oil; or (iii) any loss or unauthorized alteration of records related to cannabidiol oil or THC-A oil or qualifying patients, a pharmacist or pharmaceutical processor shall immediately notify appropriate law-enforcement authorities and the board.

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

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

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

2. A breach of security;

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

4. Corrective measures taken if any.

D. A pharmacist or pharmaceutical processor shall immediately notify the board of an employee convicted of a felony or any offense referenced in § 54.1-3442.6 of the Code of Virginia.

Part VI

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

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

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

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

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

18VAC110-60-285. Registration of products.

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

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD);

4. Cannabidiolic acid (CBDA); and

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

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

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

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

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

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

4. Is obscene or indecent;

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

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

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

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

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

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

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

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

2. Labeled with:

a. The name and address of the pharmaceutical processor;

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

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

d. The date of testing and packaging;

e. The expiration date;

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

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

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD);

(4) Cannabidiolic acid (CBDA); and

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

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

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

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

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

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

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

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

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

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A); and

c. Cannabidiol (CBD);

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

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

9. The name of the certifying practitioner;

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

11. Name and address of the pharmaceutical processor; and

12. Any cautionary statement required by statute or regulation.

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

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

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

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

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical

processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

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

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

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

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

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 body weight/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 Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.

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

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

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

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

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

2. The name or kind of cannabidiol oil or THC-A oil and its strength;

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

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

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

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

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

8. 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 necessary cautionary statement; 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 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 the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor. The policies and procedures shall include:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated Cannabis plants, including seeds, parts of plants, extracts, cannabidiol oil, or THC-A oil by

disposal in accordance with a plan approved by the board and in a manner as to render the cannabidiol oil or THC-A oil nonrecoverable.

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

1. The date and time of disposal;

2. The manner of disposal;

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

4. The signatures of the persons disposing of the cannabidiol oil or THC-A oil.

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

FORMS (18VAC110-60)

Application for registration of a patient, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a parent or legal guardian, online form available at https://www.license.dhp.virginia.gov/apply

Application for registration of a practitioner to issue certifications, online form available at https://www.license.dhp.virginia.gov/apply

Application for a pharmaceutical processor

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

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

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

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

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

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

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

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

2. The name or kind of cannabidiol oil or THC-A oil and its strength;

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

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

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

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

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

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

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

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

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

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

Statutory Authority

§§ 54.1-2400 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume , Issue , eff. Month dd, yyyy.

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Agenda Item: Emergency/Exempt Actions – Regulations for Pharmaceutical Processors

Enclosed:

Copy of SB1557 and SB1719 of the 2019 General Assembly

Staff note:

SB1719 requires the adoption of emergency regulations regarding the registration of agents for patients certified to receive cannabidiol or THC-A oil. The Board will not be able to adopt emergency regulations until final regulations are effective (August 2019). Since the Regulation Committee is not scheduled to meet again prior to the September Board meeting, it should discuss the limit that should be set on the number of patients for whom any individual is authorized to act as an authorized agent.

SB1557 has provisions that will require changes in regulations that may be adopted as an exempt action in September.

CHAPTER 690

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

[S 1719]

Approved March 21, 2019

Be it enacted by the General Assembly of Virginia:

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

§ 18.2-250.1. Possession of marijuana unlawful.

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

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

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

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

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

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

A. As used in this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

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

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

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

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

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

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

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

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

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

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

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

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

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

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

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

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

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

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

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

VIRGINIA ACTS OF ASSEMBLY -- 2019 SESSION

CHAPTER 681

An Act to amend and reenact §§ 54.1-3408.3 and 54.1-3442.6 of the Code of Virginia, relating to Board of Pharmacy; cannabidiol oil and THC-A oil; regulation of pharmaceutical processors.

[S 1557]

Approved March 21, 2019

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3 and 54.1-3442.6 of the Code of Virginia are amended and reenacted as follows:

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

A. As used in this section:

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

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, *a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.*

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

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

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

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

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

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

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

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

to information related to such registered patient.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

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

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

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (x) the secure disposal of plant remains; ~~and~~ (xi) a process for registering a cannabidiol oil and THC-A oil product; *and (xii) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol.*

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

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

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

2. That the Secretary of Health and Human Resources and the Secretary of Agriculture and Forestry shall convene a work group to review and recommend an appropriate structure for oversight in Virginia. The work group shall report, by November 1, 2019, its findings and recommendations to the Chairmen of the Senate Committees on Agriculture, Conservation and Natural Resources and Education and Health and the House Committees on Agriculture, Chesapeake and Natural Resources and Health, Welfare and Institutions.

Agenda Item: Consideration of Possible 2020 Legislative Proposals – Pharmacy Technician Education Standards

Enclosed:

Excerpt from March 2019 full board meeting draft minutes regarding comment received

Written comment received from NCPA and NHA at March 2019 meeting

Copy of Florida Regulation referenced in comment received at March 2019 meeting

Model Law from NABP regarding Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates

Draft Legislative Proposal Option 1 and Option 2

Committee action:

1. Recommend adoption of legislative proposal option 1 or option 2 as presented or amended;
2. Recommend no action

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

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

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

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

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT: James L. Jenkins, Jr.

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

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

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

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

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

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

in Schedule I

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

(motion by Bolyard, second by Boone)

PUBLIC COMMENTS:

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

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

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

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

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

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

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

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

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

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

DHP DIRECTOR'S REPORT:

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

March 25, 2019

Caroline Juran
Executive Director, Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Dear Ms. Juran,

I am writing to you today on behalf of the National Community Pharmacists Association (NCPA) regarding the Virginia Board of Pharmacy's upcoming preliminary discussion of 2020 legislative proposals related to pharmacy technician training requirements.

The National Community Pharmacists Association (NCPA) represents the interests of America's community pharmacists, including the owners of more than 22,000 independent community pharmacies across the United States and 353 independent community pharmacies in Virginia. Together, they represent a $76 billion health care marketplace and employ over 250,000 people. Our members are small business owners who are among America's most accessible health care providers.

The proposed language to amend the *Code of Virginia* 54.1-3300 and 54.1-3321 would require all pharmacy technicians to complete a training program accredited by the American Society of Health-Systems Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE). NCPA supports quality training programs to adequately prepare the pharmacy technician workforce; however, we have serious concerns that this language inappropriately delegates the Board's authority to regulate pharmacy technicians to ASHP, is too restrictive, and will cause unintended negative financial and workforce supply effects.

NCPA recommends against changes to the *Code of Virginia* that take away the Board's ability to and adopt and modify policies that approve, by extension, any pharmacy technician program accredited by a specified accreditation program (e.g. ASHP/ACPE, Accreditng Bureau of Health Education Schools) and any certification program accredited by a specified accreditiaon program (e.g. National Commission for Certifying Agencies).

Currently, only two pharmacy technician training programs within the state of Virginia are accredited by ASHP/ACPE. Additionally, the majority of Virginia pharmacy technicians receive their training from employer-based programs, of which 60 are approved by the Board but only 12 are accredited by ASHP/ACPE. If these and other Board-approved but non-ASHP/ACPE-accredited programs, such as career and technical education (CTE) programs, are no longer allowed to offer

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training without this specific accreditation, this could create serious access issues for pharmacy technicians and trainees. The proposed language also places pharmacy technicians trained by a branch of the U.S. military at a serious disadvantage when transitioning to the civilian workforce in Virginia.

NCPA encourages the Board to reconsider the proposed bill language and to expand the language to encompass additional quality training programs for pharmacy technicians, including programs provided through a branch of the U.S. military, CTE programs that comply with the Virginia Department of Education Curriculum Framework for Pharmacy Technician II, and employer-based programs approved by the Board. NCPA also encourages the Board to consider language that does not limit it from adopting policies that allow registerting technicians who have sufficient work experience in another state to meet the competencies of an accredited training program.

Sincerely,

Lisa A. Schwartz

Lisa Schwartz, PharmD, RPh
VA License 0202210413
Senior Director, Professional Affairs
National Community Pharmacists Association

cc: Members of the Virginia Board of Pharmacy

nha

Jessica Langley
National Healthcareer Association
11161 Overbrook Road
Leawood, KS 66211

March 22, 2019

By Overnight Delivery and Email
Virginia Board of Pharmacy
C/O Caroline Juran, Exec. Director
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463

NHANOW.COM

RE: Amending of the *Code of Virginia* 54.1-3300 and 54.1-3321

Dear Caroline Juran and Virginia Board of Pharmacy,

We, at NHA, support the Board's continued efforts to establish and revisit Pharmacy Technician rules pertaining to education, training and certification requirements. We share your goals and desires to advance the pharmacy technician profession and empower these individuals with the appropriate resources to have a successful career.

We understand that the Board may consider a bill to amend the *Code of Virginia* 54.1-3300 and 54.1-3321, relating, in part, to registration as a pharmacy technician. NHA notes that its name is misstated in the draft and requests that it is corrected from National Healthcare Association to National Healthcareer Association.

Additionally, NHA will like to take this opportunity to raise concerns about the changes proposed to the education requirements for pharmacy technicians. The draft language as written provides:

> *54.1-3321 C. "To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he has successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcare Association."*

While we agree that education is a key component to entering the pharmacy technician profession, the proposal will prohibit many qualified individuals from becoming registered as a Pharmacy Technician in the Commonwealth of Virginia. It may also have a negative impact on workforce supply and demand in a profession that is already experiencing shortfalls when compared to demand. It is also important to note that it will almost certainly place an increased financial hinderance on individuals wanting to enter this profession.

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nha

Currently, a large majority of Virginia pharmacy technicians are trained via employer-based training programs and non-accredited ASHP educational programs which typically are at no-cost or low cost to the individual. The restructuring of these programs to become ASHP/ACPE accredited will likely lead to increased costs for students in tuition-based programs, the closing of programs that find the cost prohibitive or that serve a student community that cannot afford tuition increases and, for some retail pharmacies, a quandary about whether expanding the scope of their training program to include hospital pharmacy practices that are not applicable to retail practice makes risk management, employee retainment and financial sense.

NHA agrees that the curriculum accredited by ASHP/ACPE is comprehensive. A large number of pharmacy technicians certified by NHA have completed training programs accredited by ASHP/ACPE. That said, only two of the educational institutions listed on the Board's posted list of approved pharmacy technician programs are also listed on the ASHP/ACPE list of accredited programs, -- American National University and Piedmont Virginia Community College. *See* https://accred.ashp.org/aps/pages/directory/technicianProgramDirectory.aspx, last visited March 19, 2019. There are many other postsecondary programs included on the Board's Directory of Approved Pharmacy Technician Training Programs that do not have ASHP/ACPE accreditation.

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Similarly, there are approximately 60 employer-based pharmacy technician training programs currently recognized by the Board, but roughly 12 of those programs hold some form of ASHP/ACPE accreditation.[1] Nationally, approximately half of all pharmacy technicians receive their training on-the-job in the retail pharmacy setting. Thus, the impact on the supply of pharmacy technicians in Virginia may be substantially reduced if the remaining employer-based programs are no longer viable routes for pharmacy technicians to meet the Board's registration requirements.

The proposal also excludes individuals that receive training in career and technical education (CTE) programs within Virginia's secondary institutions. Currently there are thirteen (13) school systems and technical programs noted on the Virginia Board of Pharmacy approved training program list. Many of these programs have been approved for and accept federal Perkins funds. A requirement for obtaining these federal funds is that these CTE programs demonstrate the effectiveness of their programs. Accordingly, pharmacy technician students in these programs must obtain a recognized industry credential, such as the CPhT, so that the CTE programs may continue to receive Perkin funds.

We would also like to note that there is no pathway identified for individuals completing their pharmacy technician training in a branch of the U. S. military. NHA works very closely to form partnerships with our military programs to reduce the burden on servicemembers transitioning from active duty to civilian workforce.

[1] Earlier this year, new standards were introduced by ASHP/ACPE. It is unclear what impact the new standards will have on the number of retail training programs that will be able to maintain their accreditation,

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nha

We would like to recommend the following language:

54.1-3321 C. "To be registered as a pharmacy technician, a person shall:
(i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration;
(ii) provide satisfactory evidence that he has successfully completed a training program that meets the criteria approved by the Board in regulation or one of the following criteria:
a. accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education; or
b. provided by a branch of the federal armed services; or
c. training programs which have been approved by the Board and are listed on the Board's Directory of Approved Pharmacy Technician Training Programs until such time the Board removes any program listed therein, or
d. any other programs approved by the Board hereafter.
(iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcareer Association."

We respectfully request your consideration of correcting our organization name and allowing for further discussion regarding the points noted above.

Sincerely,

Jessica Langley
Executive Director of Education and Provider Markets
National Healthcareer Association

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Florida Regulation

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.

Pursuant to section 465.014, F.S., in order to be registered as a pharmacy technician in Florida, an applicant must have completed a pharmacy technician training program approved by the Board. The standards for approval of a registered pharmacy technician training program are as follows.

(1) Preapproved pharmacy technician training programs. The standard for approval of Registered Pharmacy Technician Training programs provided or offered by accredited institutions or entities is whether the program or institution is, as of December 1, 2018,

(a) accredited by a regional or national accrediting agency; a regional or national institutional accrediting agency; or a specialized accrediting agency recognized by the Secretary of the United States Department of Education;

(b) accredited by an accrediting agency whose accreditation establishes eligibility to participate in the Title IV student financial assistance program administered by United States Department of Education; or

(c) Pharmacy technician training programs within the public-school system of the State of Florida that comply with the Florida Department of Education Curriculum Framework for Pharmacy Technician (2018-2019), program number H170500; which is incorporated herein by reference and which can be obtained at https://www.flrules.org/Gateway/reference.asp?No=Ref-10356 or http://www.fldoe.org/core/fileparse.php/18567/urlt/H170500-1819.rtf.

(2) Federal Armed Services programs. The standard for approval of pharmacy technician training programs provided by a branch of the federal armed services shall be whether the curriculum of such course was developed on or before June 1, 2018.

(3) Other non-employer based programs. The standard for approval of all programs offered or accredited by an entity not listed in subsection (1) or (2), and which are not employer based programs, is whether the program:

(a) Meets the requirements of and is licensed by the Commission for Independent Education pursuant to chapter 1005, F.S., or the equivalent licensing authority of another state or jurisdiction or is within the public school system of the State of Florida;

(b) Offers a course of study that includes classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA).

2. Pharmacy law:

a. Federal law;

b. Florida State law;

c. Florida State rules;

d. Pharmacy technician Florida rules and law.

3. Pharmaceutical – medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention;

b. Prescriptions and medication orders.

4. Records management and inventory control:

a. Pharmaceutical supplies;

b. Medication labeling;

c. Medication packaging and storage;

d. Controlled substances;

e. Adjudication and billing.

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications;

b. Empathetic communications;

c. Ethics governing pharmacy practice;

d. Patient and caregiver communication.

6. Pharmaceutical calculations.

(c) Applies directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs." All applications must include the following information:

1. Sample transcript and diploma;

2. Copy of curriculum, catalog or other course descriptions; and,

3. Faculty credentials.

(d) Uses materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(e) Demonstrates that the faculty is qualified to teach the subject-matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

(4) Employer sponsored training programs. All other pharmacy technician training programs not identified in subsections (1)-(3) must be employer sponsored by a Florida permitted pharmacy, or affiliated group of pharmacies under common ownership and, must:

(a) Meet the requirements of paragraphs (3)(b), (3)(d), and (3)(e), above;

(b) Be provided solely to employees of the permitted pharmacy or affiliated group;

(c) Contain a minimum of one hundred sixty (160) hours of training, which shall not exceed six (6) months. Employer sponsored pharmacy technician training programs may request the program length exceed six (6) months in length under the following circumstances:

1. For programs containing a minimum of one hundred eighty (180) hours, the program length shall not exceed nine (9) months;

2. For programs containing a minimum of two hundred (200) hours, the program length shall not exceed twelve (12) months.

3. In no event shall the total length of the training program exceed twelve (12) months.

For programs of any length, the Program Director may extend participation in the program for an individual employee. In no event shall an employee's training be extended more than six (6) months beyond the program's length.

(d) Give participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering. To ensure participants will be given an opportunity to evaluate the program, the applicant must submit a sample evaluation to be reviewed by the Board.

(e) Ensure that self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses evaluate participant knowledge at the completion of the learning experience. The evaluation must include a minimum of one hundred (100) questions. The participant must achieve a minimum score of seventy percent (70%) on the evaluation to receive the certificate of completion. The evaluation must be graded by the provider.

(f) Designate a Program Director to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision shall be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

(g) Establish written policies and procedures for implementation of the registered pharmacy technician training program.

(h) Maintain a system of record-keeping which provides for storage of program information.

(i) Maintain program records for a period not less than three (3) years during which time the records must be available for inspection by the board or department.

(j) Furnish each participant with an authenticated individual Certificate of Completion.

(k) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Application for Registered Pharmacy Technician Training Programs."

(5) Reenrollment in employer-sponsored training programs. Any student who failed to complete an employer sponsored training program within the time periods established in paragraph (4)(c) must be terminated from the program. After termination, the Program Director may allow a student to reenroll in the program, at the Program Director's discretion and pursuant to the program's written policies and procedures. Reenrolled students must complete the entire program, including all required program hours, and no coursework or hours previously completed may be carried forward into the subsequent enrollment.

(6) All applications for approval of a Registered Pharmacy Technician Training Program shall be made on approved form DH-

MQA 1239 "Application for Registered Pharmacy Technician Training Programs," 06/18, which is hereby incorporated by reference. Applications may be obtained from https://www.flrules.org/Gateway/reference.asp?No=Ref-10116, or the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, (850)488-0595, or the board's website at http://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf, and must include the items required by subsection (3) or (4), above.

Rulemaking Authority 465.005, 465.014(4), (7) FS. Law Implemented 465.014(2), (4) FS. History–New 6-23-10, Amended 11-17-11, 6-19-17, 6-14-18, 12-10-18, 4-4-19.

from *NABP Model State Pharmacy Act and Model Rules,* August 2018*:*

Section 307. Registration of Certified Pharmacy Technicians.

(a) In order to be registered as a Certified Pharmacy Technician in this State, an applicant shall:[1]

(1) have submitted an application in the form prescribed by the Board of Pharmacy;
(2) have attained the age of _____;
(3) have good moral character;
(4) have graduated from high school or obtained a Certificate of General Educational Development (GED) or equivalent;
(5) have[2]:
  (i) graduated from a competency-based pharmacy technician education and training program approved by the Board of Pharmacy;[3]
  (ii) been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific, competency-based education and training program approved by the Board of Pharmacy;[4]
(6) have successfully passed an examination developed using nationally recognized and validated psychometric and pharmacy practice standards approved by the Board of Pharmacy;
(7) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule; and
(8) have paid the fees specified by the Board of Pharmacy for the examination and any related materials, and have paid for the issuance of the registration.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician.[5]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technicians.

Section 308. Registration of Certified Pharmacy Technician Candidates.

(a) In order to be registered as a Certified Pharmacy Technician Candidate in this State, an applicant shall:

(1) have submitted an application in the form prescribed by the Board of Pharmacy;

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[1] In 2015, the *Model State Pharmacy Act and Model Rules* was amended to require persons seeking to become Certified Pharmacy Technicians to complete each of the requirements outlined in Sections 307(a)(5)(i), 307(a)(5)(ii), and 307(a)(6).

[2] Boards should avoid mention of specific examinations or other contracted services in their practice act and regulations to avoid challenges related to an unconstitutional delegation of authority. It is contemplated that Boards will utilize the Certified Pharmacy Technician Candidate Certification Board examination as part of their assessment of technician competence to assist in the practice of pharmacy.

[3] It is recommended that states adopt this requirement, if not currently required, through a process that incorporates provisions for grandfathering.

[4] It is contemplated that Boards will approve those Certified pharmacy technician Candidate training programs whose standards are at least equivalent to the minimum standards being developed by an accrediting organization recognized by state Boards, such as ACPE. See Comment to Section 213(a)(4) above for further discussion of the Board's proper role in the accreditation process.

[5] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

(2) have attained the age of _____;
(3) have good moral character;
(4) have undergone a state and federal fingerprint-based criminal background check as specified by Board rule;
(5) have paid the fees specified by the Board; and
(6) have been documented by the Pharmacist-in-Charge of the Pharmacy where the applicant is employed as having successfully completed a site-specific training program and having successfully completed an objective assessment mechanism prepared in accordance with any rules established by the Board.

(b) No Pharmacist whose license has been denied, Revoked, Suspended, or restricted for disciplinary purposes shall be eligible to be registered as a Certified Pharmacy Technician Candidates.[6]

(c) The Board of Pharmacy shall, by rule, establish requirements for registration of Certified Pharmacy Technician Candidates.

[6] The Board may specifically authorize a pharmacist whose license has been disciplined to register as a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate under terms and conditions deemed appropriate.

Comments

Section 301(c). Comment.

Boards of Pharmacy are often confronted with the problem of preventing unlicensed individuals from engaging in one or more facets of the Practice of Pharmacy. The regulation of the Practice of Pharmacy, including the control of unlicensed practice in the profession, has a reasonable and rational relationship to public health, safety, and welfare. See, for example, *State v Wakeen*, 57 N.W.2d 364 (Wis, 1953). cf. *State v VanKeegan*, 113 A.2d 141 (Conn, 1955) and *Williamson v Lee Optical of Oklahoma*, 348 U.S. 483 (1955), concerning prohibitions on the unlicensed practice of ophthalmology. For this reason, vesting the power in the Board to regulate the illicit practice would not appear to violate the constitutional due process requirements. Monetary fines are another enforcement action Boards can utilize to protect the public health. Although monetary fines are not generally considered criminal sanctions, it can be forcibly argued that there are no constitutional barriers impeding the imposition of fines by a Board of Pharmacy. See, for example, *Helvering v Mitchell*, 303 U.S. 376 (1938); *City of Waukegan v Pollution Control Board*, 311 N.E.2d 146 (Ill, 1974); *County Council for Montgomery County v Investors Funding Corp*, 312 A.2d 225 (Md, 1973); and *Rody v Hollis*, 500 P.2d 97 (Wash, 1972).

One area that could present a serious question of law in regard to Section 301(b), however, involves the constitutional limitation on the delegation of authority to administrative agencies. It is likely that the delegation contemplated in Article III of the *Model Act* would be valid in a majority of jurisdictions. See, for example, *Jordan v Board of Insurance*, 334 S.W. 2d 278 (Tex, 1960); *Sutherland v Ferguson*, 397 P. 2d 335 (Kan, 1964); and *Kovack v Licensing Board of City of Waterville*, 173 A. 2d 554 (Me, 1961); see generally L. Davis, Administrative Law Treatise, Section 2.10 (1970 Suppl.). Be cautioned, however, that certain jurisdictions require very specific standards in a delegation of authority that could render Section 301(b) constitutionally suspect. See, for example, *People v Tibbits*, 305 N.E. 2d 152 (Ill, 1973); *Sarasota County v Barg*, 302 So. 2d 737 (Fla, 1974). In these jurisdictions, revisions of Article III may be necessary.

(Option #1)

Board of Pharmacy

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3300 and 54.1-3321, relating to registration as a pharmacy technician.

Be it enacted by the General Assembly of Virginia:

1. **That §§ 54.1-3303, and 54.1-3321 of the *Code of Virginia* are amended and reenacted as follows:**

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the board for the purpose of performing duties restricted to a pharmacy technician for completing an accredited pharmacy technician training program in accordance with § 54.1-3321 E of the Code of Virginia.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

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

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

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

B. To be registered as a pharmacy technician trainee, a person shall submit application to the Board and fee established in regulation.

C. To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program accredited by the Association of Health-Systems Pharmacists and Accreditation Council for Pharmacy Education and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcare Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~.

~~C.~~D. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

~~D.~~E. In addition, a ~~person~~ a pharmacy technician trainee enrolled in an ~~approved~~ accredited training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for ~~registration as a pharmacy technician~~ completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

~~E.~~F. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

~~F.~~G. The Board shall waive the initial registration fee ~~and the first examination fee for the Board-approved examination~~ for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the amendments to subsection C of this section shall not become effective until July 1, 2021.

(Option #2)

Board of Pharmacy

2019 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending §§ 54.1-3300 and 54.1-3321, relating to registration as a pharmacy technician.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3303, and 54.1-3321 of the *Code of Virginia* are amended and reenacted as follows:

§ 54.1-3300. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the board for the purpose of performing duties restricted to a pharmacy technician for completing a pharmacy technician training program in accordance with § 54.1-3321 E of the Code of Virginia.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

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

4. The counting, measuring, or compounding of the drug to be dispensed;

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

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

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

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

B. To be registered as a pharmacy technician trainee, a person shall submit application to the Board and fee established in regulation.

C. To be registered as a pharmacy technician, a person shall: (i) submit to the Board an application and fee established in regulation to obtain a pharmacy technician registration; (ii) satisfactory evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ successfully completed a training program that meets the criteria approved by the Board in regulation and (iii) successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or National Healthcare Association ~~that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board~~.

~~C.~~D. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

~~D.~~E. In addition, a ~~person~~ a pharmacy technician trainee enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for ~~registration as a pharmacy technician~~ completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

~~E.~~F. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

~~F.~~G. The Board shall waive the initial registration fee ~~and the first examination fee for the Board-approved examination~~ for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

3. That the amendments to subsection C of this section shall not become effective until July 1, 2021.

Agenda Item: Consideration of Possible 2020 Legislative Proposals – Compounding of Essentially Copies

Enclosed:

Draft Legislative Proposal

Committee action:

1. Recommend adoption of legislative proposal as presented or amended;
2. Recommend no action

Draft 2020 Legislative Proposal

§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § **54.1-3303** relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § **54.1-3420.2**.

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.

Pharmacists who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA; or are manufactured by an establishment that is registered by the FDA; and

2. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the Board and the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, ~~or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product;~~ or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ **54.1-3301**, **54.1-3304**, and **54.1-3304.1** shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ **54.1-3300** et seq.) or Chapter 34 (§ **54.1-3400** et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

Agenda Item: Consideration of Possible 2020 Legislative Proposals – Telepharmacy

Enclosed:

Excerpts from NABP Model State Pharmacy Act and Model Rules

Suggested statutory and regulatory amendments from CardinalHealth

Committee action:

1. Recommend adoption of legislative proposal to authorize telepharmacy
2. Recommend no action

from *NABP Model State Pharmacy Act and Model Rules,* August 2018*:*

Definitions in Model Law

(d6) "Telepharmacy Technologies" means secure electronic communications, information exchange, or other methods that meet applicable state and federal requirements.

(b6) "Remote Dispensing Site" means a location, other than where a pharmacist is located, where Drugs are maintained and prescriptions are filled by a certified pharmacy technician and dispensed under the direct, remote supervision of a pharmacist.

Appendix G

Model Rules for the Practice of Telepharmacy

(a) General Requirements

(1) The Pharmacy shall:

(i) obtain a resident or nonresident permit issued by the Board prior to engaging in the Practice of Telepharmacy;

(ii) comply with appropriate federal and state controlled substance laws and rules for each Pharmacy if controlled substances are maintained;

(iii) maintain additional policies and procedures specific to Telepharmacy.

(b) Remote Dispensing Site Requirements

(1) Shall submit an application to the Board.

(2) The Pharmacist-in-Charge of supervising pharmacy shall be responsible for all operations.

(3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with federal and state pharmacy laws and rules.

(4) The Pharmacist-in-Charge shall oversee monthly inspections, maintenance and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.

(5) A Pharmacist must be designated to be available within (_) hours, in case of emergency.

(6) Unless staffed by a Pharmacist, a Remote Dispensing Site must be staffed by at least one (1) Certified Pharmacy Technician. All Certified Pharmacy Technicians and Certified Pharmacy Technician Candidates shall be under the supervision of a Pharmacist at the supervising Pharmacy at all times that the remote site is operational. The Pharmacist shall supervise Telepharmacy operations electronically from the supervising pharmacy.

(7) The Remote Dispensing Site and the supervising Pharmacy must utilize a common electronic recordkeeping system that must be capable of the following:

(i) Electronic records must be available to, and accessible from, both the supervising pharmacy and the Remote Dispensing Site at all times of operations; and

(ii) Prescriptions dispensed at the Remote Dispensing Site must be distinguishable from those dispensed from the supervising pharmacy.

(8) Controlled substance records must be maintained at the registered location unless specific approval is granted for central storage as permitted by, and in compliance with, state and federal law.

(9) A supervising Pharmacy of a Remote Dispensing Site must maintain a video and audio communication system that provides for effective communication between the supervising Pharmacy and the Remote Dispensing Site personnel and patients or caregivers. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or Delivery of Drugs. The Remote Dispensing Site must retain a recording of facility surveillance, excluding patient communications, for a minimum of (_) days.

(i) Adequate supervision by the pharmacist in this setting is maintaining uninterrupted visual supervision and auditory communication with the site and full supervisory control of the automated system, if applicable, and must not be delegated to another person or entity.

(ii) Each component of the communication system must be in good working order. Unless a pharmacist is present onsite, the Remote Dispensing Site must be, or remain, closed to the public if any component of the communication system is malfunctioning, until system corrections or repairs are completed.

(iii) The video and audio communication system used to counsel and interact with each patient or patient's caregiver must be secure and compliant with state and federal confidentiality requirements.

(10) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access to it during times the supervising Pharmacy is closed. The security system must allow for tracking of entries into the Remote Dispensing Site, and the Pharmacist-in-Charge must periodically review the provision of access and record of entries.

(11) If Drugs are maintained or dispensed from the Remote Dispensing Site, Drug transfers to the Remote Dispensing Site must comply with applicable state and federal requirements.

(12) A Remote Dispensing Site must display a sign, easily visible to the public, that informs patients:

(i) this is a remote site

(ii) location of supervising Pharmacy; and

(iii) that a Pharmacist will counsel the patient using audio and video communication systems each time a new medication is delivered, and on a refill, if necessary, at a Remote Dispensing Site.

(13) The Remote Dispensing Site must use Telepharmacy Technology that confirms that the Drug selected to fill the prescription is the same as indicated on the prescription label and Prescription Drug Order.

Section 301. Unlawful Practice.

(a) Except as otherwise provided in this Act, it shall be unlawful for any individual, whether located in or outside this State, to engage in the Practice of Pharmacy in this State unless currently licensed to practice under any facet of the provisions of this Act.

(b) The provision of Pharmacist Care Services to an individual in this State, through the use of Telepharmacy Technologies, regardless of the location of the pharmacist, shall constitute the Practice of Pharmacy and shall be subject to regulation.[1]

(1) Licensed Pharmacies located outside this State that provide Pharmacist Care Services to individuals in this State must be licensed within this State under Article V of this Act.

(2) Pharmacists located outside this State who are providing Pharmacist Care Services outside of a licensed Pharmacy to individuals located in this State must register with this State to engage in the nonresident Practice of Pharmacy.

(c) Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

(See comment list.)

(d) It shall be unlawful for any individual to perform the activities of a Certified Pharmacy Technician or Certified Pharmacy Technician Candidate unless currently registered to do so under the provisions of this Act.

(e) (1) The Board may in its own name issue a Cease and Desist order to stop an individual from engaging in an unauthorized Practice of Pharmacy.

(2) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy shall also constitute a misdemeanor punishable upon conviction as provided in the criminal code of this State.

(3) Except as otherwise indicated in this Act, any individual who, after due process, shall be found by the Board to have unlawfully engaged in the Practice of Pharmacy that resulted in harm to an individual shall be subject to a Fine to be imposed by the Board not to exceed $____ for each offense. Each such violation of this Act or the rules promulgated hereunder pertaining to unlawfully engaging in the Practice of Pharmacy that resulted in harm to an individual shall also constitute a felony punishable upon conviction as provided in the criminal code of this State.

Section 501. Licensing.

(a) The following Persons located within this State, and the following Persons located outside this State that provide services to patients within this State, shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board[2]:

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[1] NABP recognizes that protection of the public health should extend across State borders. Accordingly, the NABP *Model Act* incorporates the Practice of Telepharmacy within the scope of the "Practice of Pharmacy" and requires an independently practicing pharmacist located outside this State to obtain full licensure for providing Pharmacist Care Services from outside the State to patients within the State.

[2] State may require additional licensing/registration requirements.

(1) persons engaged in the Practice of Pharmacy (including Telepharmacy);
(2) dispensing Practitioners and Practitioner's facilities including those engaged in nonsterile Compounding;[3]
(3) persons engaged in the Manufacture or Repackaging of Drugs or Devices;
(4) persons engaged in the Wholesale Distribution of Drugs or Devices;
(5) persons engaged in Third-Party Logistics Provider activities of Drugs or Devices;
(6) pharmacies where Drugs or Devices are Dispensed, or Compounded, or Pharmacist Care Services are provided;
(7) Outsourcing Facilities;
(8) Pharmacy Benefits Managers; and
(9) Repository Programs

Where operations are conducted at more than one location, each such location shall be licensed by the Board of Pharmacy.

(b) The Board shall establish by rule, under the powers granted to it under Section 212 and 213 of this Act and as may be required from time to time, under federal law, the Criteria that each Person must meet to qualify for licensure in each classification, as well as the required practice standards applicable to each type of activity and/or facility. The Board shall adopt definitions in addition to those provided in Article I, Section 105, where necessary to carry out the Board's responsibilities. The Board may issue licenses with varying restrictions to such Persons where the Board deems it necessary.[4]

(c) Each Pharmacy shall have a Pharmacist-in-Charge. Whenever an applicable rule requires or prohibits action by a Pharmacy, responsibility shall be that of the owner and/or pharmacy permit holder and the Pharmacist-in-Charge of the Pharmacy, whether the owner and/or pharmacy permit holder is a sole proprietor, partnership, association, corporation, or otherwise.

(d) Each licensed Person located outside of this State who ships, mails, Distributes, Wholesale Distributes, or Delivers Drugs or Devices in this State, or Pharmacy located outside of this State who ships, mails, Distributes, or Delivers Drugs or Devices in this State, shall comply with the laws of patients' domicile, and shall designate a registered agent in this state for service of process. Any such licensed Person or Pharmacy who does not so designate a registered agent shall be deemed to have designated the Secretary of State of this State to be its true and lawful attorney, upon whom may be served all legal process in any action or proceeding against such licensed Person growing out of or arising from such Delivery. A copy of any such service of process shall be mailed to such Person or Pharmacy by the Board by certified mail, return receipt requested, postage prepaid, at the address such licensed Person has designated on its application for licensure in this State. If any such Person is not licensed in this State, service on the Secretary of State only shall be sufficient service.[5]

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[3] Licensed Practitioners authorized under the laws of this State to Compound Drugs and to Dispense Drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements, counseling, and all other requirements for the Dispensing of Drugs applicable to Pharmacists.

[4] Section 501(b) contemplates that the Criteria for licensure, beyond minimum requirements for all Persons and Pharmacies, established in an individual entity classification could differ. For example, the Criteria that must be met by a nuclear Pharmacy will certainly differ from that of the community Pharmacy. This type of latitude places the responsibility on the Board to adopt appropriate rules to meet the situation at hand. It also provides a forum for change to meet the changing concepts of professional practice and the Distribution of Drugs and/or Devices.

[5] This section provides for service of process on any Person who Dispenses, Distributes, or Delivers Drugs or Devices within the State.

(e) The Board may enter into agreements with other states or with third parties for the purpose of exchanging information concerning the licensure and inspection of entities located in this jurisdiction and those located outside this State.

(f) The Board of Pharmacy may deny or refuse to renew a license if it determines that the granting or renewing of such license would not be in the public interest.

(g) The Board shall establish the standards that a Person must meet for initial and continued licensure under Article V.

(h) For facilities that Compound and/or Repackage Sterile Pharmaceuticals, an initial inspection shall be required prior to initial licensure or initiation of sterile Compounding activity. Thereafter, an annual inspection shall be required for licensure renewal. For facilities that do not Compound Sterile Pharmaceuticals, an initial inspection, and thereafter an inspection that takes place not less than every 24 months, shall be required for purposes of licensure or licensure renewal[6]. Such inspection shall be performed by the following:

(1) the Board or its duly authorized agent;
(2) a duly authorized agent of a third party approved by the Board, such as the NABP Verified Pharmacy Program (VPP) (see Appendix A for the Multistate Pharmacy Inspection Blueprint); or
(3) for Nonresident Pharmacies, the resident state Board of Pharmacy, if the resident Board's inspection is substantially equivalent to inspection in this State, or a VPP inspection.

(i) Agents duly authorized to conduct inspections, whether agents of the Board or an approved third party such as VPP, must be competent to inspect the facilities they are assigned to inspect to include training on any applicable State, Federal, and USP standards.

(j) The Board may consider exempting facilities engaged solely in the Distribution of dialysate, Drugs, or Devices necessary to perform home renal dialysis to patients with chronic kidney failure from pharmacy licensure, provided that the following criteria are met:

(1) The dialysate, Drugs, or Devices are approved by Food and Drug Administration, as required by federal law.
(2) The dialysate, Drugs, or Devices are lawfully held by a manufacturer (or a manufacturer's agent) that is properly registered with the Board as a Manufacturer and/or Wholesale Drug Distributor
(3) The dialysate, Drugs, or Devices are held and delivered in their original, sealed labeled packaging from the Manufacturing facility.
(4) The dialysate, Drugs, or Devices are delivered only by the Manufacturer (or the Manufacturer's agent) and only upon receipt of a physician's order.
(5) The Manufacturer (or Manufacturer's agent) delivers the dialysate, Drugs, or Devices directly to:
    (i) a patient with chronic kidney failure, or his/her designee, for the patient's self-administration of dialysis therapy, or
    (ii) a health care provider or institution for administration or delivery of the dialysis therapy to a patient with chronic kidney failure.
(6) Records of all sales and Distribution of dialysate, Drugs, or Devices to home dialysis patients must be retained and readily available for inspection and copying by the Board for _____ years.

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[6] State resources may have to be considered when evaluating inspection scheduling in combination with risk assessment consideration.

Section 8. Shared Pharmacy Services.

(a) General Requirements[7, 8]

(1) The Pharmacy must possess a resident or nonresident permit issued by the Board prior to engaging in Shared Pharmacy Services.[9]

(2) A Pharmacy may provide or utilize Shared Pharmacy Services only if the Pharmacies involved:

(i) have the same owner; or

(ii) have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy laws and rules; and

(iii) share a common electronic file or technology that allows access to information necessary or required to perform Shared Pharmacy Services in conformance with the pharmacy act and the Board's rules.

(3) A Pharmacy engaged in Shared Pharmacy Services shall comply with appropriate federal and state controlled substance registrations for each Pharmacy if controlled substances are maintained.

(4) A Pharmacy engages in Shared Pharmacy Services shall notify the Board in writing within 10 days of a change of location, discontinuance of service, or closure of a Pharmacy.

(b) Operations

(1) Pharmacies engaging in Shared Pharmacy Services, or a Pharmacist acting independently of a Pharmacy and participating in Shared Pharmacy Services shall:

(i) maintain records identifying, individually, for each Prescription Drug Order processed, the name of each Pharmacist, or Pharmacy Intern who took part in the Drug Utilization Review, refill authorization, or therapeutic intervention functions performed at that Pharmacy and the name of any Certified Pharmacy Technician or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

(ii) maintain records identifying individually, for each Prescription Drug Order filled or dispensed, the name of each Pharmacist or Pharmacy Intern who took part in the filling, dispensing, and counseling functions performed at that Pharmacy and the name of any Certified Pharmacy Technician or Certified Pharmacy Technician Candidate if they assisted in any of those functions;

(iii) report to the Board as soon as practical the results of any disciplinary action taken by another state's Board of Pharmacy involving Shared Pharmacy Services;

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[7] The Board may want to consider the extent to which this General Requirements Section is applicable to institutional-based Shared Pharmacy Services Pharmacies, as such application may be subject to interpretation of existing state and federal law governing Institutional Facilities.

[8] In order to ensure accountability, the Pharmacist-in-Charge of a Pharmacy engaging in Shared Pharmacy Services must possess a license to practice Pharmacy in all jurisdictions that he/she is engaging in such series until such a time in which provisions for multistate practice exist.

[9] Often the terms "licensure," "registration," and "permit" are used interchangeably throughout the *Model Act*. In the case of Shared Pharmacy Services Pharmacies that utilize Automated Pharmacy Systems, Boards may determine that it is appropriate to issue a permit for the Automated Pharmacy System but not for the physical site where the Automated Pharmacy System is located.

(iv) maintain a mechanism for tracking the Prescription Drug Order during each step of the processing and filling procedures performed at the Pharmacy;
(v) maintain a mechanism for the patient to identify all Pharmacies involved in filling the Prescription Drug Order; and
(vi) be able to obtain for inspection any required record or information within 72 hours of any request by the Board or its designee.

(2) Notification to Patients
(i) Pharmacies engaging in Shared Pharmacy Services shall notify patients that their Prescription Drug Orders may be processed or filled by another Pharmacy unless the Prescription Drug is delivered to patients in Institutional Facilities where a licensed health care professional is responsible for administering the Prescription Drug to the patient.

(c) Drug Storage and Security
(1) Drugs shall be stored in compliance with state and federal laws and in accordance with these Rules, including those addressing temperature, proper containers, and the handling of outdated drugs.
(2) Drugs stored at Shared Pharmacy Services Pharmacies shall be stored in an area that is:
(i) separate from any other Drugs used by the health care facility; and
(ii) secured, so as to prevent access by unauthorized personnel.
(3) Access to the area where Drugs are stored at the Shared Pharmacy Services Pharmacy must be limited to:
(i) Pharmacists, Certified Pharmacy Technicians, Certified Pharmacy Technician Candidates, or Pharmacy Interns who are employed by the Shared Pharmacy Services Pharmacy; or
(ii) Personnel employed at the Institutional Facility or clinic where the Shared Pharmacy Services Pharmacy is located who:
(A) are licensed health care providers;
(B) are designated in writing by the Pharmacist-in-Charge or the Person responsible for the supervision and on-site operation of the facility where the Automated Pharmacy System is located; and
(C) have completed documented training concerning their duties associated with the Shared Pharmacy Services Pharmacy.
(4) Shared Pharmacy Services Pharmacies shall have adequate security to:
(i) comply with federal and state laws and regulations; and
(ii) Protect the confidentiality and integrity of Protected Health Information.

(d) Policies and Procedures
(1) Each participant in Shared Pharmacy Services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for Shared Pharmacy Services. Each participant is required to maintain this portion of the joint policies and procedures that relate to that participant's operations. The policies and procedures shall:
(i) outline the responsibilities of each of the pharmacies;
(ii) include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in Shared Pharmacy Services; and
(iii) include policies and procedures for:
(A) notifying patients that their Prescription Drug Orders may be processed or filled by another Pharmacy and providing the name of the Pharmacy;

(B) protecting the confidentiality and integrity of Protected Health Information;
(C) dispensing Prescription Drug Orders when the filled Prescription Drug Order is not received or the patient comes in before the Prescription Drug Order is received:
(D) maintaining required manual or electronic records to identify the name, initials or identification code and specific activity or activities of each Pharmacist, Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern who performed any Shared Pharmacy Services;
(E) complying with federal and state laws; and
(F) operating a Continuous Quality Improvement Program for Shared Pharmacy Services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(e) Individual Practice

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

(e) Practice of Telepharmacy – Remote Dispensing Site Requirements [10]

A Remote Dispensing Site:

(1) Shall submit an Application to the Board.
(2) The Pharmacist-in-Charge of the Shared Pharmacy Services Pharmacy shall be responsible for all operations of the Remote Dispensing Site.
(3) Shall have a written contract or agreement that outlines the services provided and the responsibilities of each party in complying with Federal and State pharmacy laws and rules.
(4) The Pharmacist-in-Charge shall oversee monthly inspections, maintenance and reconciliation of all controlled substances, including maintaining a perpetual inventory for all Schedule II controlled substances.
(5) A Pharmacist must be designated to be available within ( ) hours, in case of emergency.
(6) A functioning video and audio communication system that provides for effective communication between the Shared Pharmacy Services Pharmacy and the Remote Dispensing Site personnel and patients, and their agents or caregivers, must be maintained. The system must provide an adequate number of views of the entire site, facilitate adequate pharmacist supervision, and allow the appropriate exchanges of visual, verbal, and written communications for patient counseling and other matters involved in the lawful transaction or Delivery of

[10] For Boards of Pharmacy that have yet to add rules for the Practice of Telepharmacy and/or require more specificity, see Appendix G Model Rules for the Practice of Telepharmacy.

Drugs. The Remote Dispensing Site must retain a recording of the facility surveillance, excluding patient communications, for a minimum of ( ) days.

(7) Unless a Pharmacist is present, a Remote Dispensing Site must not be open or its employees allowed access during times the Shared Pharmacy Services Pharmacy is closed or during a system outage.

DRAFT Suggested Law and Regulatory Amendments provided by CardinalHealth

Law: Va. Code Ann.

§ 54.1-3300. Definitions.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Practice of telepharmacy" means the practice of pharmacy through the use of telecommunications and information technologies to patients at a distance.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located or is able to oversee operations of the pharmacy through electronic supervision when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Rules: 18 VAC 110-20-10 et seq.

18VAC110-20-10. Definitions.

"Electronic supervision" means that a licensed pharmacist provides supervision of the pharmacy through the utilization of HIPAA-compliant audio and visual technology.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed. For the purposes of a remote dispensing site pharmacy, a pharmacist is considered on duty at a remote dispensing site pharmacy if they are providing electronic supervision at a supervising pharmacy through a telepharmacy system.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Remote Dispensing Site Pharmacy" means a pharmacy registered with the board that may receive written and electronic prescriptions and store and dispense prescription drugs and devices, including dangerous drugs and controlled substances. A remote dispensing site pharmacy is not required to have a pharmacist physically present when electronic supervision through a telepharmacy system is provided.

"Supervising Pharmacy" means a pharmacy located in Virginia and registered by the board that provides pharmacy services through a telepharmacy system at a remote dispensing site pharmacy.

"Telepharmacy system" is an electronic system that monitors the preparation and dispensing of prescription drugs and medical devices and provides for related drug review and patient counseling by which shall include the use of the following types of technology: audio and video; still image capture; or store and forward.

Part IV. Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies. Remote dispensing site pharmacies shall not be considered in the pharmacist in charge calculation.

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department of pharmacies other than remote dispensing site pharmacies shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services

18VAC110-20-180. Security system.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.
2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.
3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or

vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. A PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.

E. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;
2. Alternate pharmacist coverage cannot immediately be obtained;
3. The technician is accompanied by a member of the pharmacy's management or administration; and
4. All requirements of subsection F of this section are met.

F. Requirements for entry into the prescription department in the absence of a pharmacist on duty.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.
2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.
3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.
5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

18VAC110-20-216. Remote Dispensing Site Pharmacy

A. Any remote dispensing site pharmacy in the Commonwealth of Virginia engaged in the practice of telepharmacy shall obtain a remote dispensing site pharmacy permit as a pharmacy from the board in accordance with 18VAC110-20-110.

B. A supervising pharmacy may commence operations with a remote dispensing site pharmacy via a telepharmacy system under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy, including confidentiality of patient information. The contract must be retained by the supervising pharmacy and made available to the Board upon request; and
2. The pharmacies shall share a common electronic file or have appropriate technology or interface which allows secure access to sufficient information necessary or required to fill or process a prescription drug order.

C. A supervising pharmacy of a remote dispensing site pharmacy must maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy. The remote dispensing site pharmacy must close to the public and cease delivery of prescriptions if there is a malfunction with the communication system. The remote dispensing site pharmacy can continue operation only after system corrections or repairs are completed.

D. Each remote dispensing site pharmacy must designate a PIC. The PIC of the remote dispensing site pharmacy shall assure that:

1. The PIC or a designated pharmacist shall complete and document an in-person inspection of the remote dispensing site pharmacy location at least once monthly.
2. Inspection criteria must be included in the policies and procedures for the remote dispensing site pharmacy, and the inspection report must be available on site at the remote dispensing site pharmacy for pharmacy investigator inspection.

E. A pharmacist shall be responsible for all operations of the licensed area and in personal attendance at the supervising pharmacy at all times that the remote dispensing site pharmacy is open for business. A pharmacist at the supervising pharmacy may not provide electronic

supervision for more than 3 (three) remote dispensing site pharmacies at one time.

F. All personnel performing tasks in the preparation and distribution of drugs, whether at the supervising or remote dispensing site pharmacy, shall comply with Virginia law and regulation with respect to requirements for supervision or electronic supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians.

1. Pharmacy technicians at the remote dispensing site pharmacy shall be registered in Virginia and possess credentials substantially equivalent to those required for a technician registered in Virginia; and
2. The remote dispensing site pharmacy may be staffed by a sufficient number of remote dispensing site pharmacy technicians as may be required to competently and safely provide pharmacy services.

G. A pharmacist licensed in Virginia, whether located at the supervising pharmacy or the remote dispensing site pharmacy, must perform the following activities related to the filling and dispensing process prior to release of a prescription:

1. A prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
2. Verification for accuracy of filling; and
3. Provide drug information or counseling concerning a patient's prescription to the patient or patient's agent through a HIPAA-compliant audio and video communication system.

H. Records may be maintained separately by each pharmacy, or shall be retrievable and accessible in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.

1. The record shall be readily retrievable for at least the past two years and shall be readily available for inspection by the board.
2. In addition to any other required records, pharmacies engaged in the practice of telepharmacy shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a function and the pharmacist who checked the function, if applicable.
3. Records of controlled substance prescriptions dispensed from a remote dispensing site pharmacy must be maintained at the remote dispensing site pharmacy.

I. Any remote dispensing site pharmacy that provides pharmacy services through a telepharmacy system shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name and address of the supervising pharmacy and that the remote dispensing site pharmacy is under video surveillance. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

J. A policy and procedure manual that relates to the practice of telepharmacy shall be maintained at each pharmacy involved in the preparation and distribution of prescriptions and available for inspection. The manual shall at a minimum include the following:

1. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in the practice of telepharmacy;
2. The responsibilities of each pharmacy to include how the remote dispensing site pharmacy will comply with federal and state laws, rules, and regulations;
3. The specific duties, tasks, and functions that a registered pharmacy technician is authorized to perform at the remote dispensing site pharmacy;
4. Procedures for the pharmacist to compare, via video or image-based communication, the drug stock, the drug dispensed, and the label including the beyond-use date;
5. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
6. Procedures for protecting the confidentiality and integrity of patient information;
7. Procedures for reviewing the prescription drug inventory and drug records maintained by the remote dispensing site pharmacy;
8. Procedures for supervising the remote dispensing site pharmacy and counseling patients prior to the dispensing of any prescription pursuant to this section;
9. Procedure by which the pharmacist uses the state prescription drug monitoring program before authorizing any controlled substance for dispensing.
10. Procedure for maintaining a perpetual inventory of the controlled substances listed in schedule (II),
11. Description of a Quality Assurance Program.
12. A recovery plan in the event the remote dispensing site pharmacy loses electronic connection with the supervising pharmacy.

Agenda Item: Consideration of Possible 2020 Legislative Proposals – White Bagging/Brown Bagging

Enclosed:

Excerpts from November 2018 and December 2018 full board meeting minutes

Committee action:

1. Recommend adoption of legislative proposal to address white bagging/brown bagging to those entities that do not maintain a Board of Pharmacy license and a delay may result in potential patient harm
2. Recommend no action

Consider Draft Proposed Regulation for White Bagging and Brown Bagging

The Board considered the draft proposed language in the agenda packet regarding regulations for white bagging and brown bagging. Staff commented that §54.1-3420.2(B) requires the delivery location to hold a current permit, license, or registration with the Board of Pharmacy that authorizes the possession of controlled substances at that location. As such, the draft regulatory language provided in the agenda packet would need to be amended since the board cannot exempt a hospital, medical clinic, or prescriber's office from this statutory requirement if a Board of Pharmacy license is not already maintained. Any reference to delivering to another pharmacy could remain in the draft regulatory language since that pharmacy would already hold licensure with the board. Additionally, it was commented that an exemption from subsection A is unnecessary.

MOTION:

The Board voted unanimously to adopt the proposed amendments to 18 VAC 110-20-275 as presented and amended by inserting subsections F and G as indicated below:

"F. The pharmacy and alternate delivery site is exempt from compliance with subsections B-E if: (1) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivery of controlled substances; (2) it does not routinely receive deliveries from the pharmacy; and (3) compliance with subsections B-E would create a delay in delivery that may result in potential patient harm.

1.To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage,

reconstitution or compounding prior to administration." (motion by Nelson, second by Ratliff)

Consider Submission of Public Comment regarding FDA Revised Draft Guidance Document – MOU Addressing Certain Distributions of Compounded Drug Products

The Board reviewed the revised draft memorandum of understanding (MOU) in the agenda packet along with the suggested changes from NABP. Ms. Juran stated that this is an opportunity for the board to offer comment to the FDA regarding the specific language within in the MOU and that the board does not need to determine at this time if it will sign the MOU.

MOTION:

The Board voted unanimously to direct staff to submit written comment to the FDA urging the FDA to strongly consider the suggested edits presented by NABP. (motion by Logan, second by Richards-Spruill)

MOTION FOR CLOSED MEETING:

Upon a motion by Mr. Logan and duly seconded by Mr. Nelson, the Board unanimously voted to convene a closed meeting pursuant to § 2.2-3711 (A) (8) of the Code of Virginia to receive legal advice regarding the Virginia Freedom of Information Act and the consideration of the applications for pharmaceutical processor permits. In addition, Mr. Saenz moved that Caroline Juran, Jim Rutkowski, Elaine Yeatts, and Sammy Johnson attend the closed session because their presence is necessary and would reasonably aid the board.

MOTION TO RECONVENE:

Upon motion by Mr. Logan and duly seconded by Mr. Jenkins, the Board certified to the best of their knowledge, that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed, or considered during the closed session that just concluded.

Board Member Statements:

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

Mr. Ratliff announced that he had written a letter of support for the Dharma pharmaceutical processor application prior to being appointed to the Board and that he would recuse himself from the Board's consideration of this particular pharmaceutical processor application.

Consider Criminal Background Check Results for Pharmaceutical Processor Conditional Approvals and Any Related Matters

Ms. Juran indicated that criminal background checks for those pharmaceutical processors awarded conditional approval did not reveal any barrier violations. Mr. Saenz indicated that two pharmaceutical processors awarded conditional approval contingent upon criminal background checks, Dalitso and Dharma, had submitted applications for a change of location and the Board would need to accept or deny the change of locations.

MOTION:

The Board voted unanimously to finalize the conditional approval for Pharmacann in health service area (HSA) I, Green Leaf in HSA IV, and Columbia Care in HSA V. (motion by Jenkins, second by Nelson)

~~application holder's~~ applicant's drug product even if the ~~application holder's~~ applicant's drug product is single source or coded as non-equivalent (e.g., BN). ~~Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder.~~"

(motion by Logan, second by Warriner)

MOTION:

The Board voted unanimously to re-adopt the following Guidance Documents as presented, along with the amended Guidance Document 110-43:

- **110-3–Guidance on alternate delivery of prescriptions, pharmacy to physician or pharmacy to controlled substance registration type of delivery**
- **110-21 – Sanction Reference Points Manual**
- **110-28 – Guidance for Free Clinic Pharmacy Permit Applicants**
- **110-30 – Drugs within animal shelters and pounds**
- **110-32 – Use of a drop-box for the collection of prescriptions**
- **110-33 – Pharmacy interns as pharmacy technicians, Pharmacy technician ratio**
- **110-37 – Guidance for conducting informal fact-finding by an agency subordinate.**
- **110-40 – Storage of Schedule II drugs in a pharmacy**
- **110-41 – Changes a pharmacist may make to a Schedule II prescription**
- **110-42 – Continuing Education audit and recommended sanctions**
- **110-43 – Dispensing with an authorized generic**

(motion by Logan, second by Richards-Spruill)

Re-Adoption of White Bagging/Brown Bagging Regulations

Following the Board's adoption of proposed regulatory amendments to 18VAC110-20-275 in November 2018, staff received several comments expressing concern that the adopted language would prohibit hemophiliac patients from receiving blood factors delivered to their residence that may be needed for emergent treatment. A handout of the proposed regulatory amendment was provided to the Board for their consideration that included an exception in subsection G that would allow emergent blood factor treatment intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that required special storage, reconstitution or compounding prior to administration, to be delivered to a patient's residence.

MOTION:

The Board voted 9 to 0 to readopt the proposed regulatory amendment to 18VAC110-20-275 as presented that inserted the following sentence at the end of subsection G, "An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment." (motion by Logan, second by Boone; abstention by Warriner)

OLD BUSINESS

Issues to be Addressed by Regulation Committee

(From comments on Periodic Review)

In section 10, amend definition of "faxed prescription" to allow an electronic image.

In section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician; or delete definition of "personal supervision"

In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians.

In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy."

In section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

In section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device.

In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.

In section 420, change the provision of a seven-day supply of a drug in unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply.

In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

Limitations on Number of Persons under Supervision of a Licensee

Physician Assistants – Code of Virginia

§ 54.1-2952. Supervision of assistants by licensed physician, or podiatrist; services that may be performed by assistants; responsibility of licensee; employment of assistants.

...No licensee shall be allowed to supervise more than six physician assistants at any one time.

Nurse Practitioners – Code of Virginia

§ 54.1-2957.01. Prescription of certain controlled substances and devices by licensed nurse practitioners.

...2. Physicians shall not serve as a patient care team physician on a patient care team at any one time to more than six nurse practitioners.

Occupational Therapy Assistants – Board Regulation

18VAC85-80-110. Supervisory Responsibilities of an Occupational Therapist.

...C. An occupational therapist may provide clinical supervision for up to six occupational therapy personnel, to include no more than three occupational therapy assistants at any one time.

Dental Hygienists – Code of Virginia and Board Regulation

Code: *§ 54.1-2724. Limitations on the employment of dental hygienists.*

The Board shall determine by regulation the total number of dental hygienists, including dental hygienists under general supervision and dental hygienists under remote supervision, who may work at one time for a dentist. No dentist shall employ more than two dental hygienists who practice under remote supervision at one time.

Regulation: *18VAC60-25-50. Utilization of Dental Hygienists and Dental Assistants.*

A dentist may utilize up to a total of four dental hygienists or dental assistants II in any combination practicing under direction at one and the same time. In addition, a dentist may permit through issuance of written orders for services additional dental hygienists to practice under general supervision in a free clinic, a public health program, or a voluntary practice.

Speech-Language Pathology Assistants – Board Regulation

18VAC30-21-140. Supervisory Responsibilities

E. Supervision of an assistant in speech-language pathology.

1. The practice of an assistant shall only be supervised by a speech-language pathologist who retains full legal and ethical responsibility for the client. A speech-language pathologist shall only supervise the equivalent of two full-time assistants.

Funeral Service Interns – Code of Virginia

§ 54.1-2817. Funeral service interns.

No more than two funeral service interns shall be concurrently registered under any one person licensed for the practice of funeral service, funeral directing or embalming.