COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearings and Full Board Meeting
December 9, 2019
9:00AM

- Revision of 110-34 *Manufacturer, Wholesale Distributor Licensure Guidance* 60
- Adoption of 110-13 *Guidance on Collaborative Practice Agreements* 61-63
- Adoption of 110-14 *Statistically Valid Sample Size for Pharmaceutical Processors* 64-65

- Recommendation of Emergency Action Prohibiting Vitamin E Acetate in CBD and THC-A Oil Vaping Formulations 66-81
- Consideration of Amendments to Incorporate Changes Currently in Approved Innovative Pilots 82-92
- Discussion of Immunization Records 93-99
- Consideration of an Interpretation of the term "New" Prescription as it relates to Requiring an Offer to Counsel 100-103

Old Business:

- Review Pharmacy Closing Statistics 104-115

New Business:

- Discuss Request from VPhA to Require CE for Statewide Standing Order for Dispensing Naloxone
- Discuss Request from VPhA to Review Recommendations from National Consensus Conference on *Enhancing Well-Being and Resilience Among the Pharmacist Workforce* 116-126
- Prescription Monitoring Program Update, Ashley Carter, Deputy Director, PMP

Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Inspection and Licensure Program – Sammy Johnson
- Report on Pharmaceutical Processors – Annette Kelley 127-138
- Report on Disciplinary Program – Ellen B. Shinaberry 139
- Executive Director's Report – Caroline D. Juran 140

Consideration of consent orders, summary suspensions, or summary restrictions, if any.

Adjourn

****The Board will have a working lunch at approximately 12pm and will honor former board member Rafael Saenz.****

*****A panel of the Board will tentatively convene at 12:30pm or immediately following adjournment of the board meeting, whichever is later.*****

Proposed Regulations for Public Hearing

Delivery of Schedule VI Devices

White bagging/Brown bagging

10. College of Optometrists in Vision Development.

11. The Accreditation Council for Continuing Medical Education of the American Medical Association for Category 1 credit.

12. Providers of training in cardiopulmonary resuscitation (CPR).

13. Optometric Extension Program.

H. In order to maintain approval for continuing education courses, providers or sponsors shall:

1. Provide a certificate of attendance that shows the date, location, presenter or lecturer, content hours of the course, and contact information of the provider or sponsor for verification. The certificate of attendance shall be based on verification by the sponsor of the attendee's presence throughout the course, either provided by a post-test or by a designated monitor.

2. Maintain documentation about the course and attendance for at least three years following its completion.

I. Falsifying the attestation of compliance with continuing education on a renewal form or failure to comply with continuing education requirements may subject a licensee to disciplinary action by the board, consistent with § 54.1-3215 of the Code of Virginia.

VA.R. Doc. No. R18-5205; Filed September 18, 2019, 11:13 a.m.

BOARD OF PHARMACY

Proposed Regulation

Title of Regulation: **18VAC110-50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (adding 18VAC110-50-55).**

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information:

December 9, 2019 - 9:05 a.m. - Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA 23233

Public Comment Deadline: December 13, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Regulations are promulgated under the general authority of § 54.1-2400 of the Code of Virginia. The specific authority to promulgate regulations for delivery of medical devices is in Chapters 241 and 242 of the 2018 Acts of Assembly, which added § 54.1-3415.1 of the Code of Virginia.

Purpose: The primary purpose of the proposed action is to implement legislative action that allows a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider, or registered nonresident manufacturer or nonresident wholesale distributor to deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence in accordance with an agreement signed with a medical equipment supplier or a medical director.

The goal is to facilitate provision of Schedule VI devices more economically and efficiently by allowing delivery to the ultimate user or consumer without a party in the middle of the transaction having to physically possess and store the devices and ensuring existence of an order or request from a prescriber for the safety and integrity of prescription devices and the protection of the patient or ultimate user. The medical equipment supplier may have a valid order from a prescriber that is conveyed to a wholesale distributor or other entity with whom there is an agreement. Before passage of Chapters 241 and 242 of the 2018 Acts of Assembly, the distributor or other entity did not have legal authority to deliver directly to the consumer. Likewise, the director of a home health agency may now request that oxygen be delivered directly to a consumer's residence, rather than the agency possessing and storing the oxygen with a subsequent delivery to the consumer or patient.

Substance: Board requirements for delivery of Schedule VI devices are intended to implement the provisions of § 54.1-3415.1 of the Code of Virginia, which requires an agreement between the delivering party and a medical equipment supplier or a medical director. The agreement can cover multiple entities under shared ownership so it does not become burdensome but does ensure existence of an order or request from a prescriber.

Issues: The advantage to the public is direct delivery of Schedule VI devices from an entity without delays and costs associated with interim deliveries. There are no disadvantages to the public. There are no advantages or disadvantages to the agency or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Pursuant to Chapter 241 of the 2018 Acts of Assembly,[1] the Board of Pharmacy (Board) proposes to permanently allow certain regulated entities to deliver Schedule VI medical devices directly to a consumer on behalf of an equipment supplier. These changes have already been implemented under an emergency regulation.[2]

Result of Analysis. The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact. Pursuant to the 2018 General Assembly mandate, the Board proposes to permanently set out the requirements for delivery of Schedule VI devices directly to an ultimate user or consumer on behalf of a medical equipment supplier upon a valid order from a prescriber or upon request from the medical director of home health agency, nursing home, assisted living facility, or hospice.

Schedule VI devices are complex or invasive devices that have the potential for harm if incorrectly used (e.g., nebulizer, ostomy bags, catheters, etc.). Prior to the emergency regulation, direct delivery of these devices to the ultimate user was not permitted. A medical supplier would have to first obtain the possession of the device then deliver it to the ultimate user. Under the new language, a medical supplier can enter into agreements with its sources and have the device directly delivered to the patient. This change eliminates the need to store the equipment at the medical equipment supplier and an extra step in the purchase process. Thus, the change has the potential to reduce storage/delivery costs and speed up the delivery. However, according to the Department of Health Professions (DHP), some suppliers had already been facilitating direct delivery and are unlikely to be affected other than coming into compliance under the new language.

Businesses and Entities Affected. Currently, there are 28 manufacturers, 81 wholesale distributors, 98 warehousers, 5 third-party logistics providers, 134 nonresident manufacturers, 673 nonresident wholesale distributors, and 237 medical suppliers regulated by the Board. DHP has no estimate on the number of entities that may take advantage of the new delivery model permitted by the proposed changes.

Localities Particularly Affected. No locality is expected to be particularly affected.

Projected Impact on Employment. The proposed amendments eliminate the need to store Schedule VI devices at the medical suppliers' location and may reduce the demand for labor associated with that type of storage.

Effects on the Use and Value of Private Property. The proposed changes may benefit some medical equipment suppliers in terms of reduced storage/delivery costs which would positively affect their asset values.

Real Estate Development Costs. The proposed amendments do not affect real estate development costs.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. How many of the medical equipment suppliers are small business is not known. However, the proposed amendments may reduce the storage/delivery costs for some medical equipment suppliers as discussed above.

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not adversely affect small businesses.

Adverse Impacts:

Businesses. The proposed amendments do not adversely affect businesses.

Localities. The proposed amendments do not adversely affect localities.

Other Entities. The proposed amendments do not adversely affect other entities.

[1]http://lis.virginia.gov/cgi-bin/legp604.exe?181+ful+CHAP0241

[2]https://townhall.virginia.gov/l/ViewStage.cfm?stageid=8333

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the analysis of the Department of Planning and Budget.

Summary:

Chapters 241 and 242 of the 2018 Acts of Assembly, which enacted § 54.1-3415.1 of the Code of Virginia, establish the requirements for delivery of Schedule VI devices directly to an ultimate user or consumer on behalf of a medical equipment supplier upon a valid order from a prescriber or upon request from the medical director of a home health agency, nursing home, assisted living facility, or hospice. The proposed action adds 18VAC110-50-55 to implement Chapters 241 and 242.

18VAC110-50-55. Delivery of Schedule VI devices.

A. In accordance with the provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in this subsection and a medical equipment supplier in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the

medical equipment supplier who require delivery of Schedule VI prescription devices.

3. The medical equipment supplier shall represent to the delivering entity that it has complied with the provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the responsibility of the medical equipment supplier upon request of the board or delivering entity.

B. In accordance with the provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons authorized to administer such devices, provided that (i) such delivery is made on behalf of a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device and directs the delivery of such device to the ultimate user's or consumer's residence and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in this subsection and a medical director of a home health agency, nursing home, assisted living facility, or hospice and in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.

3. The home health agency, nursing home, assisted living facility, or hospice shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility, or hospice upon request of the board or delivering entity.

C. The agreement, as required by subdivisions A 1 and B 1 of this section, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect and for two years after the date the agreement is terminated or concluded.

D. An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191.

VA.R. Doc. No. R19-5526; Filed September 18, 2019, 11:59 a.m.

BOARD OF PHYSICAL THERAPY

Emergency Regulation

Title of Regulation: **18VAC112-20. Regulations Governing the Practice of Physical Therapy (amending 18VAC112-20-10, 18VAC112-20-27, 18VAC112-20-60, 18VAC112-20-65, 18VAC112-20-90, 18VAC112-20-130, 18VAC112-20-140, 18VAC112-20-200; adding 18VAC112-20-82).**

Statutory Authority: §§ 54.1-2400 and 54.1-3474 of the Code of Virginia.

Effective Dates: January 1, 2020, through June 30, 2021.

Agency Contact: Corie Tillman Wolf, Executive Director, Board of Physical Therapy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233, telephone (804) 367-4674, FAX (804) 527-4413, or email ptboard@dhp.virginia.gov.

Preamble:

Section 2.2-4011 B of the Code of Virginia states that agencies may adopt emergency regulations in situations in which Virginia statutory law or the appropriation act requires that a regulation be effective in 280 days or less from its enactment, and the regulation is not exempt under the provisions of § 2.2-4006 A 4 of the Code of Virginia.

The amendments are necessary for Virginia to participate in the Physical Therapy Compact, which allows a physical therapist or physical therapist assistant who has obtained a compact privilege to practice in the Commonwealth without a Virginia license. To comply with compact rules, the amendments require all applicants for licensure to have criminal background checks and all holders of a compact privilege to adhere to the laws and regulations governing practice in Virginia. As permitted by the compact rules, the amendments set the fee in Virginia at $50, which is similar to the fee charged by other states.

Part I
General Provisions

18VAC112-20-10. Definitions.

In addition to the words and terms defined in § §§ 54.1-3473 and 54.1-3486 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:

"Active practice" means a minimum of 160 hours of professional practice as a physical therapist or physical therapist assistant within the 24-month period immediately preceding renewal. Active practice may include supervisory, administrative, educational, or consultative activities or responsibilities for the delivery of such services.

"Approved program" means an educational program accredited by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association.

"Assessment tool" means oPTion or any other self-directed assessment tool approved by FSBPT.

"CLEP" means the College Level Examination Program.

"Compact" means the Physical Therapy Licensure Compact (§ 54.1-3485 of the Code of Virginia).

"Contact hour" means 60 minutes of time spent in continuing learning activity exclusive of breaks, meals, or vendor exhibits.

"Direct supervision" means a physical therapist or a physical therapist assistant is physically present and immediately available and is fully responsible for the physical therapy tasks or activities being performed.

"Discharge" means the discontinuation of interventions in an episode of care that have been provided in an unbroken sequence in a single practice setting and related to the physical therapy interventions for a given condition or problem.

"Evaluation" means a process in which the physical therapist makes clinical judgments based on data gathered during an examination or screening in order to plan and implement a treatment intervention, provide preventive care, reduce risks of injury and impairment, or provide for consultation.

"FCCPT" means the Foreign Credentialing Commission on Physical Therapy.

"FSBPT" means the Federation of State Boards of Physical Therapy.

"General supervision" means a physical therapist shall be available for consultation.

"National examination" means the examinations developed and administered by the Federation of State Boards of Physical Therapy and approved by the board for licensure as a physical therapist or physical therapist assistant.

"Physical Therapy Compact Commission" or "commission" means the national administrative body whose membership consists of all states that have enacted the compact.

"Reevaluation" means a process in which the physical therapist makes clinical judgments based on data gathered during an examination or screening in order to determine a patient's response to the treatment plan and care provided.

"Support personnel" means a person who is performing designated routine tasks related to physical therapy under the direction and supervision of a physical therapist or physical therapist assistant within the scope of this chapter.

"TOEFL" means the Test of English as a Foreign Language.

"Trainee" means a person seeking licensure as a physical therapist or physical therapist assistant who is undergoing a traineeship.

"Traineeship" means a period of active clinical practice during which an applicant for licensure as a physical therapist or physical therapist assistant works under the direct supervision of a physical therapist approved by the board.

"TSE" means the Test of Spoken English.

"Type 1" means continuing learning activities offered by an approved organization as specified in 18VAC112-20-131.

"Type 2" means continuing learning activities which may or may not be offered by an approved organization but shall be activities considered by the learner to be beneficial to practice or to continuing learning.

18VAC112-20-27. Fees.

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

B. Licensure by examination.

1. The application fee shall be $140 for a physical therapist and $100 for a physical therapist assistant.

2. The fees for taking all required examinations shall be paid directly to the examination services.

C. Licensure by endorsement. The fee for licensure by endorsement shall be $140 for a physical therapist and $100 for a physical therapist assistant.

D. Licensure renewal and reinstatement.

1. The fee for active license renewal for a physical therapist shall be $135 and for a physical therapist assistant shall be $70 and shall be due by December 31 in each even-numbered year.

2. The fee for an inactive license renewal for a physical therapist shall be $70 and for a physical therapist assistant

shall be $35 and shall be due by December 31 in each even-numbered year.

3. A fee of $50 for a physical therapist and $25 for a physical therapist assistant for processing a late renewal within one renewal cycle shall be paid in addition to the renewal fee.

4. The fee for reinstatement of a license that has expired for two or more years shall be $180 for a physical therapist and $120 for a physical therapist assistant and shall be submitted with an application for licensure reinstatement.

E. Other fees.

1. The fee for an application for reinstatement of a license that has been revoked shall be $1,000; the fee for an application for reinstatement of a license that has been suspended shall be $500.

2. The fee for a duplicate license shall be $5, and the fee for a duplicate wall certificate shall be $15.

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

4. The fee for a letter of good ~~standing/verification~~ standing or verification to another jurisdiction shall be $10.

5. The application fee for direct access certification shall be $75 for a physical therapist to obtain certification to provide services without a referral.

6. The state fee for obtaining or renewing a compact privilege to practice in Virginia shall be $50.

18VAC112-20-60. Requirements for licensure by examination.

Every applicant for initial licensure by examination shall submit:

1. Documentation of having met the educational requirements specified in 18VAC112-20-40 or 18VAC112-20-50;

2. The required application, fees, and credentials to the board, including a criminal history background check as required by § 54.1-3484 of the Code of Virginia; and

3. Documentation of passage of the national examination as prescribed by the board.

18VAC112-20-65. Requirements for licensure by endorsement.

A. A physical therapist or physical therapist assistant who holds a current, unrestricted license in the United States, its territories, the District of Columbia, or Canada may be licensed in Virginia by endorsement.

B. An applicant for licensure by endorsement shall submit:

1. Documentation of having met the educational requirements prescribed in 18VAC112-20-40 or 18VAC112-20-50. In lieu of meeting such requirements, an applicant may provide evidence of clinical practice consisting of at least 2,500 hours of patient care during the five years immediately preceding application for licensure in Virginia with a current, unrestricted license issued by another ~~U.S.~~ United States jurisdiction;

2. The required application, fees, and credentials to the board, including a criminal history background check as required by § 54.1-3484 of the Code of Virginia;

3. A current report from the Healthcare Integrity and Protection Data Bank ~~(HIPDB)~~;

4. Evidence of completion of 15 hours of continuing education for each year in which the applicant held a license in another ~~U.S.~~ United States jurisdiction, or 60 hours obtained within the past four years;

5. Documentation of passage of an examination equivalent to the Virginia examination at the time of initial licensure or documentation of passage of an examination required by another state at the time of initial licensure in that state; and

6. Documentation of active practice in physical therapy in another ~~U.S.~~ United States jurisdiction for at least 320 hours within the four years immediately preceding his application for licensure. A physical therapist who does not meet the active practice requirement shall:

a. Successfully complete 320 hours in a traineeship in accordance with requirements in 18VAC112-20-140; or

b. Document that he attained at least Level 2 on the FSBPT assessment tool within the two years preceding application for licensure in Virginia and successfully complete 160 hours in a traineeship in accordance with the requirements in 18VAC112-20-140.

C. A physical therapist assistant seeking licensure by endorsement who has not actively practiced physical therapy for at least 320 hours within the four years immediately preceding his application for licensure shall successfully complete 320 hours in a traineeship in accordance with the requirements in 18VAC112-20-140.

18VAC112-20-82. Requirements for a compact privilege.

To obtain a compact privilege to practice physical therapy in Virginia, a physical therapist or physical therapist assistant licensed in a remote state shall comply with the rules adopted by the Physical Therapy Compact Commission in effect at the time of application to the commission.

18VAC112-20-90. General responsibilities.

A. The physical therapist shall be responsible for managing all aspects of the physical therapy care of each patient and shall provide:

1. ~~Provide a certificate of attendance that shows the~~ The date, location, presenter or lecturer, content hours of the course and contact information of the provider or sponsor for verification. The certificate of attendance shall be based on verification by the sponsor of the attendee's presence throughout the course, either provided by a post-test or by a designated monitor.

2. ~~Maintain documentation about the course and attendance for at least three years following its completion.~~ Whether the course was in real-time and interactive, including in-person or electronic presentations.

I. Falsifying the attestation of compliance with continuing education on a renewal form or failure to comply with continuing education requirements may subject a licensee to disciplinary action by the board, consistent with § 54.1-3215 of the Code of Virginia.

VA.R. Doc. No. R17-5114; Filed October 15, 2019, 3:40 p.m.

BOARD OF PHARMACY

Proposed Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-275).**

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Hearing Information:

December 3, 2019 - 9:10 a.m. - Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 4, Richmond, VA 23233

Public Comment Deadline: January 10, 2020.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4456, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system. Section 54.1-3307 of the Code of Virginia authorizes the board to regulate the dispensing of prescription drugs.

Purpose: The purpose of the proposed regulatory action is to address patient safety concerns relating to brown bagging and white bagging. Specific requirements for notification and patient information to the receiving pharmacy or alternative delivery site of the shipment will better ensure appropriate coordination of patient care in white bagging. Requiring appropriate storage and security for a shipped product will protect public health and safety. The prohibition on delivering drugs to a patient's residence for administration, if the drug requires special storage, reconstitution, or compounding, will protect patients and the entities responsible for the integrity of the drug administered.

Substance: At the 2016 annual meeting of the National Association of Boards of Pharmacy (NABP), the membership authorized a study of "white bagging" and "brown bagging." A copy of the report may be viewed at https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final.pdf.

Based on the NABP report and the expertise of pharmacist members of the board and the pharmacy benefits manager workgroup, the board proposes regulations:

1. Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy or alternative delivery site of the shipment to ensure appropriate coordination of patient care;

2. Requiring the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped;

3. Requiring appropriate storage and security for a shipped product; and

4. Prohibiting delivery to a patient's residence of any drug that requires special storage, reconstitution, or compounding prior to administration is intended and that will be subsequently transported by the patient for administration.

Issues: The advantage to the public is less risk of a drug that requires special storage or has a short shelf life will be delivered to a pharmacy or other entity without preparations in place to receive that drug. There are no disadvantages.

There are no advantages or disadvantages to this agency or the Commonwealth.

Department of Planning and Budget's Economic Impact Analysis:

Summary of the Proposed Amendments to Regulation. Under specified circumstances, the Board of Pharmacy (Board) proposes to ease burdens related to the delivery of prescription drugs from a pharmacy to an alternative delivery site. The alternative delivery site may be another pharmacy, a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or an authorized person or entity holding a controlled substances registration. The Board also proposes to prohibit delivering 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 if the drugs require special storage, reconstitution or compounding prior to administration.

Result of Analysis. The benefits likely exceed the costs for one or more proposed changes. For other amendments,

whether the benefits exceed the costs depend on the policy views of the observer.

Estimated Economic Impact.

Background:

In addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, under specified conditions 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.

When the delivery is to another pharmacy, the two pharmacies must 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 (including counseling, return of any prescription medications not delivered to the patient, etc.), and the manner in which each pharmacy will comply with all applicable federal and state law. When the delivery is to a practitioner of the healing arts licensed by the Board to practice pharmacy or to sell controlled substances or another authorized person or entity holding a controlled substances registration authorized for this purpose, there must be a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party. According to the Department of Health Professions, sometimes this is impractical or causes delay in the delivery of a medication that a patient needs. If a specialty drug is needed, the pharmacy benefits manager or insurer may require that the drug be obtained from a specialty pharmacy or the pharmacy to which the prescription is sent may not carry that drug.

Proposals:

The Board proposes to permit deliveries from a pharmacy to an alternative delivery site without the detailed written contract or same ownership if the alternate delivery site does not routinely receive deliveries from the pharmacy and producing and agreeing to the contract and paperwork details would create a delay in delivery that may result in potential patient harm. The pharmacy would be required to 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. Similar to current requirements, 1) the pharmacy would have to provide counseling or ensure a process is in place for the patient to receive counseling, 2) prescriptions delivered to the alternate delivery site would have to 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, and 3) the pharmacy would have to provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

This proposed amendment may substantially reduce delays in some patients receiving needed medications. Consequently, it may produce large health benefits. Given the safety procedures accompanying the proposal, it seems unlikely that there would be an increase in health risk. Thus, the benefits very likely exceed the costs.

The Board also proposes to prohibit delivering 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 if the drugs require special storage, reconstitution or compounding prior to administration. The proposed language includes an exception for patients with hemophilia who may require emergent blood factor treatment.

When drugs require special storage, reconstitution or compounding, there is increased risk that they may become ineffective or dangerous if not handled properly. Prohibiting the delivery of such drugs to a patient's residence that are intended to be subsequently transported as described above would likely reduce the occurrences where drugs that become ineffective or dangerous due to mishandling are administered to patients. This is beneficial. On the other hand, there may be circumstances where such delivery is the most practical way for certain patients to quickly receive needed treatment. The Board has recognized this by providing the exemption for patients with hemophilia. There may be other patients for which this is true who are not exempted by the proposal. In addition, some individuals may believe that they should not be prevented from taking their own informed risks.

Businesses and Entities Affected. The proposed amendments potentially affect the 1,813 pharmacies, practitioners of the healing arts licensed to practice pharmacy or to sell controlled substances, authorized persons or entities holding a controlled substances registration, and patients.

Localities Particularly Affected. The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment. The proposed amendments are unlikely to substantially affect employment.

Effects on the Use and Value of Private Property. The proposal to permit deliveries from a pharmacy to an alternative delivery site without a detailed written contract may reduce costs for small firms involved. This may modestly increase their value.

Real Estate Development Costs. The proposed amendments do not affect real estate development costs.

Small Businesses:

Definition. Pursuant to § 2.2-4007.04 of the Code of Virginia, small business is defined as "a business entity, including its affiliates, that (i) is independently owned and operated and (ii) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million."

Costs and Other Effects. The proposal to permit deliveries from a pharmacy to an alternative delivery site without a detailed written contract may reduce costs for small firms involved.

Alternative Method that Minimizes Adverse Impact. The proposed amendments do not adversely affect small businesses.

Adverse Impacts:

Businesses. The proposed amendments do not adversely affect businesses.

Localities. The proposed amendments do not adversely affect localities.

Other Entities. The proposed amendments do not adversely affect other entities.

Agency's Response to Economic Impact Analysis: The Board of Pharmacy concurs with the analysis of the Department of Planning and Budget.

Summary:

The proposed amendments (i) require the specialty pharmacy participating in white bagging to notify the receiving pharmacy or alternative delivery site of the shipment to ensure appropriate coordination of patient care; (ii) require the pharmacy to provide to the receiving pharmacy an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped; (iii) require appropriate storage and security for a shipped product; and (iv) prohibit delivery to a patient's residence of any drug that requires special storage, reconstitution, or compounding prior to administration is intended and that will be subsequently transported by the patient for administration.

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;

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.

F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) 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 delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

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 that cannot be easily moved and that 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. An exception to this requirement may be made for patients with hemophilia who may require emergent blood factor treatment.

VA.R. Doc. No. R18-5376; Filed October 23, 2019, 11:42 a.m.

BOARD OF PHARMACY

Final Regulation

REGISTRAR'S NOTICE: The Board of Pharmacy is claiming an exemption from Article 2 of the Administrative Process Act in accordance with § 2.2-4006 A 13 of the Code of Virginia, which exempts amendments to regulations of the board to schedule a substance in Schedule I or II pursuant to subsection D of § 54.1-3443 of the Code of Virginia. The board will receive, consider, and respond to petitions by any interested person at any time with respect to reconsideration or revision.

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-322).**

Statutory Authority: §§ 54.1-2400 and 54.1-3433 of the Code of Virginia.

Effective Date: December 11, 2019.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300,

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Friday September 20, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 am.
PRESIDING:	Kris Ratliff, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jess Kelley, DHP Adjudication Specialist
DHARMINDRA SEOPARSAN License No. 0202-209101	Dharmindra Seoparsan, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 9, 2019 Notice. He was represented by Nathan Mortier, Esq.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Dharmindra Seoparsan. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee voted unanimously enter an Order for a Reprimand.
NADIA ZADRAN Registration No. 0230-031696	Nadia Zadran, pharmacy technician, did not appear and was not represented at the informal conference to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 13, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Nadia Zadran. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order for the indefinite suspension of the right of Ms. Zadran to renew her registration.
SCOTT BRIERTON Pharmacist Endorsement Applicant	Scott Brierton, pharmacist, appeared on his own behalf to consider his application for a pharmacy license by endorsement and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 12, 2019 Notice.

Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Scott Brierton. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee voted unanimously enter an Order approving Mr. Brierton's application for licensure subject to the completion of certain terms and conditions.
RONALD BENNETT License No. 0202-010021	Ronald Bennett, pharmacist, appeared on his own behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 13, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Ronald Bennett. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the

decision.

Decision:

Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee voted unanimously enter an Order to issue a reprimand and require the completion of four hours of continuing education.

DWAIN WILKERSON
License No. 0202-207917

Dwain Wilkerson, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 02, 2019 Notice. He was represented by Lindsay Walton, Esq.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Dwain Wilkerson. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee voted unanimously to refer the case to a Formal Administrative Hearing, and to offer a Consent Order for the suspension of Mr. Wilkerson's license for one year.

TIMBERLAKE FAMILY PHARMACY
F.K.A. RUSTBURG FAMILY PHARMACY
Permit No. 0201-004716

James V. Ettare, Pharmacist-in-Charge of Timberlake Family Pharmacy, F.K.A. Rustburg Family Pharmacy, appeared to discuss allegations that Timberlake Family Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 05, 2019 Notice. The pharmacy was represented by

Howard Estes Esq.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of James Rivers. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Boone and duly seconded by Mr. Ratliff, the Committee voted unanimously to dismiss the case.

ADJOURNED:

7:38 pm

_____
Kris Ratliff, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

September 24, 2019

Second Floor
Board Room 4

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

CALL TO ORDER:	A meeting of an informal conference committee of the Board of Pharmacy was called to order at 3:10 PM
PRESIDING:	Cynthia Warriner, Committee Chairman
MEMBER PRESENT:	Ryan Logan
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Anne Joseph, DHP Adjudication Specialist
Kroger Pharmacy #523 Technician Product Verification (TPV)	Alexis Page, PharmD, Community-based Pharmacy Leadership and Management Fellow with Kroger; Michele Fountain, PharmD, Regional Clinical Manager for Kroger Pharmacy; David Flammia, Pharmacy Practice Coordinator for Kroger Pharmacy; Anne Harrison, Pharmacy Manager for Kroger Pharmacy;Micah Cost, CEO of Tennessee Pharmacist Association, were present to discuss the application, received April 18, 2019, for approval of an Innovative (Pilot) program from Kroger Pharmacy. Kroger Pharmacy is seeking permission to move forward with a Technician Product Verification pilot at six Kroger Pharmacies located in the state of Virginia. Kroger Pharmacy is seeking a waiver of 18VAC110-20-270 subsection C of the regulations governing the Practice of Pharmacy dealing with dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians, and § 54.1-3300 (A)(6) dealing with Acts Restricted to Pharmacist.
Other:	David Flammia left at approximately 4:10 PM.
Discussion:	Representatives of Kroger Pharmacy presented additional information related to their application previously requested

by the Committee. The CEO of the Tennessee Pharmacist Association shared information and responded to questions related to the Technician Product Verification pilot they are currently conducting in the state of Tennessee. The pilot began May 1, 2019.

Decision: After consideration of the application and supporting documents and after hearing statements from the applicant concerning the proposed Innovative (Pilot) program, the Board denied the application for Technician Product Verification.

ADJOURN: With all business concluded, the meeting adjourned at 5:30 PM.

Cynthia Warriner
Committee Chairman

Date

Caroline D. Juran
Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

September 25, 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 9:20 am.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Kristopher S. Ratliff, Vice Chairman
Glen Bolyard
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
William Lee
Ryan Logan
Cheryl H. Nelson (Arrived at 9:34)
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP (Departed 12:28pm)
James Rutkowski, Assistant Attorney General
Mykl Egan, Disciplinary Case Manager (Arrived 12:32pm)
Kiara Christian, Executive Assistant

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

APPROVAL OF AGENDA: Ms. Warriner advised that an amended agenda had been provided as a handout that included the following new agenda items: Amend Guidance Document 110-36, *Compliance with USP Standards;* Adopt Guidance Document for *Pharmacies Within Opioid Treatment Programs*; and, an oral report from board counsel. She also requested that the board move the "New Business" section to after the "Possible Summary Suspension/Consent Orders" section of the agenda.

MOTION: **The amended agenda was adopted unanimously as presented and amended. (motion by Ratliff, seconded by Rebecca)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION:

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

- **June 5, 2019, Full Board Meeting**
- **June 5, 2019, Public Hearing for Increase in Fees**
- **June 27, 2019, Special Conference Committee**
- **July 18, 2019, Special Conference Committee**
- **July 25, 2019, Special Conference Committee**
- **July 31, 2019, Formal Hearing**
- **August 14, 2019, Special Conference Committee- Innovative Pilot Program**
- **August 22, 2019, Formal Hearing**

(motion by Ratliff, seconded by Richards-Spruill)

PUBLIC COMMENTS:

Aaron Lopez, representing Political Capital, offered public comment on implementation of new USP requirements. Mr. Lopez acknowledged that the board appears to be addressing the implementation of USP 795, 797, and 800, and that Political capital is interested in a possible 6-month delay.

Christina Barrille, Executive Director, Virginia Pharmacists Association, began her comment by congratulating Ms. Warriner for her appointment as Chairman, Mr. Ratliff as Vice Chairman and welcoming Mr. Lee. She referred the board to the public comment offered by VPhA and VSHP in a joint letter dated September 24, 2019 that was given as a handout and urged the board to review the action items suggested. She also asked the board to consider implementing a requirement in 2020 for pharmacists to obtain one hour of CE related to the dispensing of naloxone.

Mark Hickman, representing Commonwealth Strategy Group, asked the board to consider the public comments offered in the joint letter submitted by VPhA and VSHP concerning the enforcement of new USP 797 and 800 requirements. Mr. Hickman also expressed concerns specifically on USP 797 requirements and the possible impact of patient access to care.

Cynthia Williams, Vice President, Riverside Health Systems, asked the board to review the two letters submitted by Riverside Health Systems. Ms. Williams shared concerns of challenges regarding the USP implementation date. She provided an estimated cost of $5 million for Riverside to comply with new requirements. Ms. Williams also shared challenges related to remodeling, such as finding contractors and budget resources, and how this may impact patient access.

David Creecy, pharmacist with Poquoson Compounding, shared concerns related specifically to retail pharmacies, and decrease in patient access pending the implementation of USP 795, 797, and 800. He also said that he had concerns about the significant cost for the required renovations and how this may impact patient cost and services. Mr. Creecy said that a delay in USP 800 would be helpful.

Katie Hellabush, Virginia Cannabis Association, shared support of the passing of SB 1719.

DHP DIRECTOR'S REPORT:

Dr. Brown welcomed Mr. Lee to the Board and provided information related to the security at the Perimeter Center. He shared that DHP will host an agency-wide board member training on October 7th and encouraged attendance.

UPDATE FROM VCU'S SCHOOL OF PHARMACY

Joseph DiPiro, Dean of the VCU School of Pharmacy shared a handout with informational updates from the VCU School of Pharmacy.

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Update on Regulatory/Policy Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found in the agenda packet. She also stated that DHP has learned that the board's legislative proposals will not be included in the Governors legislative packet for the 2020 General Assembly session.

Adoption of exempt regulation to schedule certain chemicals in Schedule I

MOTION:

The board voted unanimously to place the drugs identified by the Department of Forensic Science into Schedule I by amending 18VAC110-20-322 as follows: 1) delete subsections A through D as the chemicals have been now scheduled in the Drug Control Act and 2) insert a new subsection C to read "C. Pursuant to subsection D of §54.1-3443 of the Code of Virginia, the Board of Pharmacy placed the following chemicals into Schedule I of the Drug Control Act:

1. Synthetic opioids:

a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF17), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

2. Research Chemicals

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

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

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

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

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

3. Cannabimimetic agents:

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

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

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

Adoption of emergency regulations for Pharmaceutical Processors

The board reviewed SB1719 passed during the 2019 General Assembly session and draft amendments relating to registered agents and wholesale distribution of CBD and THC-A oil. It was noted that SB1719 required the adoption of emergency regulations regarding the registration of registered agents for patients certified to receive cannabidiol or THC-A oil and for the wholesale distribution of oils between processors. During discussion, it was noted by the board that a Power of Attorney could obtain registration as a registered agent, but not as a parent/guardian.

MOTION:

The board voted unanimously to adopt the emergency regulations and Notice of Intended Regulatory Action to replace the emergency regulations for Pharmaceutical Processors as presented. (motion by Logan, seconded by Boone)

Adoption of exempt regulations for Pharmaceutical Processors

The board reviewed SB1719 and draft amendments to 18VAC110-60-130 and 18VAC110-60-170. SB1719 allows a processor to employ individuals with less than two years of experience to perform certain tasks under supervision and allows a processor to begin cultivation as soon as a permit is issued. These statutory amendments require an exempt regulatory action to conform the requirements in regulation to the new statutory allowances.

MOTION:

The board voted unanimously to adopt the exempt regulations for Pharmaceutical Processors as presented. (motion by Ratliff, seconded Nelson)

During discussion, several board members expressed concern for vaped products based on recent warnings from the CDC and FDA involving patient harm.

ACTION ITEM:

The board requested staff to research with counsel whether it had legal discretion in registering CBD and THC-A oil products that are intended to be vaped or it could prohibit pharmaceutical processors from producing vaped products.

Adoption of Proposed Regulations for Labeling Dispensed Prescriptions

At the June 5, 2019 board meeting, the board requested that staff send a letter regarding the proposed regulations for Labeling Dispensed Prescriptions to consumer groups such as Senior Connections and AARP to obtain feedback on this topic. The board was provided copies of the letters sent to Senior Connections, Virginia Citizen Consumer Council, Virginia Association of Area Agencies on Aging, Virginia Navigators, and Virginia AARP. The board did not receive any feedback from these organizations. The board reviewed the proposed amendments to 18VAC110-20-275 as recommended by the Regulation Committee and included in the agenda packet.

MOTION:

The board voted 7:3 to adopt the proposed amendments as recommended by the Regulation Committee. (motion by Nelson, seconded Boone; opposed by Warriner, Ratliff, and Jenkins)

Adoption of Final Regulations for Fee Increase

The board was provided a handout containing projected revenue and expenditures over the next few years and reviewed the proposed regulations for an increase in fees as found in the agenda packet. A public hearing was conducted on June 5, 2019. Public comments were accepted from May 27, 2019 to July 27, 2019. No comment was received.

MOTION:

The board voted 9:1 to adopt the final regulations as presented regarding an increase in licensure fees. (motion by Logan, seconded by Richards-Spruill; opposed by Jenkins)

Amend Guidance Document 110-7, *Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self*, and Guidance Document 110-8, *Information on Prescriptive Authority in Virginia*

The board reviewed the amended draft of Guidance Documents 110-07 *Practioner/Patient Relationship and the Prescribing of Drugs for Family or Self*, and 110-08 *Prescriptive Authority in Virginia* for readoption. It was shared that there were no substantial changes to the documents and that the text was revised for clarity, and the text of the statutes were revised to be current.

MOTION:

The board voted unanimously to adopt the amendments to Guidance Document 110-07 *Practitioner/Patient Relationship and the Prescribing of Drugs for Family or Self* as presented.(motion by Jenkins, Seconded by Bolyard)

MOTION:

The board voted unanimously to adopt the amendments to Guidance Document 110-08 *Information on Prescriptive Authority in Virginia* as presented. (motion by Nelson, seconded by Boone)

Amend Guidance Document 110-36, Compliance with USP Standards for Compounding

The board was provided a handout containing draft amendments of Guidance Document 110-36 *Compliance with USP Standards for Compounding* in response to certain USP chapters being under appeal which will delay the effective date of the chapters. Staff explained that on September 23, 2019, USP published a Notice of Intent to Revise which stated Chapters 795, 797, and 825 were under appeal and that "USP's Bylaws provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice. In the interim, the currently official chapters of <795> (last revised in 2014) and <797> (last revised in 2008) including the section Radiopharmaceuticals as CSPs will remain official. General Chapter <800> is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable." While USP and the Board encourages utilization of <800> in the interest of advancing public health, the Board

cannot legally require compliance with requirements in 800 related to compounding until the appeals of 795 and 797 are resolved and the revised chapters become effective.

During discussion, the board suggested the following amendment:

"51.) If the pharmacy does not compound with hazardous drugs, but ~~does split~~ performs splitting of tablets of hazardous drugs, must the pharmacy comply with the requirements of Chapter <800>?"

Ms. Yeatts indicated that if the board adopts the amendments, the guidance document will be published in the Registrar after permission to publish is received and a public comment period of 30 days must conclude prior to the guidance document being effective.

MOTION:

The board voted unanimously to adopt amendments to Guidance Document 110-36 *Compliance with USP Standards for Compounding* as presented and amended by changing "does split" to "performs splitting of" in question number 51. (motion by Jenkins, seconded Richards-Spruill)

Amend Guidance Document 110-44, *Naloxone Protocols* and Guidance Document 110-1, *List of Categories of Facility Licenses*, and Repeal Guidance Document 110-45

The board reviewed an amended draft of Guidance Documents 110-44 *Naloxone Protocols* and 110-1 *List of Categories of Facility Licensure*. It was shared that because of substantial changes in the Code relating to the dispensing and distribution of naloxone the protocols adopted by the Board for such activities need to be amended. The draft combines both 110-44 and 110-45 into one document in effort to streamline the information to reduce any possible confusion with having two separate protocols. Additionally, minor edits were necessary in Guidance Document 110-1 as a result of the statutory requirement for obtaining a controlled substances registration when certain entities dispense naloxone.

MOTION:

The board voted unanimously to adopt amendments to Guidance Documents 110-44 and 110-1 as presented, and to repeal Guidance Document 110-45. (motion Logan, seconded Thornbury)

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

The board reviewed the amended draft of Guidance Documents 110-28 *Guidance for Free Clinic Pharmacy Applications*. Ms. Juran shared that a physician selling controlled substances applicant requested a waiver of regulation to allow for use of a bathroom sink as the source of hot and cold running water. The chairman and executive director denied the request and the physician requested further consideration. If the matter was to be considered by the board, the chairman and staff requested that the board consider a similar allowance for free clinic pharmacies. Counsel advised that it would be better for an informal conference committee of the board to further consider the physician selling controlled substances waiver request. The board directed staff to inform the physician of this information and the board took no action on Guidance Document 110-28.

New Guidance Document 110-6 Guidance for Pharmacies within Opioid Treatment Programs

The board was provided with a draft handout of new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs*. Ms. Juran explained that DEA expressed concern for practices within opioid treatment programs that may pose a risk for diversion. It was requested that the board educate licensees practicing in this environment.

MOTION:

The board voted unanimously to adopt the new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs* as presented. (motion by Thornbury, seconded Boone)

REPORTS

Chairman's Report

Ms. Warriner shared her experience of attending the NABP/AACP Districts 1 & 2 meeting, and encouraged the board to participate in NABP meetings moving forward. She was elected to serve as the District 2 representative on the NABP Resolution Committee. Ms. Warriner also shared her concerns with the number of recent pharmacy closings and patient access to pharmaceutical needs. She asked that staff provide a report reflecting the number of pharmacy closures to include the pharmacy name, address, and license number.

ACTION ITEM:

Board staff will provide the board at a subsequent meeting with a list of pharmacies that have closed each year for the last several years. The list will contain the pharmacy names, addresses, and license numbers, at a minimum.

Report on Board of Health Professions

Mr. Logan shared that he could not attend the last Board of Health Professions meeting and that he would provide an update at the next Full Board Meeting

Report on Inspection and Licensure Program

Ms. Juran provided an update of the licensing/inspection report included in the agenda packet.

Report on Pharmaceutical Processors

Ms. Kelley reviewed the Pharmaceutical Processor report included in the agenda packet. She shared that the report to be prepared by the Secretaries of Health and Human Resources and Agriculture regarding the appropriate structure for oversight of industrial hemp products is due to the legislators by November 1, 2019, and may be available as a public document by the next board meeting.

Report on Disciplinary Program

Ms. Shinaberry provided an overview of the update included in the agenda packet. She introduced Mr. Mykl Egan, J.D. as the new Disciplinary Case Manager.

Executive Director's Report

Ms. Juran provided an overview of the update included in the agenda packet. She shared information regarding the NABP/AACP Districts 1 & 2 Meeting in Vermont and encouraged attendance at the next District 1&2 meeting.

Board Counsel's Report

Mr. Rutkowski provided the board with an update on the New Age case. He shared that New Age has appealed the Board of Pharmacy's decision to deny its pharmaceutical processor application to the Virginia Court of Appeals.

New Business

The board confirmed 2020 meeting dates as follows:

Full Board Meeting: March 24, 2020, June 16, 2020, September 9, 2020, December 10, 2020

Formal Hearing: January 14, 2020, February 5, 2020, April 22, 2020, May 13, 2020, July 21, 2020, August 5, 2020, October 7, 2020, November 12, 2020

Special Conference Committee: January 7, 2020, February 18, 2020, March 10, 2020, April 1, 2020, May 5, 2020, June 23, 2020, July 7, 2020, August 18, 2020

Regulation Committee: May 13, 2020 and November 12, 2020

Consideration of Consent Orders

MOTION:

The board voted unanimously to enter into closed session pursuant to §2.2-3711(A)(11) to consult with counsel regarding actual or probable litigation. Additionally, it was moved that Caroline Juran, Ellen Shinaberry, and Kiara Christian attend the closed meeting because their presence was deemed necessary and would aid the Board. (motion by Ratliff, seconded by Jenkins)

MOTION:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Ratliff, seconded by Logan)

Innocent Akani

License No. 0202-205580

DECISION:

Upon a motion by Ms. Thornbury, and duly seconded by Ms. Richards-Spruill, the panel voted 8 in favor, 1 opposed (Jenkins), and 1 abstained (Nelson) to accept the consent order for revocation of the pharmacist license for Innocent Akani.

Nayan Patel

License No. 0202-209826

DECISION: **Upon a motion by Mr. Lee, and duly seconded by Mr. Boone, the panel voted unanimously to accept the consent order to reinstate the pharmacist license for Nayan Patel.**

Central Drugs

Permit No. 0214-001254

DECISION: **Upon a motion by Mr. Ratliff, and duly seconded by Mr. Bolyard, the panel voted unanimously to accept the consent order to reinstate the non-resident pharmacy registration for Central Drugs.**

ADJOURN: With all business concluded, the meeting adjourned at 2:50 pm.

Cynthia Warriner, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR POSSIBLE SCHEDULING CERTAIN CHEMICALS IN SCHEDULE I OF THE DRUG CONTROL ACT

September 25, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The public hearing was called to order at 9:15 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Glenn L. Bolyard, Jr.
Melvin L. Boone, Sr.
Ryan K. Logan
Kristopher S. Ratliff
Patricia Richards-Spruill
Rebecca Thornbury
William Lee
James L. Jenkins, Jr.

STAFF PRESENT:
Caroline D. Juran, Executive Director
Annette Kelley, 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
Kiara Christian, Executive Assistant

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

Pursuant to article § 54.1-3443(D), the Virginia Department of Forensic Science (DFS) has identified nine (9) compounds for recommended inclusion into the Code of Virginia:

The following compounds are classified as powerful synthetic opioids:

- N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF17)
- N-[2-(dimethylamino)cyclohexyl]-N-

phenylpropionamide (other name: UF-17)

The following compounds are classified as research chemicals:

- 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT)
- 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB)
- 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone)
- N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA)
- 3,4-methylenedioxy-N-benzylcathinone (other name: BMDP)

The following compounds are classified as cannabimimetic agents:

- Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA)
- Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA)

If approved by the Board of Pharmacy, the placement of these substances into 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.

PUBLIC COMMENT:

Scott May, Director of the Northern Virginia Lab, Department of Forensic Science offered comment on the identified chemicals. Because of a job promotion, he will no longer provide information to the board on this subject. He introduced the new Chemical Director who will assist the board in the future.

ADJOURN:

The public hearing adjourned at 9:20am.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

September 25, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 3:10 p.m.

PRESIDING: Rebecca Thornbury, Chair

MEMBERS PRESENT:
Glenn Bolyard
Cheryl Nelson
Rafael Saenz
Ryan Logan
Melvin Boone
William Lee
Patricia Richards-Spruill
James Jenkins

STAFF PRESENT:
Caroline Juran, Executive Director, Board of Pharmacy (Exited at 5:15 p.m.)
Ellen Shinaberry, Deputy Director, Board of Pharmacy
Beth O' Halloran, Deputy Director, Board of Pharmacy
Mykl Egan, Disciplinary Case Manager, board of Pharmacy
Kiara Christian, Executive Asst, Board of Pharmacy
Sean Murphy, Assistant Attorney General
James Rutkowski, Assistant Attorney General
Jessica Kelley, Adjudication Specialist, APD

QUORUM: With nine (9) members of the Board present, a panel was established.

FORMAL HEARING

Olympia Compounding Pharmacy
License #: 0214-001826

A formal hearing was held in the matter of Olympia Compounding Pharmacy to discuss the reinstatement of its non-resident pharmacy permit.

Sean Murphy, Assistant Attorney General, presented the case. He was assisted by Jessica Kelly, Adjudication Specialist.

Gail Miller, DHP Senior Investigator testified on behalf of the Commonwealth.

Olympia Compounding Pharmacy was represented by Julia Krebs-Markrich, Esquire and Rachel Pontikes, Esquire.

Lou Diorio, RPh, FAPhA, of LDT Health Solutions, Inc., testified on behalf of Olympia Compounding Pharmacy.

CLOSED MEETING:

Upon a motion by Mr. Ratliff, and duly seconded by Ms. Nelson, the panel voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Olympia Compounding Pharmacy. Additionally, he moved that Ellen Shinaberry, Mykl Egan, Beth O'Halloran, Kiara Christian, and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Mr. Jenkins and duly seconded by Mr. Boone, the Board voted 8 in favor, 1 opposed (Nelson) to reinstate the non-resident pharmacy permit contingent upon the additional submission and approval of a non-resident outsourcing facility application.

ADJOURNED:

With all business concluded, the meeting adjourned at 9:20 PM.

Rebecca Thornbury, Chair

Caroline D. Juran
Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, October 9, 2019

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on October 9, 2019, at 2:15 p.m., to consider the summary suspension of the registration of Paulette Toller to practice as pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Cynthia Warriner, Chair

MEMBERS PRESENT:
Glenn Bolyard
Melvin Boone
James Jenkins
William Lee
Cheryl Nelson
Kristopher Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Mykl D. Egan, Discipline Case Manager
Ellen Shinaberry, Deputy Executive Director
Jess Kelley, DHP Adjudication Specialist
James Rutkowski, Senior Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General

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

With nine (9) members participating and one (1) member unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

PAULETTE TOLLER
Registration No. 0230-004204

James Schliessmann, Senior Assistant Attorney General, presented a summary of the evidence in this case.

DECISION:

Upon a motion by Mr. Jenkins and duly seconded by Mr. Ratliff, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Paulette Toller poses a substantial danger to the public; and therefore, the registration of Ms. Toller shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Toller for the indefinite suspension of her registration for not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at 2:35 p.m.

Cynthia Warriner, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, October 23, 2019
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:04 am.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: Glen Bolyard, Committee Member

STAFF PRESENT: Ellen B. Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Ileita Redd, Discipline Program Specialist
Jess Kelley, DHP Adjudication Specialist

ATHANASIOS MASTROKOSTAS
Pharmacist Endorsement Applicant

Athanasios Mastrokostas, pharmacist, appeared on his own behalf to consider his application for a pharmacy license by endorsement and to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 4, 2019 Notice.

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

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

Decision:	Upon a motion by Mr. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order approving Mr. Mastrokostas' application for licensure.
CHIQUITA LYNETTE AMANDA LOVING License No. 0202-211347	Chiquita Lynette Amanda Loving, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 22, 2019 Notice. She was represented by Carteia Basnight, Esq.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Chiquita Lynette Amanda Loving. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to order Ms. Loving to pay a monetary penalty and to satisfy certain terms and conditions.
MARIO BLOUNT Pharmacist Endorsement Applicant	Mario Blount, pharmacist, appeared on his own behalf to consider his application for a pharmacy license by endorsement and to discuss allegations

that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 27, 2019 Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order denying Mr. Blount's application for licensure.

ADJOURNED:

4:15 pm

_____
Patricia Richards-Spruill, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, October 31, 2019

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on October 31, 2019, at 2:00 p.m., to consider the summary suspension of the license of Tien Phan to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: Kristopher Ratliff, Chair

MEMBERS PRESENT:
Glenn Bolyard
Melvin Boone
James Jenkins
William Lee
Patricia Richards-Spruill

STAFF PRESENT:
Caroline D. Juran, Executive Director
Mykl D. Egan, Discipline Case Manager
Ellen Shinaberry, Deputy Executive Director
Jess Kelley, DHP Adjudication Specialist
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General

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

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

TIEN PHAN Sean J. Murphy, Assistant Attorney General, presented

License No. 0202-214002	a summary of the evidence in this case.
DECISION:	Upon a motion by Mr. Bolyard and duly seconded by Mr. Boone, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by Tien Phan poses a substantial danger to the public; and therefore, the license of Mr. Phan shall be summarily suspended. Further, upon a motion by Mr. Jenkins and duly seconded by Ms. Richards-Spruill, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Mr. Phan for the indefinite suspension of his license for not less than two years.
ADJOURN:	With all business concluded, the meeting adjourned at 2:15 p.m.

Kristopher Ratliff, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

Board of Pharmacy
Chart of Regulatory Actions as of November 25, 2019

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *Register Date: 11/11/19* *Comment ends: 1/10/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] Proposed - *At Secretary's Office for 3 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 551 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 15 and 21 [Action 4538] Final - *Register Date: 11/11/19* *Effective: 12/11/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals [Action 5396] Final - *Register Date: 11/11/19* *Effective: 12/11/19*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Final - *At Secretary's Office for 33 days*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *Register Date: 10/14/19* *Comment ends: 12/13/19*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Emergency/NOIRA - *DPB Review in progress* [Stage 8778]

Agenda item: Guidance documents

Staff note:

In accordance with the requirement for review of guidance documents every four years, the Regulation Committee recommends:

- Reaffirmation of 110-18 and 110-23 without revision
- Revision of 110-15 – Delegation of Authority for Disciplinary Matters

Due to changes in regulations, the Committee recommends:

- Revision to 110-27 – PIC Responsibilities

Due to questions from stakeholders/interested parties in the course of a study on collaborative practice by the Joint Commission on Health Care in the General Assembly, the Committee recommends:

- Adoption of 110-13 – Guidance on Collaborative Practice Agreements

For implementation of regulations for pharmaceutical processors, relating to statistically valid samples for testing (18VAC110-60-300), the Committee recommends:

- Adoption of 110-14 – Statistically valid sample size for pharmaceutical processors

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

Board action:

Adoption of Guidance Documents as specified above.

Guidance document: 110-18 Reaffirmed: December 9, 2019

Virginia Board of Pharmacy

Interpretation of "administer" to include preparation for administration

The Board of Pharmacy finds that the term "administer", as defined in § 54.1-3401, can be reasonably interpreted to include the advance preparation or "set up" of medications to be administered to patients provided such advance preparation is performed only by a person licensed to dispense or administer drugs (medical practitioner, pharmacist, registered nurse, licensed practical nurse, or physician assistant) and the advance preparation is reasonably concurrent with the actual administration and should not extend beyond the next scheduled dosage administration.

However, if the advance preparation is to assist a patient, living in a private residence, in the administration of drugs which would normally be self administered, including insulin, such advance preparation shall not exceed a fourteen (14) day supply.

If the advance preparation, as performed by a person licensed to dispense or administer drugs, is to assist in the administration of medications to students during a single-day field trip, such advance preparation shall not be made prior to the last working day before the day of the field trip and shall not exceed a one-day supply. Any packaging used in such advance preparation shall include the student's name and any other appropriate student identifier; physician's name; drug name and strength, and quantity; and appropriate directions for administration. For any field trip which is longer than one day in length, a student's prescription medication should be provided by the student's parent or guardian in a properly labeled prescription vial which has been dispensed from a pharmacy and, for oral medications, which contains only the quantity needed for the duration of the field trip.

Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. Practitioner selling on an expired license.	18VAC110-30-30	Per individual	100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling location without application or Board approval.	18VAC110-30-80	must submit an application and fee	250
4. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks.	18VAC110-30-40	Per individual	250
6. Refrigerator/freezer temperature out of range greater than +/- 4 degrees.	18VAC110-30-110	determined using inspector'calibrated thermometer	100 Drugs may be embargoed

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.	500
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
11. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 & 18VAC110-30-180	Minor 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
16. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000
19. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
22. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
25. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
26. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
29. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500
30. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
31. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		500
32. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		5000
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
34. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
35. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

Minor Deficiencies

If five (5) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial five.

Minor Deficiency	Law/Regulation Cite	Conditions
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
3. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	

10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock.	18VAC110-30-150	10% threshold
Minor Deficiency	**Law/Regulation Cite**	**Conditions**
12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
14. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
16. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	

20. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
23. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
24. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	
30. Equipment for non-sterile compounding does not comply with USP-NF standards.	54.1-3410.2	

Virginia Board of Pharmacy

Delegation of Authority for Disciplinary Matters

The Board of Pharmacy delegates to the executive director the authority to offer a prehearing consent order (PHCO) in the following circumstances:

1. Action taken by another state board of pharmacy – PHCO would require compliance with other state's action.
2. Single dispensing error with no patient harm involving an individual who is a minor or medically compromised, or a drug with a narrow therapeutic index – PHCO would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.
3. Inspection report as part of an investigation which resulted in the citing of deficiencies, as identified in Guidance Document 110-9, for which the guidance document recommends a monetary penalty – PHCO would impose the recommended monetary penalty as indicated in Guidance Document 110-9.
4. Application for a change in pharmacist-in-charge (PIC) is submitted beyond the required timeframe for designating a new PIC – PHCO would impose recommended monetary penalty as indicated in Guidance Document 110-9 for either not having a PIC fully engaged in the practice at the pharmacy location or having a PIC in place, inventory taken, but application not filed with Board within the required timeframe.
5. Voluntary surrender of a license or registration for reasons not related to disciplinary action.

The Board of Pharmacy delegates to the executive director the authority to offer a confidential consent agreement (CCA) in the following circumstances:

1. Single dispensing error with no patient harm, except as noted in #2 above – CCA would require licensee to obtain hours of continuing education in the subject of medication dispensing errors.

The Board of Pharmacy delegates to the executive director the authority to close cases that have insufficient evidence of a violation of law or regulation. The Board further delegates to the executive director the authority to issue an advisory letter to the person who was the subject of a complaint pursuant to §54.1-2400.2(G), when it is determined that a disciplinary proceeding will not be instituted.

§ 54.1-2400.2. (Effective January 1, 2020) Confidentiality of information obtained during an investigation or disciplinary proceeding; penalty.

G. Whenever a complaint or report has been filed about a person licensed, certified, or registered by a health regulatory board, the source and the subject of a complaint or report shall be provided information about the investigative and disciplinary procedures at the Department of Health Professions. Prior to interviewing a licensee who is the subject of a complaint or report, or at the time that the licensee is first notified in writing of the complaint or report, whichever shall occur first, the licensee shall be provided with a copy of the complaint or report and any records or supporting documentation, unless such provision would materially obstruct a criminal or regulatory investigation. If the relevant board concludes that a disciplinary proceeding will not be instituted, the board may send an advisory letter to the person who was the subject of the complaint or report. The relevant board may also inform the source of the complaint or report (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv), if appropriate, that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report. In providing such information, the board shall inform the source of the complaint or report that he is subject to the requirements of this section relating to confidentiality and discovery.

§ 54.1-2400.2. (Effective until January 1, 2020) Confidentiality of information obtained during an investigation or disciplinary proceeding; penalty.

G. Whenever a complaint or report has been filed about a person licensed, certified, or registered by a health regulatory board, the source and the subject of a complaint or report shall be provided information about the investigative and disciplinary procedures at the Department of Health Professions. Prior to interviewing a licensee who is the subject of a complaint or report, or at the time that the licensee is first notified in writing of the complaint or report, whichever shall occur first, the licensee shall be provided with a copy of the complaint or report and any records or supporting documentation, unless such provision would materially obstruct a criminal or regulatory investigation. If the relevant board concludes that a disciplinary proceeding will not be instituted, the board may send an advisory letter to the person who was the subject of the complaint or report. The relevant board may also inform the source of the complaint or report (i) that an investigation has been conducted, (ii) that the matter was concluded without a disciplinary proceeding, (iii) of the process the board followed in making its determination, and (iv), if appropriate, that an advisory letter from the board has been communicated to the person who was the subject of the complaint or report. In providing such information, the board shall inform the source of the complaint or report that he is subject to the requirements of this section relating to confidentiality and discovery.

Virginia Board of Pharmacy

PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued

until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

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

- 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.

Upon taking over responsibility as PIC:

- A pharmacy permit application must be submitted to the Board indicating the effective date you intend to assume the role as PIC. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Assuming you are eligible to assume the role of PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on April 30th annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of all Schedule II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, prior to opening for business on the date you first assume the role as PIC, i.e., the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business, if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy ~~calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification~~.

- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board-approved training program for not more than 9 months from the date the trainee began performing duties restricted to a pharmacy technician.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov/~~Enforcement/enf_guidelines.htm~~. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between ~~-4°~~ -13°F and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Safeguards against Diversion of All Controlled Substances:

- The PIC "shall provide safeguards against diversion of all controlled substances". This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.

- It is the policy of the Board to include the name of the PIC (s) in the findings of fact in any disciplinary proceeding involving diversion of drugs.

- The PIC shall:

  - Ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;

  - Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.

  - 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.

- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:

  - Perform state and federal criminal background checks on all personnel with access to controlled substances;

  - Require periodic urine drug screening of all personnel with access to controlled substances;

  - Prohibit personnel from bringing smocks or bags into the prescription department;

  - Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;

- Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;

- In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconcile all discrepancies;

- Do not delegate the management of drug inventory to solely one individual;

- Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;

- Install surveillance cameras to prevent and/or identify theft or loss of controlled substances; and

- Have full and timely access to all reports relating to inventories, invoices, and audits

- In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

Upon leaving as PIC:

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.

- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

Virginia Board of Pharmacy

Manufacturer, Third-party Logistics Provider, Warehouser, and Wholesale Distributor Licensure Guidance

The holder of a New Drug Application or Abbreviated new Drug Application located in Virginia, regardless of whether it physically receives, stores or ships prescription drugs into the Commonwealth is deemed to be engaged in the practice of manufacturing and therefore must obtain a non-restricted manufacturer permit, prior to engaging in business in Virginia.

A non-resident wholesale distributor, nonresident third-party logistics provider, nonresident warehouser, or nonresident manufacturer does not need to obtain a Virginia Controlled Substances Registration in order to distribute Schedule II-V controlled substances. This registration is required for a licensed wholesale distributor, third-party logistics provider, warehouser, or manufacturer located within Virginia that possesses Schedule II-V controlled substances.

An individual that "brokers" the sale of prescription drugs (takes title of the drugs and transfers ownership but does not physically possess or distribute the drugs), must be licensed as a wholesale distributor.

To comply with the requirements for submission of a social security number or control number as required in Regulation 18VAC110-50-70, the following individuals shall provide a social security number or control number:

- the person serving as the responsible party, and;
- the individual owner or sole proprietor, or;
- each partner, or corporate officer and director, who is specifically responsible for the operations of the facility listed on the application.

VIRGINIA BOARD OF PHARMACY

Guidance Regarding Collaborative Practice Agreements

To clarify whether a collaborative practice agreement is required for each patient, the Board offers the following guidance.

1. A pharmacist and a practitioner or other authorized person as found in the definition of "collaborative agreement" in §54.1-3300 may enter into a collaborative practice agreement. Such agreement is not executed for each patient, but rather serves as a general agreement between the pharmacist and practitioner for how a pharmacist may implement, modify, continue, or discontinue drug therapy; order laboratory tests; or complete other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.
2. The agreement may only be implemented for an individual patient pursuant to an order from the practitioner for that patient.
3. Documented informed consent must then be obtained from the patient by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

References:

Code of Virginia:

§ 54.1-3300. Definitions.

"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.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (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 in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

No patient shall be required to participate in a collaborative procedure without such patient's consent. A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

Regulations of the Board:

18VAC110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate

pharmacists, provided the alternates are involved directly in patient care at a single physical location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.

2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.

3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

Guidance document: 110-14

Adopted: December 9, 2019
Effective:

VIRGINIA BOARD OF PHARMACY

Statistically Valid Sample Size for Pharmaceutical Processors

The Board deems that a sample size consistent with the sampling requirements found in the United States Pharmacopeia Chapter < 561> *Articles of Botanical Origin* will satisfy the requirement in Regulation 18VAC110-60-300 for a "statistically valid sample."

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

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

⟨561⟩ ARTICLES OF BOTANICAL ORIGIN

SAMPLING

In order to reduce the effect of sampling bias in qualitative and quantitative results, it is necessary to ensure that the composition of the sample used be representative of the batch of drugs being examined. The following sampling procedures are the minimum considered applicable to vegetable drugs. Some articles, or some tests, may require more rigorous procedures involving more containers being sampled or more samples per container.

Gross Sample

Where external examination of containers, markings, and labels indicates that the batch can be considered to be homogeneous, take individual samples from the number of randomly selected containers indicated below. Where the batch cannot be considered to be homogeneous, divide it into sub-batches that are as homogeneous as possible, then sample each one as a homogeneous batch. It is recommended to include samples from the first, middle, and last containers where the *No. of Containers in Batch* (*N*) is 11 or more and each container in the batch is numbered or lettered in order.

No. of Containers in Batch (*N*)	**No. of Containers to Be Sampled** (*n*)
1–10	All
11–19	11
>19	$n = 10 + (N/10)$

(Round calculated "*n*" to next highest whole number.)

Samples are taken from the upper, middle, and lower sections of each container. If the crude material consists of component parts that are 1 cm or less in any dimension, and in the case of all powdered or ground materials, withdraw the sample by means of a sampling device that removes a core from the top to the bottom of the container, not less than two cores being taken from different angles. For materials with component parts over 1 cm in any dimension, withdraw samples by hand. In the case of large bales or packs, samples should be taken from a depth of 10 cm because the moisture content of the surface layer may be different from that of the inner layers.

Prepare the gross sample by combining and mixing the individual samples taken from each opened container, taking care not to increase the degree of fragmentation or significantly affect the moisture content.

For articles in containers holding less than 1 kg, mix the contents, and withdraw a quantity sufficient for the tests. For articles in containers holding between 1 and 5 kg, withdraw equal portions from the upper, middle, and lower parts of the container, each of the samples being sufficient to carry out the tests. Thoroughly mix the samples, and withdraw an amount sufficient to carry out the tests. For containers holding more than 5 kg, withdraw three samples, each weighing not less than 250 g, from the upper, middle, and lower parts of the container. Thoroughly mix the samples, and withdraw a portion sufficient to carry out the tests.

Laboratory Sample

Prepare the laboratory sample by repeated quartering of the gross sample.

NOTE—Quartering consists of placing the sample, adequately mixed, as an even and square-shaped heap and dividing it diagonally into four equal parts. The two opposite parts are then taken and carefully mixed. The process is repeated as necessary until the required quantity is obtained.

The laboratory sample should be of a size sufficient for performing all the necessary tests.

Test Sample

Unless otherwise directed in the individual monograph or test procedure below, prepare the test sample as follows.

Decrease the size of the laboratory sample by quartering, taking care that each withdrawn portion remains representative. In the case of unground or unpowdered drugs, grind the withdrawn sample so that it will pass through a No. 20 standard-mesh sieve, and mix the resulting powder well. If the material cannot be ground, reduce it to as fine a state as possible, mix by rolling it on paper or sampling cloth, spread it out in a thin layer, and withdraw the portion for analysis.

Official text. Reprinted from *First Supplement* to *USP38-NF33*.

Agenda Item: Emergency Action – Regulations for Pharmaceutical Processors

Enclosed:

Excerpt from Board minutes of September 25, 2019
FDA Statement issued October 4, 2019
CDC Statement updated November 14, 2019
Quarantine Order issued by Massachusetts Cannabis Control Commission
Copy of amendments to regulations as recommended by the Regulation Committee

Staff note:

The Board will need to decide whether there is potential for public harm and emergency action on this regulation.

The Administrative Process Act authorizes adoption of emergency regulations as follows:

§ 2.2-4011. Emergency regulations; publication; exceptions.

A. Regulations that an agency finds are necessitated by an emergency situation may be adopted by an agency upon consultation with the Attorney General, which approval shall be granted only after the agency has submitted a request stating in writing the nature of the emergency, and the necessity for such action shall be at the sole discretion of the Governor.

Board action:

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

2) Adoption of amendments by a fast-track action.

Adoption of emergency regulations for Pharmaceutical Processors

The board reviewed SB1719 passed during the 2019 General Assembly session and draft amendments relating to registered agents and wholesale distribution of CBD and THC-A oil. It was noted that SB1719 required the adoption of emergency regulations regarding the registration of registered agents for patients certified to receive cannabidiol or THC-A oil and for the wholesale distribution of oils between processors. During discussion, it was noted by the board that a Power of Attorney could obtain registration as a registered agent, but not as a parent/guardian.

MOTION:

The board voted unanimously to adopt the emergency regulations and Notice of Intended Regulatory Action to replace the emergency regulations for Pharmaceutical Processors as presented. (motion by Logan, seconded by Boone)

Adoption of exempt regulations for Pharmaceutical Processors

The board reviewed SB1719 and draft amendments to 18VAC110-60-130 and 18VAC110-60-170. SB1719 allows a processor to employ individuals with less than two years of experience to perform certain tasks under supervision and allows a processor to begin cultivation as soon as a permit is issued. These statutory amendments require an exempt regulatory action to conform the requirements in regulation to the new statutory allowances.

MOTION:

The board voted unanimously to adopt the exempt regulations for Pharmaceutical Processors as presented. (motion by Ratliff, seconded Nelson)

During discussion, several board members expressed concern for vaped products based on recent warnings from the CDC and FDA involving patient harm.

ACTION ITEM:

The board requested staff to research with counsel whether it had legal discretion in registering CBD and THC-A oil products that are intended to be vaped or if it could prohibit pharmaceutical processors from producing vaped products.

Adoption of Proposed Regulations for Labeling Dispensed Prescriptions

At the June 5, 2019 board meeting, the board requested that staff send a letter regarding the proposed regulations for Labeling Dispensed Prescriptions to consumer groups such as Senior Connections and AARP to obtain feedback on this topic. The board was provided copies of the letters sent to Senior Connections, Virginia Citizen Consumer Council, Virginia Association of Area Agencies on Aging, Virginia Navigators, and Virginia AARP. The board did not receive any feedback from these organizations. The board reviewed the proposed amendments to 18VAC110-20-275 as recommended by the Regulation Committee and included in the agenda packet.

MOTION:

The board voted 7:3 to adopt the proposed amendments as recommended by the Regulation Committee. (motion by Nelson, seconded Boone; opposed by Warriner, Ratliff, and Jenkins)

FDA STATEMENT

Statement on consumer warning to stop using THC vaping products amid ongoing investigation into lung illnesses

For Immediate Release:

October 04, 2019

Statement From:

Norman E. "Ned" Sharpless MD

Español (/news-events/press-announcements/declaracion-del-comisionado-interino-de-la-fda-ned-sharpless-md-advirtiendo-los-consumidores-que)

Over the past several weeks, the U.S. Food and Drug Administration has been working tirelessly along with the U.S. Centers for Disease Control and Prevention (CDC) and other federal, state and local partners to investigate the distressing incidents of severe lung injuries and deaths associated with the use of vaping products. The latest number of reported cases and deaths (https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html#what-we-know), released by the CDC yesterday, continues to underscore the need for us to gather critical information and provide consumers with actionable information to help best protect themselves and their loved ones.

This is why today, we're strengthening our message to the public in an updated consumer alert (/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping) stating that they should not use vaping products containing tetrahydrocannabinol (THC), the primary psychoactive component of the cannabis plant. Additionally, consumers who choose to use any vaping products should not modify or add any substances such as THC or other oils to products purchased in stores and should not purchase any vaping products, including those containing THC, off the street or from other illicit channels.

This is a complex, ongoing and evolving investigation. In addition to our own analyses, we are also diligently reviewing published literature of third-party analyses of samples and data, which are beneficial to our ongoing investigation. At this time, the FDA does not have enough data to identify the cause, or causes, of the lung injuries in these cases. Additionally, while no one compound or ingredient has emerged as a singular culprit, we do know that THC is present in most of the samples being tested. Because of this, the agency believes it is prudent to stop using vaping products that contain THC or that have had any substances added to them, including those purchased from retail establishments. Simply put, inhaling harmful contaminants in the lungs could put a patient's health at risk and should be avoided.

For those who choose to continue the use of vaping products, particularly those containing THC, we urge you to monitor for symptoms and promptly seek medical attention if you have concerns about your health. We are also continuing to encourage the public to submit detailed reports of any unexpected tobacco- or vaping-related health or product issues to the FDA via the online Safety Reporting Portal (/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products). And, importantly, no youth or women who are pregnant should be using any vaping product, regardless of the substance.

This alert builds on initial recommendations the FDA issued several weeks ago and is based on new information we're continuing to learn from both patients and the samples that have been tested so far. For example, additional testing revealed that a majority of the hundreds of samples of vaping products tested by the states or by the FDA so far have been identified as containing THC. Additionally, according to recent findings (https://www.cdc.gov/mmwr/volumes/68/wr/mm6839e1.htm?s_cid=mm6839e1_w), most of the patients impacted by these illnesses reported using THC-containing products, suggesting THC products are playing a role in the these illnesses. That said, some patients have reported using both THC products and nicotine products, as well as a smaller number reporting using only nicotine products. Similarly, testing on the samples collected or received by the FDA shows a variety of products, or product components, with different ingredients or delivery systems making this investigation especially challenging.

Federal, state and local agencies will continue to work as quickly as possible to get to the bottom of what's causing people to become ill by following up with patients and doctors to collect important details about the products or substances involved, where they were purchased and how they were being used. In particular, the FDA's work to investigate the illnesses includes sample collections in coordination with states, sample analysis, criminal and civil investigations, and coordination with state and federal partners.

Although these cases present similarly in patients, it is not clear if they have a common cause, or if they have differing pathogenesis with similar presentation. The investigation has not identified any specific substance or product that is linked to all cases. The FDA is using state-of-the-art methods to assess the presence of a broad range of chemicals, including nicotine, THC and other cannabinoids along with opioids, cutting agents/diluents and other additives, pesticides, poisons and toxins. To date, the agency has collected or received more than 440 samples from 18 states – and that number continues to grow. The FDA is working quickly and thoroughly in testing the samples, prioritizing those associated directly with patient illnesses. More than half of the vaping liquid products have undergone some form of evaluation, with additional testing on these and other samples continuing daily.

We are leaving no stone unturned in following all potential leads regarding any particular product, constituent or compound that may be at issue. In that spirit, the FDA's Office of Criminal Investigations (OCI) began parallel investigative efforts shortly after the emergence of the associated illnesses.

Our OCI agents are focused on identifying the products that are making people ill and following the supply chain to the source. We are not pursuing any enforcement actions associated with personal use of any vaping products; our interest is in the suppliers. And as I previously said, if we determine that someone is manufacturing or distributing illicit, adulterated vaping products that caused illness and death for personal profit, we would consider that to be a criminal act. We are prepared to use our authorities to the fullest extent possible, and will work with other federal, state and local authorities to take appropriate action as the facts emerge in order to protect the public health.

What we've learned so far is that this ongoing investigation is complex and evolving. Every day we're gathering more information, and every day we seek to use that information to better understand the relationship between any specific products or substances and the reported illnesses.

We're committed to working to answer these and other critical questions as quickly as possible, but we also recognize that it will likely take some time. Importantly, the demographic diversity of the patients, as well as the products or substances they've reported using and the samples being tested may mean there are multiple causes of these illnesses—some of which may escape us or may never be fully understood.

As this complex investigation continues, we urge consumers to take heed of our warning and stop using THC vaping products, and to not use vaping products of any kind that are purchased off the street or from unknown sources. And we remain steadfast in our commitment to work with our federal, state and local partners to identify the cause or causes of these illnesses.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Inquiries

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301-348-1956

Consumer:

888-INFO-FDA

Related Information

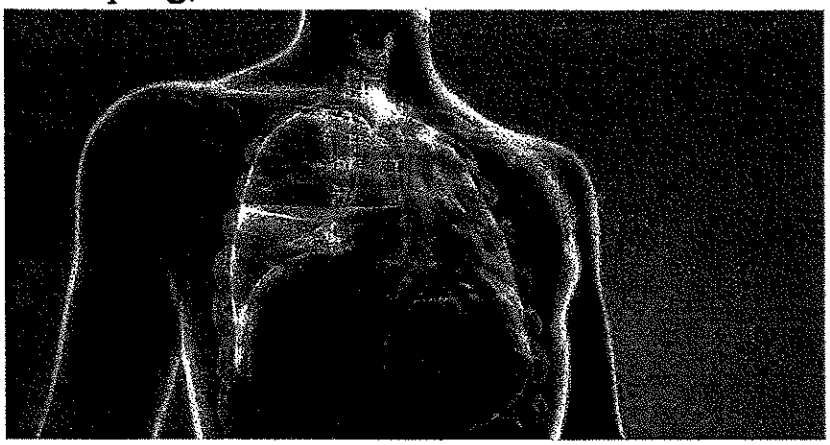
- Vaping Illness Update: FDA Warns Public to Stop Using Tetrahydrocannabinol (THC)-Containing Vaping Products and Any Vaping Products Obtained Off the Street (/consumers/consumer-updates/vaping-illness-update-fda-warns-public-stop-using-tetrahydrocannabinol-thc-containing-vaping)
- Lung Illnesses Associated with Use of Vaping Products (/news-events/public-health-focus/lung-illnesses-associated-use-vaping-products)
- Safety Reporting Portal for Tobacco Products (/tobacco-products/tobacco-science-research/safety-reporting-portal-tobacco-products)

More Press Announcements (/news-events/newsroom/press-announcements)

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Smoking & Tobacco Use

Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products



CDC, the U.S. Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners are investigating a multistate outbreak of e-cigarette, or vaping, product use associated lung injury (EVALI).

Updated November 14, 2019, at 1:00 PM EST

What is New

CDC has identified vitamin E acetate as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI). Recent CDC laboratory testing of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) from 29 patients with EVALI submitted to CDC from 10 states found vitamin E acetate in **all** of the samples. Vitamin E acetate might be used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.

CDC recommends that people should not use e-cigarette, or vaping, products that contain THC, particularly from informal sources like friends, or family, or in-person or online dealers. Until the relationship of vitamin E acetate and lung health is better understood, vitamin E acetate should not be added to e-cigarette, or vaping, products. In addition, people should not add any substance to e-cigarette or vaping products that are not intended by the manufacturer, including products purchased through retail establishments. CDC will continue to update guidance, as appropriate, as new data become available from this outbreak investigation.

What We Know

New Laboratory Findings:

- Analyses of bronchoalveolar lavage (BAL) fluid samples (fluid samples collected from the lungs) of patients with e-cigarette, or vaping, product use associated lung injury identified vitamin E acetate, an additive in some THC-containing products.
- Recent CDC laboratory test results of BAL fluid samples from 29 patients submitted to CDC from 10 states found vitamin E acetate in **all** of the samples.
  - THC was identified in 82% of the samples and nicotine was identified in 62% of the samples.
  - CDC tested for a range of other chemicals that might be found in e-cigarette, or vaping, products, including plant oils, petroleum distillates like mineral oil, MCT oil, and terpenes (which are compounds found in or added to THC products). None of these chemicals of concern were detected in the BAL fluid samples tested.
- This is the first time that we have detected a chemical of concern in biologic samples from patients with these lung injuries. These findings provide direct evidence of vitamin E acetate at the primary site of injury within the lungs.
- These findings complement the ongoing work of FDA and some state public health laboratories to characterize e-liquid exposures and inform the ongoing multistate outbreak.

About the Outbreak:

- As of **November 13, 2019**, 2,172* cases of e-cigarette, or vaping, product use associated lung injury (EVALI) have been reported to CDC from 49 states (all except Alaska), the District of Columbia, and 2 U.S. territories (Puerto Rico and U.S. Virgin Islands).
  - Forty-two deaths have been confirmed in 24 states and the District of Columbia **(as of November 13, 2019)**.
  - Latest outbreak information is updated every Thursday.
  - CDC continues to work closely with FDA, states, public health partners, and clinicians on this investigation.

About Patient Exposure:

- All EVALI patients have reported a history of using e-cigarette, or vaping, products.
  - Vitamin E has been identified as a chemical of concern among people with e-cigarette, or vaping, product use associated lung injury (EVALI).
  - THC is present in most of the samples tested by FDA to date, and most patients report a history of using THC-containing e-cigarette, or vaping, products.
  - The latest national and state findings suggest products containing THC, particularly from informal sources like friends, or family, or in-person or online dealers, are linked to most of the cases and play a major role in the outbreak.

What We Don't Know

- While it appears that vitamin E acetate is associated with EVALI, evidence is not yet sufficient to rule out contribution of other chemicals of concern to EVALI. Many different substances and product sources are still under investigation, and it may be that there is more than one cause of this outbreak.

What CDC Recommends

- CDC recommends that you do not use THC-containing e-cigarette, or vaping, products.
- CDC also recommends that people should **not**:

- Buy any type of e-cigarette, or vaping, products, particularly those containing THC from informal sources like friends, or family, or in-person or online dealers.
- Modify or add any substances such as vitamin E acetate to e-cigarette, or vaping, products that are not intended by the manufacturer, including products purchased through retail establishments.

- Since the specific cause or causes of lung injury are not yet known, the only way to assure that you are not at risk while the investigation continues is to consider refraining from use of all e-cigarette, or vaping, products.
- Adults using e-cigarettes to quit smoking should not go back to smoking; they should weigh all risks and benefits and consider utilizing FDA-approved nicotine replacement therapies
- Adults who continue to use an e-cigarette, or vaping, product, should carefully monitor themselves for symptoms and see a healthcare provider immediately if they develop symptoms like those reported in this outbreak.
- Irrespective of the ongoing investigation:
  - E-cigarette, or vaping, products should never be used by youths, young adults, or women who are pregnant.
  - Adults who do not currently use tobacco products should not start using e-cigarette, or vaping, products. There is no safe tobacco product. All tobacco products, including e-cigarettes, carry a risk.
  - THC use has been associated with a wide range of health effects, particularly with prolonged frequent use. The best way to avoid potentially harmful effects is to not use THC-containing e-cigarette, or vaping, products. Persons with marijuana use disorder should seek evidence-based treatment by a health care provider.

Key Facts about Use of E-Cigarette, or Vaping, Products

- Electronic cigarettes — or e-cigarettes — are also called vapes, e-hookahs, vape pens, tank systems, mods, and electronic nicotine delivery systems (ENDS).
- Using an e-cigarette product is commonly called vaping.
- E-cigarettes work by heating a liquid to produce an aerosol that users inhale into their lungs.
- The liquid can contain: nicotine, tetrahydrocannabinol (THC) and cannabinoid (CBD) oils, and other substances and additives. THC is the psychoactive mind-altering compound of marijuana that produces the "high".

Key Facts about Vitamin E Acetate

- Vitamin E acetate might be used as an additive, most notably as a thickening agent in THC-containing e-cigarette, or vaping, products.
- Vitamin E is a vitamin found in many foods, including vegetable oils, cereals, meat, fruits, and vegetables. It is also available as a dietary supplement and in many cosmetic products, like skin creams.
- Vitamin E acetate usually does not cause harm when ingested as a vitamin supplement or applied to the skin. However, previous research suggests when vitamin E acetate is inhaled, it may interfere with normal lung functioning.

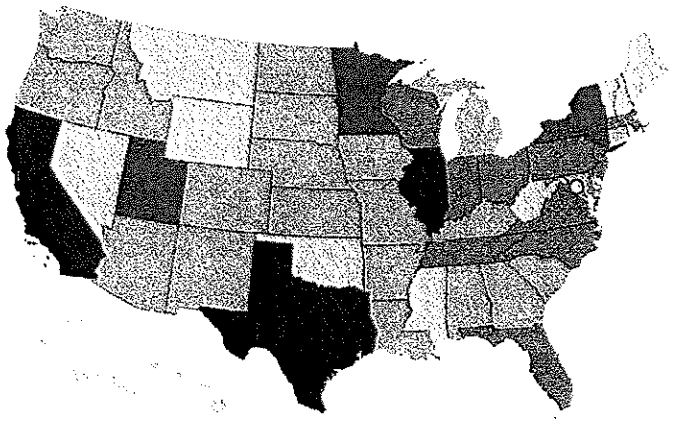
If you have questions about CDC's investigation into the lung injuries associated with use of e-cigarette, or vaping, products, contact CDC-INFO or call 1-800-232-4636.

Latest Outbreak Information

Updated every Thursday

- This complex investigation spans almost all states, involves over 2,000 patients, and a wide variety of brands and substances and e-cigarette, or vaping, products.
- As of **November 13, 2019**, 2,172* cases of e-cigarette, or vaping, product use associated lung injury (EVALI) have been reported to CDC from 49 states (all except Alaska), the District of Columbia, and 2 U.S. territories (Puerto Rico and U.S. Virgin Islands).
  - Forty-two deaths have been confirmed in 24 states and the District of Columbia **(as of November 13, 2019)**.
    - The median age of deceased patients was 52 years and ranged from 17 to 75 years **(as of November 13, 2019)**.
  - More deaths are under investigation.
- Among 1,378 patients with data on sex **(as of October 15, 2019)**:
  - 70% of patients are male.
- Among 1,364 patients with data on age **(as of October 15, 2019)**:
  - The median age of patients is 24 years and ages range from 13 to 75 years.
  - 79% of patients are under 35 years old.
  - By age group category:
    - 14% of patients are under 18 years old;
    - 40% of patients are 18 to 24 years old;
    - 25% of patients are 25 to 34 years old; and
    - 21% of patients are 35 years or older.
- Among 867 patients with information on substances used in e-cigarette, or vaping, products in the 3 months prior to symptom onset** **(as of October 15, 2019)**:
  - About 86% reported using THC-containing products; 34% reported exclusive use of THC-containing products.
  - About 64% reported using nicotine-containing products; 11% reported exclusive use of nicotine-containing products.

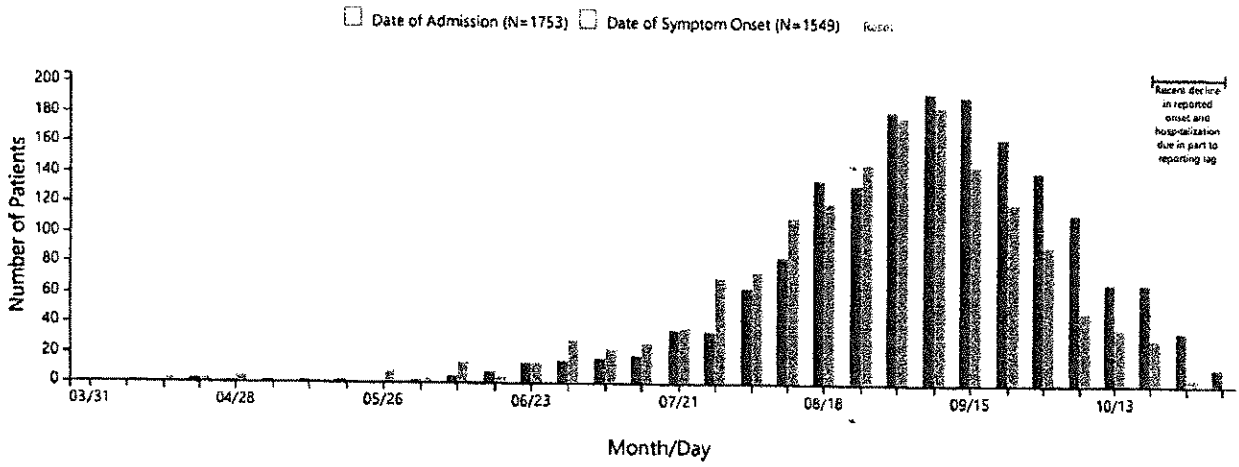
Number of Lung Injury Cases Reported to CDC as of November 13, 2019



Territories AS GU MH FM PW PR VI

Data Table

Dates of symptom onset and hospital admission for patients with lung injury associated with e-cigarette use, or vaping — United States, March 31–November 9, 2019



Data Table

	03/31/2019	04/07/2019	04/14/2019	04/21/2019	04/28/2019	05/05/2019	05/12/2019	05/19/20
Date of Admission (N=1753)	1	0	0	3	1	2	2	
Date of Symptom Onset (N=1549)	2	2	3	3	5	1	1	

Scroll for additional info

Region Name	Start Date	End Date
Recent decline in reported onset and hospitalization due in part to reporting lag	10/20/2019	11/03/2019

What CDC is Doing

Public Health Response:

- CDC's Lung Injury response efforts are committed to:
  - Identify and define the risk factors and the source for lung disease associated with e-cigarette product use, or vaping.
  - Detect and track confirmed and probable cases in the US.
  - Communicate actionable recommendations to state, local, and clinical audiences.
  - Establish lab procedures that can assist with the public heath investigation and patient care.

Partnerships:

- CDC is working 24/7 to identify the cause or causes of this outbreak.
- CDC continues to work closely with FDA, states, public health partners, and clinicians on this investigation by providing consultation and technical assistance to states on communication, health alerts, public outreach, and surveillance

- CDC has activated the Emergency Operations Center (EOC) to coordinate activities and provide assistance to states, public health partners and clinicians around the nation.
- CDC worked with states to create primary and out-of-hospital case definitions to classify confirmed and probable cases in a consistent way. States are in the process of classifying patients.
  - CDC will report numbers of confirmed and probable lung injury cases once states have finalized their classification of cases.
- By invitation, CDC has deployed Epidemic Intelligence Service (EIS) officers and other CDC staff to support states.

Media and Communication:

- CDC is maintaining an outbreak webpage with key messages and weekly updates on case counts, deaths, and resources.
- CDC is holding congressional briefings, media telebriefings, and regular calls with health departments, clinicians to provide timely updates.

Laboratory Testing:

- CDC is currently testing bronchoalveolar lavage (BAL) fluid samples and other samples.
- CDC is testing pathologic specimens, including lung biopsy or autopsy specimens, associated with patients.
- CDC is offering aerosol emission testing of case-associated product samples from e-cigarette, or vaping, products and e-liquids. Analysis of aerosol emissions will augment FDA's ongoing work to characterize e-liquid and will improve our understanding of exposure among case-patients associated with the Lung Injury outbreak. CDC is coordinating e-cigarette, or vaping, product analysis with FDA.
- Results may provide insight into the nature of the chemical exposure(s) contributing to this outbreak.
- CDC developed guidance documents to assist public health laboratories, healthcare providers, pathologists, and others with specimen collection, storage, and submission to CDC for testing.
- For more information and resources visit For the Public, For Healthcare Providers and For State and Local Health Departments as well as our Publications and Resources page.

* The increase in lung injury cases from last week represents both new patients and recent reporting of previously-identified patients to CDC.

** Based on complete reports received.

Page last reviewed: November 14, 2019
Content source: Office on Smoking and Health, National Center for Chronic Disease Prevention and Health Promotion

Cannabis Control Commission
COMMONWEALTH OF MASSACHUSETTS

November 12, 2019

Licensed Marijuana Establishments
Licensed Medical Marijuana Treatment Centers

Case No. 2019AM-0065-00

QUARANTINE ORDER
APPLYING TO VAPORIZER PRODUCTS
M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi),
935 CMR 500.340: Quarantine Order, and
935 CMR 501.340: Quarantine Order

Relying on M.G.L. c. 94I, M.G.L. c. 94G, § (a)(xix) and (a½)(xxxi) and associated regulatory authority, the Commonwealth of Massachusetts Cannabis Control Commission (Commission), acting through its Executive Director, orders all licensed Marijuana Establishments and Medical Marijuana Treatment Centers (each, the "Respondent" and collectively, the "Respondents") to quarantine vaporizer products based on his determination that these products pose an immediate or serious threat to the public health, safety, or welfare and the quarantine is necessary to protect the public health, safety or welfare. Marijuana Establishments remain subject to compliance with the existing order issued by the Commissioner of the Department of Public Health (DPH) and emergency regulations issued by DPH banning adult-use vaporization products.

This order shall be effective upon all Respondents issued a final license on or before November 12, 2019, at 12:01 P.M. ("effective date"). Respondents issued a final license after the effective date shall be subject to the order on receipt of notice of the order.

Findings

In making its determination, the Commission finds as follows:

(1) In the course of an ongoing investigation into the nation-wide outbreak of e-cigarette, or vaping, product use-associated lung injury (EVALI), the Centers for Disease Control (CDC), Food and Drug Administration (FDA), state and local health departments, and public health partners collected data from EVALI patients during from August 2019 to October 2019. In response to this outbreak, the DPH Commissioner banned vaporization products and DPH subsequently issued emergency regulations.

(2) The Commission remains in contact with CDC, FDA, and DPH to receive updates on reported cases of illness associated with vaporizer products and devices.

that "[t]he parties have not presented any evidence specifically linking the vaping of crushed cannabis flower to the outbreak" of vaping-related illnesses. Based on this finding, he ordered that the display and sale of medical-use products for the vaping of crushed marijuana flower sold lawfully in the Commonwealth be permitted.

Order

Based on his authority and these findings, the Executive Director has determined that additional testing of certain products for vitamin E acetate and other substances of concern and the development of additional regulatory and policy safeguards is necessary to protect the public health, safety and welfare.

The Commission, acting through its Executive Director, hereby **ORDERS** as follows:

(1) Respondent shall quarantine and cease the sale and distribution of the following marijuana products and devices:

(a) All vaporizer products defined as any product intended for human consumption by THC inhalation whether for one-time use or reusable, that relies on vaporization or aerosolization, including but not limited to vape pens, vape cartridges, aerosol products, and inhalers ("vaporizer products" or "quarantine products"); and

(2) Nothing herein shall prevent the display, sale or distribution of devices designed to exclusively vaporize marijuana flower for medical-use patients.

(3) Respondent shall place quarantined products on administrative hold in the Commission's seed-to-sale tracking system of record. Respondent shall similarly designate quarantined products in any secondary seed-to-sale tracking system utilized by the Respondent;

(4) Respondent may transfer, transport or otherwise distribute vaporizer products to other Marijuana Establishments, Medical Marijuana Treatment Centers and Independent Testing Laboratories subject to compliance with the Commission's laws, regulations, and policies, but may not sell the vaporizer products subject to this order to patients, caregivers or consumers, unless otherwise authorized by the Commission;

(5) In accordance with the Commission vote at the public meeting on November 7, 2019, and as otherwise allowed by law, the Commission may promulgate regulations and policies pertaining to new and existing vaporizer products to ensure public safety, including additional testing for vaporizer products and devices.

(6) Respondent may request an amendment or modification of this order to authorize the sale of specific vaporizer products that have been tested and deemed compliant with the Commission's regulations and policies;

(7) Nothing herein prohibits or otherwise prevents a certifying health care provider and qualifying patient from discussing the respective risks and benefits of marijuana products, including vaporizer products, within the context of a bona fide healthcare provider-patient relationship;

(8) Respondent shall post notice of this order in a conspicuous location at the Marijuana Establishment or Medical Marijuana Treatment Center;

(9) Respondent shall immediately comply with the requirements of this order upon its receipt.

(10) Respondent shall comply with all provisions of 935 CMR 500.340 and 935 CMR 501.340; and

(11) Respondent shall comply with all provisions of 935 CMR 500.000, *et seq.* 935 CMR 501.000, *et seq.*, and 935 CMR 502.000, *et seq.*.

Notice is provided pursuant to 801 CMR 1.02(6)(a)(1)(b) that his order shall take effect on Tuesday, November 12, 2019, at 12:01 P.M. The Commission may amend the effective date of this order based on developing public health findings, legal proceedings, or other matters not known to the Commission at the time the order was issued. Failure to comply with the above conditions may result in action against Respondent up to and including suspension and/or revocation of licensure.

Nothing herein should be construed as precluding or limiting the Commission's authority to take additional administrative action to protect the public health, safety, and welfare. The Commission may investigate whether certain marijuana products and/or marijuana accessories or their component parts pose a substantial risk to public health and take appropriate action.

The order shall remain in effect until the Commission rescinds or amends the order or until such other time specified in 935 CMR 500.500 and 935 CMR 501.500. The Commission may amend or modify this order as applicable to one particular licensee, a group of licensees or as applicable to all Commission licensees. The Commission may adjust the scope of quarantined products in accordance with this order and 935 CMR 500.321: *Administrative Hold* and 935 CMR 501.321: *Administrative Hold.*

Respondent may request a hearing within twenty-one (21) calendar days after the effective date stated below by making such request in writing to the Commission at 101 Federal Street, 13th Floor, Boston, MA 02210. The Commission may consolidate multiple hearing requests into a single group hearing based on common issues of fact and law.

Questions about the order may be directed in writing to the above address, by phone (617-701-8400) on Monday – Friday from 9:00 A.M. – 5:00 P.M. or email at CannabisCommission@ma.state.us.

Effective this 12th day of November 2019:

Commonwealth of Massachusetts Cannabis Control Commission

Shawn Collins, Executive Director

go back | open in word

Project 6250 - none

BOARD OF PHARMACY

restriction on vaping

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.

D. No cannabidiol oil or THC-A oil intended to be vaporized or inhaled shall contain Vitamin E acetate.

Agenda Item: Consideration of amendments to incorporate changes currently in approved as pilots

Included in your agenda package is:

DRAFT amendments to 18VAC110-20-425 and NEW section 18VAC110-20-505

Staff note:

Amendments would incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock.

Board action:

1) The Board can decide to publish a Notice of Intended Regulatory Action (NOIRA) with the draft amendments; OR

2) The Board can adopt the amendments by a fast-track action

18VAC110-20-425. Robotic pharmacy systems.

A. Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in barcoded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking, and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and complied with and shall include at a minimum procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter and assigned barcodes;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

8. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

B. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAVC110-20-270 B.

C. Medication carousels that are a component of a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

    a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and,

    b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient.

3. A pharmacist is not required to verify the accuracy of drug removed from the medication carousel by a pharmacy technician that is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia if:

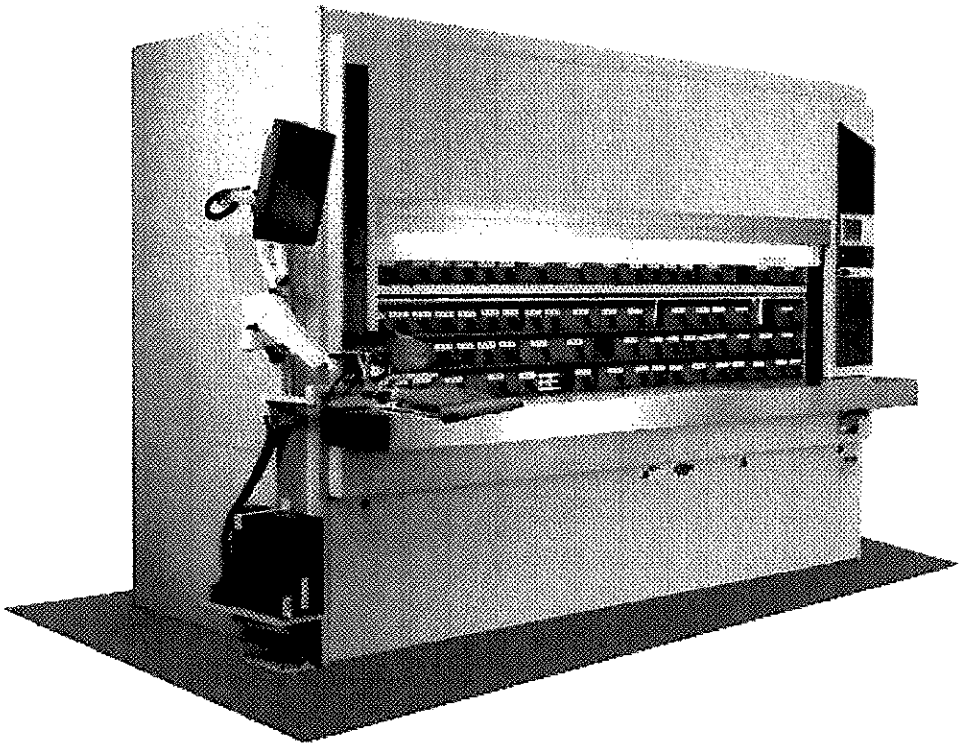
    a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and,

    b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug

is placed into an automated drug dispensing system wherein a nurse or other person authorized to administer drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug at the time of placing the drugs into the automated dispensing system.

4. A pharmacist shall verify the accuracy of all drugs prior to dispensing or leaving the pharmacy that are manually removed from the medication carousel by a pharmacy technician without the use of the robotic pharmacy system to guide the selection of the drug product.

Medication Carousel



8VAC110-20-505. Use of Radio-Frequency Identification.

A. A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:
   a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and,
   b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.
2. A pharmacy technician may place the RFID tag on the drugs and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.
3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist, and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.
4. A pharmacist shall perform a daily random check for verification of the accuracy of 5% of all kits prepared that day utilizing the RFID technology:
   a. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:
      i) The date of verification.
      ii) Description of all discrepancies identified, if any.
      iii) Initials of pharmacist verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in 18 VAC 110-20-490 (C), 18 VAC 110-20-460 (A) and 18 VAC 110-20-355 (A)

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this drug kit. Except as authorized in 18VAC110-20-505, a ~~A~~ pharmacist shall check each drug kit after filling the kit, and initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The drug kit is sealed, secured, and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of such theft or loss.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an EMS provider upon an oral or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the

Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. Accurate records of the following shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year:

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

4. If such drugs or devices are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the pharmacist-in-charge, which shall include a requirement to record the date of exchange, name of licensed person providing drug or device, name of the EMS agency and provider receiving the drug or device, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

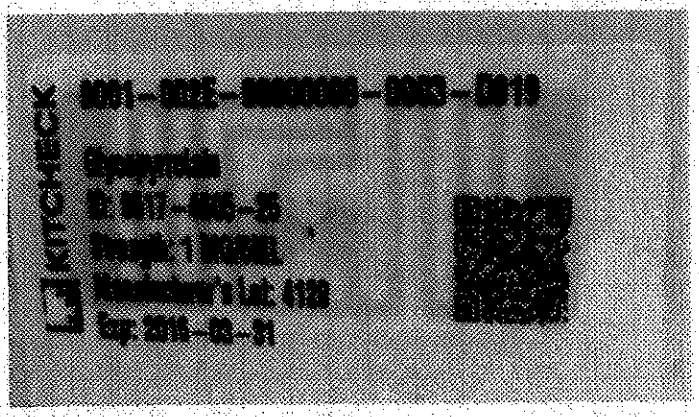
Radio Frequency Identification (RFID)

Source: https://kitcheck.com/kit-check/

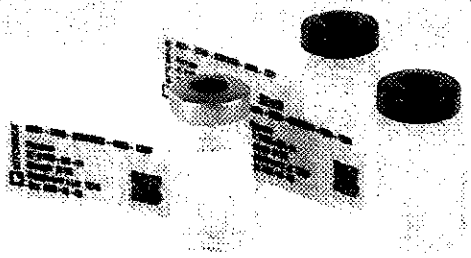
Automated Medication Tray Management

Tagging and Scanning for Better Visibility. Kit Check is an automated medication inventory management system designed to help hospital pharmacies gain better visibility into their medication usage lifespan, increase efficiencies, and free up staff to focus on patient care.

Kit Check uses RFID tags to track each medication that passes through your pharmacy. These RFID tags are applied to the vials, syringes, bags, and other medication packages and supplies in your hospital trays and kits.



Detail Tags



Basic Tags

Detail tags are printed with specifics of each medication, so you can compare the information on the tags against the manufacturer label, and create printed, beyond-use dating for refrigerated goods. Detailed tags can either be applied in house or by a third-party repackager (see below).

Basic tags have no identifiable information on them other than the basic medication name and lot number, so there is no need for a printer. Basic tags are applied in-house. Basic tags are just as safe as the detailed tags, and save a step in your workflow.

Agenda Item: Discussion of immunization records:

Included in your agenda package is:

Copy of minutes of 3/29/18 – referral to Regulation Committee

Copy of petition for rulemaking regarding maintenance of records

Information about the Virginia Immunization Information System (VIIS)

Staff note:

The Regulation Committee recommended gathering more information from VDH and its capacity for reports to VIIS

- **3,4-methylenedioxy-N-tert-butylcathinone**
- **4-fluoro-N-ethylamphetamine**
- **beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)**

Classified as powerful synthetic opioids:

- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl)**
- **2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)**
- **N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)**

(motion by Saenz, second by S. Elliott)

PETITION FOR RULEMAKING:

- Amend 18VAC110-20-240, *Manner of maintaining records, prescriptions, inventory records*

The Board reviewed a petition for rulemaking submitted by Judy Dietrick to amend Regulation 18VAC110-20-240 to extend the requirement for retention of records beyond two years, to include records of vaccine administration. The Board reviewed the comments regarding this petition and several questions arose. One was regarding the reporting to the VIIS system for immunizations. Ms. Allyson-Bryant informed the Board that reporting to the VIIS system is only required for EMS, although several physicians voluntarily register with VIIS for reporting even though it is not required. The request to maintain records of immunizations longer than the required 2 years was discussed and it was stated this may be overly burdensome based on volume of records. Ms. Allen noted that since there was already a system in place to report to the VIIS, possibly the Board should discuss requiring pharmacies to register and report to the system for immunizations. Ms. Yeatts stated this would be a legislative change to require such registration.

MOTION:

The Board voted unanimously to deny the petition for rulemaking and to refer the subject to the Regulation Committee for exploration of further options for immunization reporting and improvements to records retention. (motion by Allen, second by M. Elliott)

ADOPTION OF PROPOSED REGULATIONS FOR:

- Requirement for E-profile number on applications

Ms. Yeatts provided a handout of the suggested regulatory language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an e-profile ID number upon application and renewal.

MOTION:

The Board voted unanimously to adopt proposed language to require pharmacists, pharmacy technicians, and pharmacy interns to provide an E-profile ID number upon application and renewal. (motion by Cathcart, second by Boone)

- Fee increase for all

Staff provided several handouts to the Board indicating the Board will

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle Initial, Suffix,)		
Judy Lifland Dietrick		
Street Address	**Area Code and Telephone Number**	
9611 Podium Dr	703 938 4384	
City	**State**	**Zip Code**
Vienna	VA	22182
Email Address (optional)	**Fax (optional)**	
LIFLANDJ @ yahoo.com		

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18 VA 110-20-240 Manner of maintaining records, prescriptions, inventory records

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Doctors are required to keep records for 10 years. I tried to get info on pneumonia vaccines given to me at Safeway and Walgreens and I was told they do not keep records after 2 years.
I think law should be changed so records are kept 10 years as they would be in a doctor's office.
Vaccines are part of a patient's medical records and should be available longer than 2 years.

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

Signature: Judy Lifland Dietrick Date: 2/1/2018

July 2002

VDH VIRGINIA DEPARTMENT OF HEALTH
To protect the health and promote the well-being of all people in Virginia

FAQ

What is the purpose of VIIS?
The purpose of VIIS is to create one definitive and accurate immunization record for all residing in Virginia. This can increase immunization rates and decrease rates of over-immunization

How much does it cost to use the Virginia Immunization Information System (VIIS)?
There is no cost associated with maintaining a record in VIIS or with the use of the registry system. Access to authorized users, training, and customer support is free.

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Who is an authorized user?
An authorized user are:

- Health care provider or health plans
- Schools head start programs, and day care centers.
- Individuals or organizations as required by law or in the management of a public health crisis
- Other immunization registries

What is the Virginia Law concerning sharing of immunization data through VIIS?
Authority to Share Immunizations in § 32.1-46

Are schools and child-care centers able to access vaccine records in VIIS?
Yes, as long as the school has a licensed health care professional who is gaining access to VIIS.

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Has the registry been pre-populated with any historical immunization information?
Yes, VIIS contains historical information. Immunization records can also be updated with historical data.

I already have an Electronic Health Record (EHR) system, how can I still participate in the registry system?
Data exchange from your office's EHR to VIIS is possible and will afford your office most benefits of VIIS without doing data entry into the EHR and VIIS.

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How can I obtain a copy of my immunization record from VIIS?
You can contact VIIS staff by phone at 804-864-8055 or by email at VIISInfo@vdh.virginia.gov

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How will VIIS affect the workload of my busy office staff?

Many offices have successfully integrated VIIS into the current business flow without disruption. Methods for integration can be discussed with your VIIS field consultant.

How can I get access to VIIS?

To gain access to VIIS, the site must complete the enrollment forms and training. Enroll Here.

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Is VIIS HIPPA compliant?

Yes, as VIIS is run by the Virginia Department of Health and accessed by authorized users it is HIPAA compliant

Thanks for reaching out about the Virginia Immunization Information System (VIIS). VIIS is a system which combines immunization histories for persons of all ages from both the public an Immunization information is accessible to authorized users only. VIIS provides many benefits

- Consolidates vaccination records from multiple providers into one record.
- Provides updated recommendations for immunization scheduling based on the CDC
- Produces an official immunization record for patients that also serves as part of the form).
- Generates reminder notices for patients who are due for vaccines.
- Serves as a great tool for vaccinating providers.

VIIS accepts vaccines for all ages and has data reported from most major chain pharmacies in Virgi... smaller pharmacies. I'd be happy to talk to you about this in more detail if you'd like.

Thanks!
Christy
--
Christy Gray, MPH, CHES, CHTS-CP
Director, Division of Immunization
Virginia Department of Health
Richmond, VA 23219
Ph: 804-864-7928

On Fri, Nov 8, 2019 at 1:15 PM Forlano, Laurie <laurie.forlano@vdh.virginia.gov> wrote:
[Quoted text hidden]

Yeatts, Elaine <elaine.yeatts@dhp.virginia.gov> Fri, Nov 8, 2019 at 1:30 PM
To: "Gray, Christine" <christy.gray@vdh.virginia.gov>

Good to know. Participation is voluntary for all providers - is that correct?
[Quoted text hidden]

Gray, Christine <christy.gray@vdh.virginia.gov> Fri, Nov 8, 2019 at 1:32 PM
To: "Yeatts, Elaine" <elaine.yeatts@dhp.virginia.gov>

By law participation is voluntary for all providers with the exception of EMS providing vaccines.

Also, VDH policy is that if you are participating in our Virginia Vaccines for Children (VVFC) and Virginia Vaccines for Adults (VVFA) programs, all doses must be entered into VIIS.

Thanks!
Christy
--
Christy Gray, MPH, CHES, CHTS-CP
Director, Division of Immunization
Virginia Department of Health
Richmond, VA 23219
Ph: 804-864-7928

[Quoted text hidden]

54.1-3408

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, or designated emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health under the direction of an operational medical director when the prescriber is not physically present. The emergency medical services provider shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

Agenda Item: Consideration of an Interpretation of the term "new prescription"

Enclosed:

Copy of Code of Virginia – Requirement for counseling (54.1-3319)

Copy of NABP Model Act on patient counseling

Staff note:

The request for a Board interpretation came from the Office of the Attorney General

Board action:

Discussion of the Board's interpretation and action as appropriate.

From *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019

§ 54.1-3319. Counseling.

A. A pharmacist shall conduct a prospective drug review before each new prescription is dispensed or delivered to a patient or a person acting on behalf of the patient. Such review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions, including serious interactions with nonprescription or over-the-counter drugs, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse or misuse. A pharmacist may conduct a prospective drug review before refilling a prescription to the extent the pharmacist deems appropriate in his professional judgment.

B. A pharmacist shall offer to counsel any person who presents a new prescription for filling. The offer to counsel may be made in any manner the pharmacist deems appropriate in his professional judgment, and may include any one or a combination of the following:

1. Face-to-face communication with the pharmacist or the pharmacist's designee;

2. A sign posted in such a manner that it can be seen by patients;

3. A notation affixed to or written on the bag in which the prescription is to be delivered;

4. A notation contained on the prescription container; or

5. By telephone.

For the purposes of medical assistance and other third-party reimbursement or payment programs, any of the above methods, or a combination thereof, shall constitute an acceptable offer to provide counseling, except to the extent this subsection is inconsistent with regulations promulgated by the federal Health Care Financing Administration governing 42 U.S.C. § 1396r-8 (g) (2) (A) (ii). A pharmacist may offer to counsel any person who receives a refill of a prescription to the extent deemed appropriate by the pharmacist in his professional judgment.

C. If the offer to counsel is accepted, the pharmacist shall counsel the person presenting the prescription to the extent the pharmacist deems appropriate in his professional judgment. Such counseling shall be performed by the pharmacist himself and may, but need not, include the following:

1. The name and description of the medication;

2. The dosage form, dosage, route of administration, and duration of drug therapy;

3. Special directions and precautions for preparation, administration, and use by the patient;

4. Common adverse or severe side effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

5. Techniques for self-monitoring drug therapy;

6. Proper storage;

7. Prescription refill information; and

8. Action to be taken in the event of a missed dose.

Nothing in this section shall be construed as requiring a pharmacist to provide counseling when the person presenting the prescription fails to accept the pharmacist's offer to counsel. If the prescription is delivered to a person residing outside of the local telephone calling area of the pharmacy, the pharmacist shall either provide a toll-free telephone number or accept reasonable collect calls from such person.

D. Reasonable efforts shall be made to obtain, record, and maintain the following patient information generated at the individual pharmacy:

1. Name, address, telephone number, date of birth or age, and gender;

2. Individual history where significant, including known allergies and drug reactions, and a comprehensive list of medications and relevant devices; and

3. Any additional comments relevant to the patient's drug use, including any failure to accept the pharmacist's offer to counsel.

Such information may be recorded in the patient's manual or electronic profile, or in the prescription signature log, or in any other system of records and may be considered by the pharmacist in the exercise of his professional judgment concerning both the offer to counsel and content of counseling. The absence of any record of a failure to accept the pharmacist's offer to counsel shall be presumed to signify that such offer was accepted and that such counseling was provided.

E. This section shall not apply to any drug dispensed to an inpatient of a hospital or nursing home, except to the extent required by regulations promulgated by the federal Health Care Financing Administration implementing 42 U.S.C. § 1396r-8 (g) (2) (A).

(1992, c. 689.)

From NABP Model Act, August 2019

Section 6. Pharmacist Care Services. [1]

(b) Patient Counseling[2]

(1) Upon receipt of a Prescription Drug Order and following a review of the patient's record, a Pharmacist shall personally initiate discussion of matters which will enhance or optimize Drug therapy with each patient or caregiver of such patient. Such discussion shall be in Person, whenever practicable, or by telephone and shall include appropriate elements of Patient Counseling. Such elements may include the following:

(i) the name and description of the Drug;
(ii) the dosage form, dose, route of Administration, and duration of Drug therapy;
(iii) intended use of the Drug and expected action;
(iv) special directions and precautions for preparation, Administration, and use by the patient;
(v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
(vi) techniques for self-monitoring Drug therapy;
(vii) proper storage and appropriate disposal method(s) of unwanted or unused medication;
(viii) prescription refill information;
(ix) action to be taken in the event of a missed dose; and
(x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.

(2) Alternative forms of patient information shall be used to supplement Patient Counseling when appropriate. Examples include written information leaflets, pictogram labels, video programs, etc.

(3) Patient Counseling, as described above and defined in this Act, shall not be required for inpatients of a hospital or institution where other licensed health care professionals are authorized to Administer the Drug(s).

(4) A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.

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[1] Additional Pharmacist Care Services may include, but are not limited to, Patient assessment and evaluation; assessing health plan and medication eligibility and coverage; Administering Drugs, vaccines, or biologicals; performing Peer Review and peer consultations; reviewing, selecting, and developing formularies or plan /practice guidelines; consulting with other health care professionals; providing patient referrals; performing Medication Therapy Management; ordering lab tests; and performing lab tests as provided by State and Federal law.

[2] The intent of this Section is to require that the Pharmacist personally initiate counseling for all new Prescriptions and to exercise his or her professional judgment for refills. Situations may arise, however, where the prescriber specifically indicates that a patient should not be counseled. In such circumstances, it is the responsibility of the Pharmacist to provide the best patient care through appropriate communication with the prescriber and to document the reason(s) for not providing counseling to the patient.

New Guidance Document 110-6 Guidance for Pharmacies within Opioid Treatment Programs

The board was provided with a draft handout of new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs*. Ms. Juran explained that DEA expressed concern for practices within opioid treatment programs that may pose a risk for diversion. It was requested that the board educate licensees practicing in this environment.

MOTION:

The board voted unanimously to adopt the new Guidance Document 110-6 *Guidance for Pharmacies within Opioid Treatment Programs* as presented. (motion by Thornbury, seconded Boone)

REPORTS

Chairman's Report

Ms. Warriner shared her experience attending the NABP/AACP Districts 1 & 2 meeting, and encouraged the board to participate in NABP meetings moving forward. She was elected to serve as the District 2 representative on the NABP Resolution Committee. Ms. Warriner also shared her concerns with the number of recent pharmacy closings and patient access to pharmaceutical needs. She asked that staff provide a report reflecting the number of pharmacy closures to include the pharmacy name, address, and license number.

ACTION ITEM:

Board staff will provide the board at a subsequent meeting with a list of pharmacies that have closed each year for the last several years. The list will contain the pharmacy names, addresses, and license numbers, at a minimum.

Report on Board of Health Professions

Mr. Lopata shared that he could not attend the last Board of Health Professions meeting and that he would provide an update at the next Full Board Meeting

Report on Inspection and Licensure Program

Ms. Juran provided an update of the licensing/inspection report included in the agenda packet.

Report on Pharmaceutical Processors

Ms. Kelley reviewed the Pharmaceutical Processor report included in the agenda packet. She shared that the report to be prepared by the Secretaries of Health and Human Resources and Agriculture regarding the appropriate structure for oversight of industrial hemp products is due to the legislators by November 1, 2019, and may be available as a public document by the next board meeting.

Report on Disciplinary Program

Ms. Shinaberry provided an overview of the update included in the agenda packet. She introduced Mr. Mykl Egan, J.D. as the new Disciplinary Case Manager.

	A	B	C	D	E	F	G	H	I	J
1	Year	Number Closed HSA(I)	Number Closed HSA(II)	Number Closed HSA(III)	Number Closed HSA(IV)	Number Closed HSA(V)	TOTAL CLOSED	TOTAL ISSUED	TOTAL PHARMACY COUNT	POPULATION ESTIMATES
2	2002								1,584	
3	2004								1,547	
4	2006								1,600	
5	2008								1,647	
6	2010								1,701	8,001,024
7	2012								1,754	
8	2014								1,796	
9	2015	6	12	4	7	10	39	65		
10	2016	7	12	13	16	9	57	64	1,854	
11	2017	5	7	12	14	13	51	69		
12	2018	13	18	13	14	30	88	62	1,822	8,517,685
13	2019	9	25	10	14	13	71	42	As of 11/22/19 1,786	
14										
15	TOTAL:	40	74	52	65	75	306	302		

Closed in 2015

Name	AddressLine1	City/State/Zip	Issue Date
Bayview Plaza Pharmacy Long Term Care Facility	7930 Chesapeake Blvd., Suite E	Norfolk VA 23518	7/30/2007
TIMBERVILLE DRUG STORE	305 S. MAIN STREET	TIMBERVILLE VA 22853	
THE PHARMACY in Great Falls	10132 D. Colvin Run Road	Great Falls VA 22066	7/23/2014
The Pharmacy in Alexandria	3612 Forest Drive	Alexandria VA 22302	10/8/2014
The Pharmacy in Fairfax	10721 Main Street, Suite 107	Fairfax VA 22030	11/19/2014
K MART PHARMACY #3869	116 SOUTHGATE SQUARE	COLONIAL HEIGHTS VA	9/26/1974
KROGER PHARMACY #538	5601 HIGH STREET, W.	PORTSMOUTH VA 23703	6/11/1998
BAYVIEW PLAZA PHARMACY	7924A CHESAPEAKE BOULEVARD	NORFOLK VA 23518	8/11/1982
Quincy Pharmacy	927 N. Quincy Street	Arlington VA 22203	7/12/2011
MERCURY WEST DISCOUNT PHARMACY	2268 Executive Drive	Hampton VA 23666	5/17/1984
Infusion PRN, LLC	4953 Cox Road	Glen Allen VA 23060	1/28/2015
SHERWOOD HALL PHARMACY	2616 SHERWOOD HALL LANE	ALEXANDRIA VA 22306	11/14/1977
MARSHALL PHARMACY	P. O. BOX 496	MARSHALL VA 20116	5/8/1981
Family Pharmacy, Inc.	6827 Tennyson Drive	McLean VA 22101	4/2/2012
The Pharmacy in Reston	1712 Clubhouse Road #107	Reston VA 20190	1/26/2015
KROGER PHARMACY #534	101 VILLAGE AVENUE	YORKTOWN VA 23693	4/2/1998
BREMO PHARMACY @ HENRICO DOCTORS	7601 FOREST AVENUE	RICHMOND VA 23229	12/4/1990
Webb's Family Pharmacy	453 West Stuart Drive	Hillsville VA 24343	5/13/2011
GIANT PHARMACY #757	9550 BURKE ROAD	BURKE VA 22015-3132	10/16/1979
K MART PHARMACY #4997	550 FIRST COLONIAL ROAD	VIRGINIA BEACH VA 23451	11/14/1977
SUPER-D DRUG STORE	414 9th Street	ROANOKE VA 24013	1/3/1995
Hamilton Pharmacy	P.O. Box 977	Saint Paul VA 24283	1/3/2005
Walgreens #12033	12651 Apollo Drive	Woodbridge VA 22192	1/21/2011
RITE AID PHARMACY #11236	7199 STONEWALL PARKWAY	MECHANICSVILLE VA 23111	11/16/1980
James Madison University Health Center Pharmacy	724 S. Mason Street	Harrisonburg VA 22807	11/18/2014
SOUTH HILL DRUG COMPANY, INCORPORATED	1016 WEST ATLANTIC STREET	South Hill VA 23970	3/12/2004
Walgreens #10302	4106 Portsmouth Blvd	Portsmouth VA 23701	4/10/2008
K Mart Pharmacy #3942	13910 METROTECH DRIVE	CHANTILLY VA 20151	8/15/1991
LADYSMITH PHARMACY	18014 JEFFERSON DAVIS HIGHWAY	LADYSMITH VA 22501	
SUBURBAN PHARMACY	3701 KING STREET	PORTSMOUTH VA 23707	4/16/1987
RITE AID PHARMACY #2560	FERRY FARM SHOPPING CENTER	FREDERICKSBURG VA 22405	11/20/1990
PARK DRUGS, INC	2710 S. CRATER ROAD	PETERSBURG VA 23805	3/20/1986
THE MEDICINE SHOPPE	P. O. BOX 5	BOONES MILL VA 24065	1/5/1981
NEW MARKET PHARMACY	9438 CONGRESS STREET	NEW MARKET VA 22844	5/2/1997

Center for Medication Therapy Managment & Outcome Research (CMTMOR)	Hampton University School of Pharmacy	Hampton VA 23668	4/14/2014
BLAIRS DRUG STORE	3601 MECHANICSVILLE PIKE	RICHMOND VA 23223	
CVS/PHARMACY #1830	6228-C N. KING'S HIGHWAY	ALEXANDRIA VA 22303	1/8/1993
THE PHARMACY OF BOYKINS, INC.	18215 VIRGINIA AVENUE	BOYKINS VA 23827	
Stone Spring Emergency Center	24570 Gum Springs Road	Dulles VA 20166	8/2/2013

Closed in 2016

PLANNED PARENTHOOD OF METROPOLITAN WASHINGTON DC	303 S. Maple Ave, Suite 300	FALLS CHURCH VA 22046	6/24/1999
SHOPPERS PHARMACY #2361/945	SMOKETOWN STATION	DALE CITY VA 22192	3/16/2000
MedEx Health Pharmacy	2835 Gallows Road	Falls Church VA 22042	5/6/2013
K MART PHARMACY #3976	1650 GENERAL BOOTH BOULEVARD	VIRGINIA BEACH VA 23454	9/5/1991
K MART PHARMACY #9737	#1 CLAYPOOL HILL MALL	CEDAR BLUFF VA 24609	8/27/1990
K MART PHARMACY #9154	129 MALL ROAD	COVINGTON VA 24426	9/24/1990
NAI Saturn Eastern LLC dba Safeway Pharmacy #2650	43150 BROADLANDS PLAZA CENTER	Broadlands VA 20148	10/9/2003
Alexandria Care Pharmacy Store #2	611 Carlin Springs Rd, Suite #105	Arlington VA 22204	1/5/2015
RITE AID PHARMACY #11301	4408 W. HUNDRED ROAD	CHESTER VA 23831	
Richmond Area Compassionate Care Pharmacy	1300 MacTavish Avenue	Richmond VA 23230	5/19/2011
K MART PHARMACY #3868	12810 JEFFERSON DAVIS HIGHWAY	CHESTER VA 23831	6/11/1991
Servant Pharmacy of Virginia, LLC	10370 Battleview Parkway	Manassas VA 20109	8/11/2011
RITE AID PHARMACY #11303	220 MARKET DRIVE	EMPORIA VA 23847	11/9/1987
K MART PHARMACY #3154	210 W MERCURY BLVD	HAMPTON VA 23669	
RITE AID PHARMACY #11296	2004 VICTORY BOULEVARD	PORTSMOUTH VA 23702	3/20/1979
SHOPPERS PHARMACY #2380/973	9540 LIBERIA AVENUE	Manassas VA 20110	7/23/2004
OWENS PHARMACY INC	515 EAST RIDGEWAY STREET	CLIFTON FORGE VA 24422	11/6/1981
K MART PHARMACY #4850	1000 LAUREL STREET N.E.	CHRISTIANSBURG VA 24073	7/13/1992
Martin's Pharmacy #6404	3330 S. Crater Road	Petersburg VA 23805	5/23/1997
Martin's Pharmacy #6437	7324 Bell Creek Road	Mechanicsville VA 23111	1/18/1991
Martin's Pharmacy #6496	3000 Stony Point Road	Richmond VA 23235	9/21/1995

O & O Alpan	11212 Waples Mill Road, Suite 100	Fairfax VA 22030	12/30/2015
RITE AID PHARMACY #11280	2330 AZALEA GARDEN ROAD	Norfolk VA 23513	5/1/1984
CVS/PHARMACY #1548	12440 GAYTON ROAD	Richmond VA 23238	9/10/1986
COMMONWEALTH 15218- A Walgreens Pharmacy	117 EXECUTIVE DRIVE, SUITE L	DANVILLE VA 24541	8/30/1990
MEDEX Pharmacy LLC	6845 Elm Street, Suite 105	McLean VA 22101	3/23/2011
Walgreens #15133	1860 Town Center Drive, Suite G-200	Reston VA 20190	8/25/2011
Henry Schein Animal Health	5200 Anthony Road, Suite C	Sandston VA 23150	3/9/2005
HomeChoice Partners, Inc.	848 J. Clyde Morris Blvd	Newport News VA 23601	7/29/1997
Gardens Pharmacy & Compounding	1101 Executive Blvd	Chesapeake VA 23320	6/11/2015
MEDICAL CENTER PHARMACY	42 LAMBERT STREET, SUITE 311	STAUNTON VA 24401	7/10/1990
Peoples Drug Store	145 East King Street	Strasburg VA 22657	
THE APOTHECARY	42 LAMBERT STREET, SUITE 311	STAUNTON VA 24401	12/6/1999
Rite Aid Pharmacy #1027	7395 Lee Highway	Falls Church VA 22042	12/17/1980
K MART PHARMACY #3754	2876 GREENSBORO ROAD	MARTINSVILLE VA 24112	7/21/1989
K MART PHARMACY #3706	1480 E. MAIN STREET	WYTHEVILLE VA 24382	5/18/1989
Medicap Pharmacy	44081Pipeline Plaza #210	Ashburn VA 20147	10/26/2006
Legacy Consultant Pharmacy	7505 Right Flank Road, Suite 710	Mechanicsville VA 23116	8/23/2011
FARM FRESH PHARMACY #6287/708	211-15 PROVIDENCE ROAD	CHESAPEAKE VA 23325	6/18/1992
K MART PHARMACY #7259	118 WALLER MILL ROAD	WILLIAMSBURG VA 23185	5/23/1985
Shawsville Pharmacy	P.O. BOX 308	SHAWSVILLE VA 24162	4/14/1986
CUNDIFF-BLUE RIDGE PHARMACY, INC	1663 BLUE RIDGE BLVD.	TROUTVILLE VA 24175-4224	9/16/1981
VERONA PHARMACY	294 LEE HIGHWAY	VERONA VA 24482	9/21/1998
Martin's Pharmacy #6499	4591 S. Laburnum Road Avenue	Henrico VA 23231	9/14/1998
GORDONSVILLE MEDICAL PHARMACY	103 EAST GORDON AVE	Gordonsville VA 22942	12/31/1981
Downtown Drug	300 First Street	Roanoke VA 24002	3/12/2014
GRAYS PHARMACY	4712 HAMPTON BLVD	NORFOLK VA 23508	
Martin's Pharmacy #6433	10250 Staples Mill Road	Glen Allen VA 23060	10/14/2003
Martin's Pharmacy #6434	2250 John Rolfe Parkway	Henrico VA 23233	11/12/2003
Appomattox Drugs	21414 Chesterfield Ave	South Chesterfield VA 23803	8/21/2012
K MART PHARMACY #3324	3533 FRANKLIN ROAD, SW	ROANOKE VA 24014	
Home Choice Partners, Inc.	8701 Park Central Drive, Suite 600	Richmond VA 23227	5/3/2011
PEAKSIDE PHARMACY CARE CENTER	4063 QUARLES COURT	Harrisonburg VA 22801-	4/9/2002
K MART PHARMACY #3544	1355 W. MAIN STREET	SALEM VA 24153	10/10/1989
CLARK'S PHARMACY, INC.	119-A NORTH MAIN STREET	FARMVILLE VA 23901	12/1/1987

Family L.T.C. Pharmacy, Inc.	1049-B Brookdale Street	Martinsville VA 24112	5/7/2008

Closed in 2017

InfuScience, Inc. dba Home Solutions	10300 Eaton Place, Suite 170	Fairfax VA 22030	10/5/2009
Martin's Pharmacy #6435	10150 Brook Road	Glen Allen VA 23060	10/5/1999
Martin's Pharmacy #6438	13700 HULL STREET ROAD	MIDLOTHIAN VA 23112	11/3/1993
Martin's Pharmacy #6421	3460 Pump Road	Henrico VA 23233	7/12/1996
K MART PHARMACY #3598	1419 HERSHBERGER ROAD, NW	ROANOKE VA 24012	7/20/1983
Martin's Pharmacy #6494	3107-15 Boulevard	Colonial Heights VA 23834	9/26/2001
K MART PHARMACY #4988	6101 N. MILITARY	NORFOLK VA 23518	8/21/1996
Davis Drug, Inc.	2100 Executive Dr	Hampton VA 23666	5/29/2012
Walgreens #11338	2825 Wilson Blvd.	Arlington VA 22201	5/14/2009
Farm Fresh Pharmacy #220/6250	1385 Fordham Drive	Virginia Beach VA 23464	1/25/2011
RUNNINGER'S PHARMACY, INC.	P.O. BOX 25	Parksley VA 23421	6/13/2003
Commonwealth Community Pharmacy, Rx	480 Kempsville Rd. Suite 108	Chesapeake VA 23320	4/19/2016
CVS/pharmacy #4296	42994 Eastern Kingbird Plaza	Ashburn VA 20147	8/5/2008
NAI Saturn Eastern LLC dba Safeway Pharmacy #1950	7451 Mount Vernon Square	Alexandria VA 22306	3/17/2006
LIBERTY MEDICAL, LLC DBA : LIBERTY MEDICAL SUPPLY	2157 APPERSON DRIVE	SALEM VA 24153	4/16/1992
Option Care	527-B Branchway Road	North Chesterfield VA 23236	1/28/2005
BAALAAJEE INC. DBA WILLIAMSON ROAD PHARMACY	3416 WILLIAMSON ROAD	ROANOKE VA 24012	
SHOPPERS PHARMACY #2376/968	6335 MULTIPLEX DRIVE	Centreville VA 20120	9/9/2002
Walgreens #15119	7101 Jahnke Rd., Suite 100	Richmond VA 23225-4017	12/19/2006
K MART PHARMACY #3560	1205 FORDHAM DRIVE	VIRGINIA BEACH VA 23464	11/8/1985
K MART PHARMACY #3206	4715 NINE MILE ROAD	RICHMOND VA 23223	
MEADOWBROOK PHARMACY	MEADOWBROOK SHOPPING CENTER	CHARLOTTESVILLE VA 22903	7/5/1983
K MART PHARMACY #3471	2001 S MILITARY HIGHWAY	CHESAPEAKE VA 23320	
RITE AID PHARMACY #4689	1055 E. MAIN STREET	PULASKI VA 24301-5217	6/11/1997
Martin's Pharmacy #6402	4660 Monticello Avenue	Williamsburg VA 23188	10/13/1998
Martin's Pharmacy #6406	5201 Chippenham Crossing Center	Richmond VA 23234	5/13/1998
Martin's Pharmacy #6440	11361 Midlothian Turnpike	Richmond VA 23236	10/15/1997
Rite Aid Pharmacy #11269	748 Independence Blvd.	Virginia Beach VA 23455	
K MART PHARMACY #4090	1801 HYDRAULIC ROAD	CHARLOTTESVILLE VA 22901	
K MART PHARMACY #3689	300 TOWNE CENTRE DRIVE	ABINGDON VA 24210	10/27/1988
GREEN VALLEY PHARMACY	2415 S SHIRLINGTON ROAD	ARLINGTON VA 22206	

FLOYD PHARMACY	709 EAST MAIN STREET	FLOYD VA 24091	10/22/1976
Martin's Pharmacy #6498	9645 West Broad Street	Glen Allen VA 23060	10/4/1989
Cowan Pharmacy	2571 Cowan Blvd	Fredericksburg VA 22401	5/18/2012
K MART PHARMACY #3801	312 CONSTITUTION DRIVE	VIRGINIA BEACH VA 23462	10/11/1989
Martin's Pharmacy #6436	5700 Brook Road	Richmond VA 23227	4/13/1990
Martin's Pharmacy #6428	7045 Forest Hill Avenue	Richmond VA 23225	5/2/2005
Martin's Pharmacy #6588	200 Charter Colony Parkway	Midlothian VA 23114	9/3/2003
First Pharmacy of Martinsville	1105 Spruce Street	Martinsville VA 24112	10/1/2014
FARM FRESH PHARMACY #6263/321	455 MERRIMAC TRAIL	WILLIAMSBURG VA 23185	12/22/1981
Rockbridge Pharmacy	146 South Main Street	Lexington VA 24450	6/24/2015
AcariaHealth Pharmacy Inc.	8505 Arlington Blvd. #110	Fairfax VA 22031	1/16/2003
RAM of Virginia Medical Relief Charity	Riverview Elementary/Middle School	Grundy VA 24614	10/4/2017
STANLEY PHARMACY INC	P O BOX 160	STANLEY VA 22851	
Peoples Pharmacy LTC	1446 Church Street, Suite D	Norfolk VA 23504	8/8/2016
OMNICARE OF RICHMOND	1572 E. Parham Road	Henrico VA 23228	11/14/1995
FARM FRESH PHARMACY #6264/330	200 ARTHUR WAY	NEWPORT NEWS VA 23602	6/14/1995
K MART PHARMACY #4062	3311 RIVERSIDE DRIVE	DANVILLE VA 24541	
K MART PHARMACY #4084	2315 WARD'S ROAD	LYNCHBURG VA 24502	
Pioneer Health Services of Patrick County, Inc.	18688 JEB Stuart Highway	Stuart VA 24171	

Closed in 2018

Sam's Pharmacy 10-4788	4571 Laburnum Avenue	Richmond VA 23231	10/15/2008
GIANT PHARMACY #777	7558 TELEGRAPH ROAD	Alexandria VA 22315	3/1/1992
Sam's Pharmacy 10-4733	741 E. Little Creek Road	Norfolk VA 23518	10/14/2015
Wal-Mart Pharmacy 10-3618	3419 Orange Ave	Roanoke VA 24012	3/25/2015
RITE AID PHARMACY #11276	6135 E. VIRGINIA BEACH BLVD.	NORFOLK VA 23502	11/28/1983
RITE AID PHARMACY #11261	1405 N. MAIN STREET	SUFFOLK VA 23434	11/27/1984
DINWIDDIE DRUG STORE, INC.	13723 Boydton Plank Road	Dinwiddie VA 23841	1/1/1992
RITE AID PHARMACY #11252	3325 TAYLOR ROAD, SUITE 118	CHESAPEAKE VA 23321	11/23/1988
RITE AID PHARMACY #11272	5300 PRINCESS ANNE ROAD	VIRGINIA BEACH VA 23462	
Vital Care of Southwest Virginia	P O Box 269	Cedar Bluff VA 24609	1/17/2006
Rite Aid Pharmacy #7857	14610 Lee Highway	Gainesville VA 20155	9/5/2008
RITE AID #03721	9199 PRESCOTT AVENUE	MANASSAS VA 22110-5398	
FARM FRESH PHARMACY #6247/217	799 CHIMNEY HILL SHOPPING CENTER	VIRGINIA BEACH VA 23452	12/27/1976
Farm Fresh Pharmacy #6280/674	1459 Armory Drive	Franklin VA 23851	2/15/2008

Farm Fresh Pharmacy #6267/360	601 Children's Lane	Norfolk VA 23507	8/23/2000
Farm Fresh Pharmacy #6239/190	1620 CEDAR ROAD	CHESAPEAKE VA 23322	1/12/2000
FARM FRESH PHARMACY #6241/196	701-A N. BATTLEFIELD BOULEVARD	CHESAPEAKE VA 23320	6/5/1987
FARM FRESH PHARMACY #6293/911	2058 S. INDEPENDENCE BOULEVARD	VIRGINIA BEACH VA 23456	5/21/1987
FARM FRESH PHARMACY #6244/205	30 TOWNE CENTER WAY	HAMPTON VA 23666	7/17/1990
FARM FRESH PHARMACY #6265/335	115 NORGE LANE	WILLIAMSBURG VA 23188	9/16/1994
FARM FRESH PHARMACY #6262/299	460 WYTHE CREEK ROAD	Poquoson VA 23662	8/13/1998
FARM FRESH PHARMACY #6291/816	928 DIAMOND SPRINGS ROAD, #101	VIRGINIA BEACH VA 23455	10/13/1992
FARM FRESH PHARMACY #6272/467	1200 N. MILITARY HIGHWAY	NORFOLK VA 23502	11/24/1998
FARM FRESH PHARMACY #6266/338	4001 VIRGINIA BEACH BLVD.	VIRGINIA BEACH VA 23452	2/10/1999
FARM FRESH PHARMACY #6254/231	353 CHATHAM DRIVE	NEWPORT NEWS VA 23602	6/7/1991
Farm Fresh Pharmacy #6270/408	201 E. Berkley Avenue	Norfolk VA 23523	11/1/2005
FARM FRESH PHARMACY #6243/198	4876 PRINCESS ANNE ROAD	VIRGINIA BEACH VA 23462	9/7/1988
FARM FRESH PHARMACY #6275/664	4000 VICTORY BLVD.	PORTSMOUTH VA 23701	5/23/1991
PLAZA PROFESSIONAL PHARMACY INC	1717 BELLEVUE AVENUE	RICHMOND VA 23227	
PLAZA LTC PHARMACY	1717 BELLEVUE AVE., 1st FLOOR	Richmond VA 23227	12/29/2003
RITE AID PHARMACY #11283	7912 HALPRIN DRIVE	Norfolk VA 23518	
RITE AID PHARMACY #3409	30 S. ARMISTEAD AVENUE	HAMPTON VA 23669	2/25/1980
RITE AID PHARMACY #3960	1141 LONDON BOULEVARD	PORTSMOUTH VA 23704-	5/5/1983
Shoppers Pharmacy #2368/952	6200 Little River Turnpike	Alexandria VA 22312	2/1/2000
Shoppers Pharmacy #2356/939	2425 Centreville Road	Herndon VA 20171	9/11/2006
CVS/pharmacy #11103	1799 South Creek One, Suite A	Powhatan VA 23139	11/8/1985
FARM FRESH PHARMACY #6253/229	521 LASKIN ROAD	VIRGINIA BEACH VA 23451	5/7/1998
Farm Fresh Pharmacy #6279/672	1069 Independence Blvd.	Virginia Beach VA 23455	8/2/2006
Farm Fresh Pharmacy #6282/676	1400 Kempsville Road	Chesapeake VA 23320	10/20/2006

Rite Aid #01933	410 FAIRFAX PIKE	STEPHENS CITY VA 22655-	8/23/1988
RITE AID PHARMACY #4623	6711 RICHMOND HIGHWAY	ALEXANDRIA VA 22306-6712	6/26/1997
Rite Aid #11226	215 MAPLE AVE. W.	Vienna VA 22180	8/14/2002
PLAZA PHARMACY	1123 Plaza Drive	Grundy VA 24614	7/28/2003
Martinsville Pharmacy Inc.	1049-A Brookdale Street	Martinsville VA 24112	2/24/2017
Rite Aid #01195	711 W. MAIN STREET	ABINGDON VA 24210	1/30/1979
Rite Aid #04958	795 N. MAIN STREET	MARION VA 24354-3403	
RITE AID #03316	6921 LAKE HARBOUR DR	MIDLOTHIAN VA 23112	9/27/1993
RITE AID PHARMACY #4888	5500 LAKESIDE AVENUE	RICHMOND VA 23228	
RITE AID #03842	5229 JEFFERSON DAVIS HIGHWAY	FREDERICKSBURG VA 22408-2605	2/24/1999
RITE AID #03362	5215 PLANK ROAD	Fredericksburg VA 22407-	10/3/2001
H.E.L.P. Free Clinic	1320 LaSalle Ave.	Hampton VA 23669	4/5/2005
A&K Medical Supply Inc. dba Access Compounding Pharmacy	1450 Emerson Ave Suite 110	McLean VA 22101	3/21/2013
Rocky Mount Family Pharmacy	1165 Franklin Street	Rocky Mount VA 24151	5/22/2007
Chatham Family Pharmacy	13701 US Highway 29 South	Chatham VA 24531	5/7/2010
K MART PHARMACY #4483	4251 JOHN MARR DRIVE	ANNANDALE VA 22003	5/6/1987
Brosville Family Pharmacy	10372 A Martinsville Highway	Danville VA 24541	6/9/2011
RITE AID #03652	2708 WILLIAMSBURG ROAD	RICHMOND VA 23231	6/16/1982
RITE AID #01630	4205 BEULAH RD	North Chesterfield VA 23237	10/4/1985
RITE AID #03719	6335 JAHNKE ROAD	RICHMOND VA 23225	
Rite Aid #07806	1095 International Parkway	Fredericksburg VA 22406-	9/28/2006
HnR Family Pharmacy	3449 Fall Hill Ave	Fredericksburg VA 22401	1/10/2017
RITE AID PHARMACY #3745	251 W. LEE HIGHWAY	Warrenton VA 20186-2078	
RITE AID #02257	7764 GUNSTON PLZ	LORTON VA 22079	8/18/1989
SOUTHWESTERN VIRGINIA TRAINING CENTER	P. O. BOX 1328	HILLSVILLE VA 24343-7328	8/1/1997
Express Pharmacy	9705 Liberia Avenue, Suite 201	Manassas VA 20110	3/13/2014
4-WAY PHARMACY	P.O. BOX 730	NORTH TAZEWELL VA 24630	7/27/1990
Pharmacy at Great Falls	731 - D1 Walker Rd	Great Falls VA 22066	6/29/2017
Millennium Pharmacy	6305 Castle Place #1E	Falls Church VA 22044	4/23/2014
Remedium Pharmacy LLC	3957 Pender Drive, Suite #104	Fairfax VA 22030	5/30/2014
ANCHOR PHARMACY #112	2 S. MAIN STREET	KILMARNOCK VA 22482	6/11/1991
Riverside Pharmacy Services-Richmond	1300 MacTavish Avenue	Richmond VA 23230	1/27/2009
RITE AID #03686	10521 Fairfax Blvd	FAIRFAX VA 22030-3138	
WILDERNESS CENTER PHARMACY INC.	5479 GERMANNA HIGHWAY	LOCUST GROVE VA 22508	5/15/1984
GenX Pharmacy	1101 Executive Blvd, Suite A	Chesapeake VA 23320	4/11/2016
GIANT PHARMACY #228	11200 MAIN STREET	FAIRFAX VA 22030	4/27/1995
Carepac Pharmacy	8209 Whippoorwill Rd	Mechanicsville VA 23116	3/9/2016

Riverside Pharmacy Services - Charlottesville	1335 Carlton Ave	Charlottesville VA 22902	5/23/2017
Bell Creek Pharmacy	8324 Bell Creek Rd, Suite 800	Mechanicsville VA 23116	10/24/2016
Timberlake Family Pharmacy	20276 Timberlake Rd, Suite A	Lynchburg VA 24502	6/24/2016
NAI Saturn Eastern LLC dba Safeway Pharmacy #1048	1525 WILSON BOULEVARD	ARLINGTON VA 22209	1/28/1988
KROGER PHARMACY #536	205 E. LITTLE CREEK ROAD	NORFOLK VA 23505-2504	3/6/1996
K MART PHARMACY #7717	2712 W. MAIN STREET	WAYNESBORO VA 22980	10/18/1994
BEAVERDAM APOTHECARY LLC DBA BEAVERDAM PHARMACY	16151-B TRAINHAM ROAD	BEAVERDAM VA 23015	10/25/1977
Leesburg Treatment Services	209 Gibson Street, NW, Suite 202A	Leesburg VA 20176	4/12/2016
Regal Pharmacy	2068 Daniel Stuart Square	Woodbridge VA 22191	11/9/2015
Community Pharmacy Services	11600 Sunrise Valley Dr, Suite 210	Reston VA 20191	6/19/2009
Hana Pharmacy Burke, Inc.	9550 Burke Rd.	Burke VA 22015	5/16/2016

Closed in 2019

RITE AID PHARMACY #588	2141 S. CRATER ROAD	PETERSBURG VA 23805-2701	
RITE AID PHARMACY #11286	2305 JEFFERSON AVENUE	NEWPORT NEWS VA 23607	3/21/1983
RITE AID #03660	8244 RICHMOND HIGHWAY	ALEXANDRIA VA 22309	
RITE AID #02499	9520 CHAMBERLAYNE ROAD	MECHANICSVILLE VA 23116	11/13/1989
Hill City Pharmacy Inc	1602 Regents Parkway	Lynchburg VA 24515	8/24/2018
HUDGINS PHARMACY	FARMERS & FISHERMEN BLDG	MATHEWS VA 23109	9/5/1984
CVS/PHARMACY #1829	7275 ARLINGTON BOULEVARD	FALLS CHURCH VA 22042	9/28/1990
CYRUS KIRKPATRICK PHARMACY	518 S. SYCAMORE STREET	PETERSBURG VA 23803	9/14/1989
Spring Branch Rx LLC	328 W. Main Street	Waverly VA 23890	
Harris Teeter #241	7386 Harbour Towne Parkway, Suite 21	Suffolk VA 23435	5/12/2009
CVS/PHARMACY #6300	179 ELECTRIC ROAD	SALEM VA 24153	
UVA Pharmacy West Complex	1300 Jefferson Park Avenue	Charlottesville VA 22903	8/30/2017
RITE AID PHARMACY #11274	1309 FORDHAM DRIVE	VIRGINIA BEACH VA 23464	7/2/1991
RITE AID PHARMACY #11240	1303 JAMESTOWN ROAD	WILLIAMSBURG VA 23185	4/11/1979
AMBRIAR PHARMACY	198 AMBRIAR PLAZA	AMHERST VA 24521	4/23/1990
Wal-Mart PHarmacy 10-6574	2864 Virginia Beach Blvd.	Virginia Beach VA 23452	10/16/2014
Wal-Mart Pharmacy 10-3892	7000 Iron Bridge Rd.	North Chesterfield VA 23234	8/21/2015
Golden Health Pharmacy	46950 Community Plaza, Suite 112	Sterling VA 20164	4/14/2015
Johnston Memorial Cancer Center	16000 Johnston Memorial Drive	Abingdon VA 24211	12/15/2008

Wellness Concepts of Roanoke	6701 Peters Creek Rd. Suite 109	Roanoke VA 24019	1/24/2017
Shoppers Pharmacy #2384/978	9409 Lorton Market Street	Lorton VA 22079	3/24/2006
PersonalMed Virginia Pharmacy Services	12007 Sunrise Valley Drive, Suite 110	Reston VA 20191	3/24/2017
SHOPPERS PHARMACY #2365/949	3801 Jefferson Davis Highway	Alexandria VA 22305	7/26/1999
SHOPPERS PHARMACY #2358/980	7660 Richmond Highway	Alexandria VA 22306	9/20/1999
SHOPPERS PHARMACY #2364/948	6360 SEVEN CORNERS CENTER	FALLS CHURCH VA 22044	8/6/1999
Shoppers Pharmacy #2381/974	4174 Fortuna Center Plaza	Dumfries VA 22026	5/11/2005
SHOPPERS PHARMACY #2336/915	9622 MAIN STREET	Fairfax VA 22031	5/16/2002
SHOPPERS PHARMACY #2346/928	7005 MANCHESTER LAKES BLVD.	Franconia VA 22310	6/14/2001
SHOPPERS PHARMACY #2372/957	1505 STAFFORD MARKET PLACE	Stafford VA 22554	9/12/2003
SHOPPERS PHARMACY #2344/925	10864 SUDLEY MANOR DRIVE	MANASSAS VA 20109	8/18/1999
NAI Saturn Eastern LLC dba Safeway Pharmacy #1462	5821 CROSSROADS CENTER WAY	FALLS CHURCH VA 22041	10/31/1994
Rite Aid #03729	801 East Main Street	PURCELLVILLE VA 20132	
Farmville Pharmacy	308-A South Main Street	Farmville VA 23901	1/14/2013
C3 Healthcare Rx	2026A Dabney Road	Richmond VA 23230	5/23/2013
PARK VIEW PHARMACY	627 CHICAGO AVENUE	HARRISONBURG VA 22802	1/20/1976
Inova Fairfax Hospital Woodburn Infusion Pharmacy	3289 Woodburn Road, Suite 210	Annandale VA 22003	8/5/2014
Inova Fairfax Hospital Infusion at Prosperity Pharmacy	8505 Arlington Blvd, Suite 140	Fairfax VA 22031	4/17/2015
Horn Investments, LLC dba Stoney Creek Pharmacy	2831 Rockfish Valley Highway	Nellysford VA 22958	11/10/1988
RITE AID #11247	6423 IRON BRIDGE PL	North Chesterfield VA 23234	5/30/1985
Rite Aid #01181	850 UNIVERSITY CITY BLVD.	BLACKSBURG VA 24060	12/22/1981
Rite Aid #07813	4424 Fortuna Center Plaza	Dumfries VA 22025-1525	1/31/2007
Rite Aid #01625	11223 INDIAN CREEK DRIVE	POUND VA 24279	7/2/1985
Rite Aid #11225	1003 WEST BROAD STREET	Falls Church VA 22046	1/15/2002
Rite Aid Pharmacy #11222	8416 LEE HIGHWAY	Fairfax VA 22031	12/8/2003
Kroger Pharmacy #576	230 East Little Creek Rd	Norfolk VA 23505	
LotteLeah Pharmacy	13955 Metrotech Drive	Chantilly VA 20151	11/22/2016
Royal Care Pharmacy	3023 Hamaker Court Suite LL110	Fairfax VA 22031	6/19/2015
Wal-Mart Pharmacy 10-4502	912 W. Grace Street	Richmond VA 23220	4/16/2015

RITE AID #02550	2852 JEFFERSON DAVIS HWY Ste 301	STAFFORD VA 22554	5/7/1990
RITE AID #01879	8702 STAPLES MILL ROAD	RICHMOND VA 23228-2721	10/30/1987
BAILEY'S DRUG STORE	117 W. MAIN STREET	LOUISA VA 23093	
GROVE AVENUE PHARMACY	4911 GROVE AVENUE	RICHMOND VA 23226	
Springer Pharmacy	1 West Nine Mile Road	Henrico VA 23075	12/29/2011
Dickenson Drug Company	P.O. Box 215	Rural Retreat VA 24368	7/2/2012
PHARMACY PLUS INC.	2029 BOULEVARD	COLONIAL HEIGHTS VA	2/10/1988
Qurex Pharmacy LLC	3949 Pender Dr Ste 130	Fairfax VA 22030	10/24/2017
Ray's Pharmacy	1011 C. N. Augusta St.	Staunton VA 24401	11/17/2006
BENNETT'S CREEK PHARMACY	3219 BRIDGE ROAD	SUFFOLK VA 23435	6/20/1985
POTOMAC CENTER PHARMACY	2296 OPITZ BOULEVARD #100	WOODBRIDGE VA 22191	7/26/1988
Southern Virginia Consultant Pharmacy	P.O. Box 10956	Danville VA 24543	7/12/2018
The Pharmacy of Culpeper	261 Southgate Shopping Center	Culpeper VA 22701	10/16/2013
Option Care	4170 LaFayette Center Drive	Chantilly VA 20151-1254	4/10/1997
Heritage Pharmacy	5922B George Washington Memorial Hwy	Yorktown VA 23692	6/19/2018
Nickelsville Pharmacy	P.O. Box 167	Nickelsville VA 24271	6/29/2015
K MART PHARMACY #3785	5007 VICTORY BOULEVARD	TABB VA 23693	
A & B Pharmacy	6 Doctors Drive, Suite A	Emporia VA 23847	12/9/2016
FOOD LION PHARMACY #1656	43090 PEACOCK MARKET PLACE	SOUTH RIDING VA 20152	10/31/2000
FOOD LION PHARMACY #2541	12120 BERMUDA CROSSROAD LANE	Chester VA 23831	9/4/2002
WALTON & SMOOT	109 SOUTH MAIN STREET	WOODSTOCK VA 22664	
YORK DRUG, INC. T/A POQUOSON COMPOUNDING & GIFTS	498 WYTHE CREEK ROAD	POQUOSON VA 23662-1936	11/14/1990

Topic: Request from VPhA to Review Recommendations from National Consensus Conference on *Enhancing Well-Being and Resilience Among the Pharmacist Workforce*

Background: A report from the National Consensus Conference was released by APhA following the meeting. Other national associations, e.g., NABP, need to evaluate recommendations from meeting to determine what, if any, can be supported by the associations.

Included in packet:
Information regarding actions taken in 2012 and 2013 to address certain workplace conditions.

patient; no drug diversions have occurred as of yet in the stores with the new layout; Indiana, Illinois, New York, and the District of Columbia have approved the new store layout and currently have stores with the new layout located in the area; no state as of yet has denied the approval of the new store layout; and Mr. Carter intends to seek approval from all state Boards of Pharmacy.

MOTION:

The Board voted unanimously that, in concept, the new store layout as described by Walgreens appears to meet compliance with Regulations 18VAC110-20-150, 18VAC110-20-180, and 18VAC110-20-190 regarding physical and security standards, and the use of cameras and monitors for pharmacists on-duty to supervise pharmacy technicians and verify the accuracy of dispensed drugs appears to comply with 18VAC110-20-270. (motion by Munden, second by Stelly)

REQUEST FROM *THE PHARMACY ALLIANCE* TO DISCUSS IMPLEMENTING MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"

Priscilla Gale addressed the Board on behalf of *The Pharmacy Alliance* with concerns of working conditions in the pharmacy which may contribute to prescription errors. Ms. Gale explained that it was not right to hold the pharmacists accountable for errors and not the facility permit holders. Her concerns were related to long work hours, lack of meal times or breaks, not enough staff, loud music being played in the store and corporate policies that were distracting and increase errors. There was also discussion of corporate standards in which prescriptions were guaranteed within a certain length of time. To assist the Board in its discussion, Ms. Juran commented that several of the nine issues referenced in the email from The Pharmacy Alliance on page 85 of the agenda packet had recently been discussed or addressed by this Board. Specifically, #1, the prohibition of guaranteeing a dispensed prescription to be ready in a specific period of time had been discussed at a recent full Board meeting and Board counsel had advised that prohibiting this business practice could be construed as a possible violation of the Federal Trade Commission; #2 and #3 regarding restrictions on the number of hours a pharmacist may continuously work and mandatory meal breaks will be discussed at the June board meeting at the conclusion of the public comment period for a recently received petition for rulemaking; #7 and #8 regarding the reporting of medication errors has recently been addressed in statute and the development of the CQI regulations currently awaiting the Governor's signature; and #9 regarding a prohibition in influencing a pharmacist's decision regarding the practice of pharmacy is already addressed in Regulation 18VAC110-20-110B. Therefore, Ms. Juran recommended that the Board may want to focus its discussion on the other items listed.

ACTION ITEM:

Ms. Shinaberry recommended, and the full Board supported, that the following issues be referred to the Regulation Committee for further consideration: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization

administrations; requirement that other timed metrics regarding the phone, drive-thru, or cash register may only be imposed on pharmacy technicians and not pharmacists; and, prohibition of any non-pharmacist employ of the permit holder influencing the professional decision of the pharmacist. Staff was directed to research these subjects and provide information to the Regulation Committee to aid its discussion.

ACTION ITEM:

Because Board counsel was unable to attend the meeting, Mr. Adams agreed to table until the June Board meeting his request on the agenda to discuss the length of time associated with and access to final orders.

REPORTS:

BOARD OF HEALTH PROFESSIONS:

Robbie Rhodes, member of the Board of Health Professions, reported to the Board of Pharmacy the latest information concerning the Board of Health Professions. The Regulatory Research Committee and the full Board met on February 14, 2012. The Board of Health Professions voted that licensure is appropriate for Medical Laboratory Scientists and Medical Laboratory Technicians. Also, the committee's study of the Nurse Practitioner's scope of practice is currently being revised to reflect the significant changes resulting from HB 346. The committee is also moving forward with the Pharmacy review and will be researching team delivery within the context of how "patient care team" is defined in HB 346. Staff will give an update of the progress of the Pharmacy review at the May committee meeting. Lactation consultants may be submitting an application to the Board of Health Professions for review to determine if the profession needs to be regulated. The Virginia Perfusion Society requested that a study be initiated to regulate Perfusionists and the Board voted to table consideration of the request until the level of urgency can be ascertained by staff, given the Board's current workload. Delegate Dr. Christopher Stolle is expected to request the Department to conduct a study of options for accepting military training and experience as satisfying requirements for licensure, certification or registration as a health care provider. Mr. Rhodes also stated that the next full Board meeting of the Board of Health Professions is scheduled for May 8, 2012.

LICENSURE PROGRAM:

Mr. Johnson reported that the Board issued 939 licenses and registrations for the period of December 1, 2011 through February 29, 2012, including 132 pharmacists, 111 pharmacy interns, and 488 pharmacy technicians. In January 2012, the Board began receiving applications for pharmacy technician registration exclusively online eliminating the need for paper applications. Inspectors performed 281 facility inspections including 116 routine inspections of pharmacies: 31 resulted in no deficiency, 31 with deficiencies, and 54 with deficiencies and a consent order. There are currently two active innovative (pilot) programs. One additional pilot program is being reviewed for renewal and two new pilot programs were approved.

DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between September 19, 2011,

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE REGARDING PHARMACY WORKING CONDITIONS

May 2, 2012
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 1:05PM.
PRESIDING:	Jody H. Allen, Committee Chairman
MEMBERS PRESENT:	Gill B. Abernathy David C. Kozera Empsy Munden Robert M. Rhodes Crady Adams
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Howard M. Casway, Senior Assistant Attorney General Elaine J. Yeatts, Senior Policy Analyst, DHP
APPROVAL OF AGENDA:	With no changes made to the agenda, the agenda was approved as presented.
	The Regulation Committee met to discuss the specific mandates requested by The Pharmacy Alliance and referred to committee for further consideration during the March 13, 2012 full board meeting. Those mandates were: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization administration; requirement that other timed metrics regarding the phone, drive-thru, or cash register may only be imposed on pharmacy technicians and not pharmacists; and prohibition of any non-pharmacy employ of the permit holder influencing the professional decision of the pharmacist. Additionally, the Committee discussed a recent petition for rulemaking received on February 22, 2012 regarding working conditions. Specifically it requested regulations similar to West Virginia and North Carolina which require breaks for pharmacists working more than 6 continuous hours and a prohibition against pharmacists working more than 12 continuous hours per day.
* PETITION FOR RULEMAKING REGARDING PHARMACY WORKING CONDITIONS - REQUIRED BREAKS AND NUMBER OF CONTINUOUS HOURS PHARMACIST MAY WORK:	The Committee first discussed the petition for rulemaking. The public comment period had closed on April 15, 2012. Ms. Yeatts provided a summary of the approximate twenty public comments received. All, but one were completely supportive of the petition.

MOTION:

The Committee voted unanimously to recommend to the full Board in June to accept the petition for rulemaking and publish a NOIRA to address pharmacy working conditions such as a requirement that no pharmacist may work more than 12 continuous hours in any 24-hour period or more than 60 hours in any 5-day period and an allowance for pharmacists working more than 6 continuous hours to take a 30-minute uninterrupted break and one additional uninterrupted 15-minute break, with emergency provisions for addressing immediate needs of patients.

REQUEST FROM *THE PHARMACY ALLIANCE* TO IMPLEMENT MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"

The Committee then discussed the specific mandate requests received from *The Pharmacy Alliance* and referred to committee for further consideration. Public comment was received from Mr. Bob Garland, pharmacist, who believes Regulation 18VAC110-20-110 addresses the concerns raised by The Pharmacy Alliance. The regulation states that the pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy and that any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit. He stated that the corporations may not clearly understand this regulation. Comment was also received by Ms. Kristen Barratt, pharmacist, who supported the concern for a drive-thru operating when there is only one pharmacist on-duty and no pharmacy technicians. Pursuant to §54.1-100, Board counsel indicated that the promulgation of regulation may require proof that an unregulated practice can harm or endanger the health, safety or welfare of the public; without such proof, the Board may be overreaching in its authority. Through lengthy discussions, concerns were expressed by various members for the current business practices, along with concerns for the Board's ability to lawfully regulate the practices.

MOTION:

The Committee voted unanimously to recommend the following to the full Board in June: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and pharmacists to provide evidence to the Board that the identified practices referred to the Committee can or have created patient harm; and, publish an article in an upcoming Board e-newsletter expressing concern for contemporary practices and restating the relevant sections §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary

action against the pharmacy permit.

ADJOURN: With all business concluded, the meeting adjourned at 4:40PM.

Jody H. Allen, Committee Chairman

6/12/2012
Date

Caroline D. Juran, Executive Director

June 12, 2012
Date

be submitted to the Secretary's Office by August. She also reported that she has been conducting a weekly progress check of the regulations that are currently at the Governor's Office. Arne Owens, Chief Deputy Director, DHP, and Ralph Orr, Director, Prescription Monitoring Program (PMP), visited the Department of Health and Human Resources in Washington, DC to discuss the PMP with regards to interoperability between states (interstate data sharing between PMP programs). Dr. Cane also spoke on new policies being set forth by the agency that will help decrease traveling expenses.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that the comment period for the changes to the "run-dry" requirement for automated dispensing devices is now closed. Emergency regulations for Continuous Quality Improvement Programs (CQI) are at the Governor's Office. The proposed amendments to address on-hold prescriptions and the final regulations for repackaging in the Community Service Boards and Behavioral Health Authorities are also at the Governor's Office (emergency regulations for CSB's and BHA's expire 6/18/12). The proposed regulation for administrative fees for duplicate licenses and verification are at the Secretary's Office.

- Re-adoption of the proposed regulations for automated dispensing devices:

Ms. Yeatts indicated that staff did not make any substantive changes, but did reorganize the proposed regulations for automated dispensing devices to improve readability. Therefore, she requested that the Board review the changes. Ms. Yeatts stated that the Board would need to re-adopt the proposed regulations.

MOTION:

The Board voted unanimously to adopt the proposed regulations as presented for automated dispensing devices.
(motion by Yi, second by Allen)

REGULATORY COMMITTEE REPORT:

- Recommendation on Petition for Rulemaking, Kristen Barratt, Pharmacist

Ms. Yeatts presented to the Board Ms. Barratt's Petition for Rulemaking concerning professional work environment. Ms. Yeatts stated that the Board could either deny the petitioner's request for amendments and state the reason why the request was denied, or accept the request and initiate rulemaking by adopting a Notice of Intended Regulatory Action (NOIRA). Ms. Juran discussed the research that staff conducted and provided to the Regulation Committee. The Regulation Committee's motion was for the Board to accept the request and adopt a NOIRA.

MOTION:

The Board voted unanimously to approve the Regulation Committee's recommendation to accept the petition for rulemaking and adopt a Notice of Intended Regulation Action regarding the number of continuous hours a pharmacist may work and required breaks.

- Recommendation regarding request from *The Pharmacy Alliance* on pharmacy working conditions

Ms. Allen discussed with the Board the request from The Pharmacy Alliance concerning pharmacy working conditions and the Regulation Committee's recommendation. The Committee recommended the following: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and other pharmacists to submit evidence to the Board that the identified practices referred to the Committee can or have created patient harm; publish an article in the Board's e-newsletter expressing concerns for contemporary practices and restating the relevant sections of §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

MOTION:

The Board voted unanimously to approve the Regulation Committee's recommendation regarding *The Pharmacy Alliance's* request concerning pharmacy working conditions.

MISCELLANEOUS:

- Request to discuss length of time associated with and access to final orders:

Mr. Adams presented to the Board his concerns regarding pharmacists who have past disciplinary actions on their licenses and are having a difficult time getting employment as a result. Notices and Orders are public information and kept on record for eighty-five years. Mr. Casway explained that changes would necessitate the General Assembly amending the Administrative Process Act, Freedom of Information Act, title 54.1 and possibly other sections of law. Additionally, changes to the state record retention requirements and agency policy would be necessary. Mr. Kozera commented that many violations are also reportable to the National Practitioner Databank and therefore, a violation would also exist in its records.

MOTION:

A motion was presented and subsequently withdrawn by Mr. Adams for the Board to consider a process to expunge certain case violations from a pharmacist's license.

MOTION:

A new motion was made that the Department of Health Professions reconsider how it displays public information on its website with a focus of discussion on violations occurring in excess of twenty years. (motion by Adams, died for lack of a second)

- Define "annual" and "semiannual" in guidance document 110-36

To further clarify the Board's expectations regarding when media fill testing must be performed, Ms. Juran requested that the Board review staff's suggested changes to Guidance Document 110-36 concerning the definitions of "annual" and "semiannual". It was suggested the terms

February 2013

News

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Compounding Sterile Preparations

Virginia Board of Pharmacy Regulation 18VAC110-20-321 states compounding of both sterile and nonsterile drug products shall be performed in accordance with United States Pharmacopeia-National Formulary (USP-NF) compounding standards and §54.1-3410.2 of the Code of Virginia. While pharmacists often associate sterile compounding requirements with USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*, it is important not to overlook the requirements in USP Chapters <1> *Injections*, <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, and <85> *Bacterial Endotoxin Testing*.

At the December 12, 2012 Board meeting, the Board addressed several issues in Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*, related to compliance with USP-NF standards regarding the compounding of sterile preparations. Modifications, including changes for when an inspector should cite a deficiency, were made to Major Deficiencies 20, 21, 22, 24, 25, 26, and 33, and Minor Deficiencies 30, 31, and 32. To access Guidance Document 110-9, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm*.

Deficiencies Associated With Compounding Sterile Preparations

Certification of the direct compounding area, buffer or clean room, and ante room is to be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed (refer to Major Deficiencies 22 and 23). Every six months is interpreted to be six months from the date of the last certification. For example, a direct compounding area certified as ISO Class 5 on January 17, 2013, requires certification on or before July 17, 2013. The inspector will ask for documentation of at least the two most recent certifications to ensure that the areas comply with the appropriate ISO class.

Individuals preparing compounded sterile preparations (CSP) must complete media-fill testing annually when preparing low and medium-risk CSPs and semiannually when preparing high-risk level CSPs (refer to Major Deficiencies 25a and 26). The terms "annually" and "semiannually" as used in USP Chapter <797> are defined to mean every 12 months and every six months, respectively. In the event an individual fails a media-fill test, that individual may not perform high-risk level compounding prior to retraining and receipt of a passing media-fill test (refer to Major Deficiency 25c). Individuals preparing low or medium-risk level CSPs must provide documentation of passing the media-fill test within 45 days of the failed test (refer to Major Deficiency 26a). Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. The records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection. The inspector will ask for documentation that each individual who prepares CSPs has completed the required media-fill testing and retesting if required.

Compounded sterile preparations must be assigned an appropriate beyond-use date (BUD) in compliance with USP-NF standards (Major Deficiencies 25 and 33). In the absence of sterility testing, the BUD for low, medium, and high-risk CSPs are:

	Low Risk	Medium Risk	High Risk
Controlled Room Temperature	48 hours	30 hours	24 hours
2° to 8°C (36° and 46°F)	14 days	9 days	3 days
-25° to -10°C (-4° and 14°F) or colder	45 days	45 days	45 days

If performed, sterility and endotoxin testing must comply with USP Chapters <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, or <85> *Bacterial Endotoxin Testing* in addition to USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*. The inspector will ask for documentation for sterility or endotoxin testing.

Concern for Contemporary Practice: Evidence Requested

During the June 2012 full Board meeting, the Board expressed concern for several identified contemporary practices such as the advertising of a guarantee for how quickly prescriptions will be dispensed, or corporate production quotas regarding prescription dispensing or immunization administration. However, the Board determined that there was insufficient evidence proving that the identified practices can or have created patient harm. Such evidence is legally necessary for the promulgation of regulation. Therefore, the Board voted to encourage pharmacists to submit evidence to the Board when contemporary pharmacy practices can or have created patient harm and remind everyone of the following relevant sections of 54.1-3434 and Regulation 18VAC110-20-110 B:

- The pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy.

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- If the owner is not a pharmacist, he or she shall not abridge the authority of the pharmacist-in-charge (PIC) to exercise professional judgment relating to the dispensing of drugs.
- The PIC or pharmacist on duty shall control all aspects of the practice of pharmacy, and any decision overriding such control shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

Evidence of possible patient harm resulting from contemporary pharmacy practice or any violation of law, to include 54.1-3434 and Regulation 18VAC110-20-110 B, may be submitted to the Virginia Department of Health Professions, Enforcement Division by following the directions for "How to file a Complaint" found at *www dhp virginia gov/Enforcement/complaints.htm.*

Regulations for Continuous Quality Improvement Programs

On October 1, 2012, emergency regulations for continuous quality improvement (CQI) programs became effective. As emergency regulations, they will remain in effect for one year with an option for the Board to request a six-month extension, if permanent replacement regulations have not been approved by the governor at that time. Regulations were promulgated pursuant to §54.1-3434.03 of the Code of Virginia. This law requires each pharmacy to implement a program for CQI in compliance with Board regulations or actively report to a patient safety organization (PSO) that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). To provide sufficient time for pharmacies to come into compliance, the Board instructed staff to not cite a deficiency during a routine inspection for the first six months from the date the regulations became effective. Thus, through March 31, 2013, if the pharmacy is not in compliance with CQI requirements, the inspector will simply note this as a comment on the inspection report rather than citing a deficiency. As of April 1, 2013, the inspector will cite a deficiency for noncompliance.

In a pharmacy that chooses to comply with CQI requirements by actively reporting to a PSO, the inspector will look for a record indicating the date a report was submitted to the PSO. If no dispensing errors occurred within the past 30 days, the record must indicate a zero report with date. The record is to be maintained for 12 months from the date of reporting. In a pharmacy that chooses to implement its own CQI program in compliance with Board regulations, the inspector will look for a record that includes the following general information: (1) dates the analysis was initiated and completed; (2) names of the participants in the analysis; and (3) general description of remedial action taken to prevent or reduce future errors. A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. The record is to be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors. The report is not intended to be punitive by revealing patient-specific information associated with dispensing errors, but is intended to demonstrate to the inspector the pharmacy's compliance with CQI requirements.

For more information, the emergency CQI regulations may be accessed at *www.dhp.virginia.gov/Pharmacy/leg/EmergencyRegs_QualityImprovementPrograms.doc*

Pre-Populating Refill Authorization Forms for Prescribers

Drug Enforcement Administration (DEA) has recently indicated that a pharmacy, to include community and long-term care pharmacies, may not send a refill request to a prescriber that contains partially or fully pre-populated information within the "prescription" portion of the refill reminder. DEA does not characterize the pharmacy as acting as the prescriber's agent for the purposes of preparing the prescription since federal regulations require the prescriber to direct the agent as to the required elements of a valid prescription and not vice-versa. Refill reminders for drugs in Schedules III through V should instruct the prescriber to prepare and transmit a prescription to the pharmacy if the prescriber wishes to issue a new prescription for the patient. Please remember when a prescriber faxes a written prescription to a pharmacy it must bear the prescriber's manual signature. A faxed prescription containing an electronic or computer-generated signature is not a valid prescription.

Interoperability of the Virginia Prescription Monitoring Program With Other States

A report from the Virginia Prescription Monitoring Program (VPMP) reveals only those drugs in Schedules II through IV that a specific patient was dispensed by a pharmacy located in Virginia. If the patient resides in another state but is using a Virginia pharmacy to obtain a prescription drug, a query to the VPMP may not reveal a complete dispensing history assuming the patient also receives prescriptions from pharmacies in his or her home state. However, the VPMP is becoming increasingly more interoperable with other states. By sharing dispensing information across the borders, prescribers and pharmacists are able to receive a more comprehensive patient dispensing history and make more meaningful decisions regarding the appropriateness for prescribing or dispensing a controlled substance. Currently, Virginia is interoperable with nine states: Ohio, Indiana, Connecticut, Michigan, North Dakota, Kansas, Arizona, Kentucky, and South Carolina. To request PMP information from these states, a registered user of the VPMP selects the corresponding box for the state from which information is desired when submitting the request to the VPMP. The request for information is sent to the selected states. Dispensing information, if available, reported by that state(s) is provided to the requestor along with information from the VPMP.

Because other states such as West Virginia, Tennessee, and North Carolina are not currently interoperable with the VPMP, a Virginia pharmacist must directly register as a user with the other state's PMP program in order to access a patient's dispensing history within that state. It is hoped that these states will be able to implement interoperability in the near future. Information for becoming a registered user of these surrounding states' PMP programs may be accessed at:

- West Virginia: *https://65.78.228.163*
- Tennessee: *https://prescriptionmonitoring.state.tn.us*
- North Carolina: *www.ncdhhs.gov/mhddsas/controlledsubstance/index.htm*

Maryland and Washington DC do not have operational PMPs at this time. For more information, see the "Prescriptions from Out-of-State Prescribers and Patients" article, in the July 2012 Board *Newsletter,* available at *www.dhp.virginia.gov/Pharmacy/newsletters/VA072012.pdf.*

The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc. to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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Guidance Document: 110-39 Adopted: March 21, 2017

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

Virginia Board of Pharmacy
Inspection Report
December 9, 2019
Licenses Issued

	6/1/18-8/31/18	9/1/18-11/30/18	12/1/18-2/28/19	3/1/19-4/20/19	5/1/19-7/31/19	8/1/19-10/31/19	License Count 11/15/2019
Business CSR	50	59	41	19	36	32	1,429
CE Courses	0	2	0	0	0	0	9
Limited Use Pharmacy Technician	0	1	0	0	0	0	11
Medical Equipment Supplier	4	1	2	1	3	7	232
Nonresident Manufacturer	4	7	24	8	11	11	184
Nonresident Medical Equipment Supplier	12	9	10	5	30	12	349
Non-resident Outsourcing Facility	1	2	0	0	1	0	27
Non-resident Pharmacy	33	27	24	22	27	18	777
Non-resident Third Party Logistics Provider				8	58	42	109
Non-resident Warehouser				6	10	16	32
Non-resident Wholesale Distributor	16	12	13	3	22	13	669
Non-restricted Manufacturer	0	1	1	1	2	0	31
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	439	250	157	134	316	328	15,730
Pharmacist Volunteer Registration	2	0	0	0	2	1	0
Pharmacy	18	21	13	7	13	10	1,784
Pharmacy Intern	140	189	122	74	65	225	1,752
Pharmacy Technician	420	378	388	249	426	433	14,157
Pharmacy Technician Training Program	2	4	3	2	3	3	140
Physician Selling Controlled Substances	25	42	44	7	25	18	679
Physician Selling Drugs Location	10	4	8	3	7	4	177
Pilot Programs	1	0	0	2	1	0	24
Registered Physician For CBD/THC-A Oil	118	83	40	25	52	59	380
Repackaging Training Program	0	0	0	1	0	0	2
Restricted Manufacturer	0	0	1	0	1	0	48
Third Party Logistics Provider	0	1	0	0	1	0	5
Warehouser	10	7	9	0	0	1	110
Wholesale Distributor	3	0	0	0	1	3	70
Total	**1,308**	**1,100**	**900**	**577**	**1,113**	**1,236**	**38,917**

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Inspections Completed

	6/1/18-8/31/18		9/1/18-11/30/18		12/1/18-2/28/19		3/1/19-4/30/19		5/1/19-7/31/19		8/1/19-10/31/19	
License Type												
Controlled Substances Registration	120		174		164		83		145		177	
Medical Equipment Supplier	25		19		10		11		21		19	
Non-restricted Manufacturer	0		3		3		1		3		0	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	31		38		30		11		39		30	
Restricted Manufacturer	0		0		1		0		1		0	
Third Party Logistics Provider	0		2		1		0		1		2	
Warehouse	14		12		10		7		10		7	
Wholesale Distributor	7		7		9		2		11		7	
Pharmacy	328		306		227		207		348		284	
Pilot	0		1		0		1		0		0	
Total	**525**		**562**		**455**		**323**		**579**		**526**	
Pharmacy (0201) Inspections												
Change of Location	9		7		0		0		7		5	
New	19		18		12		6		13		10	
Reinspection	6		13		14		4		9		15	
Remodel	31		42		40		38		53		49	
Routine	242		222		159		159		253		193	
Focus	1		4		0		0		2		3	
Federal Agency	18		0		0		0		11		9	
Compliance	2		0		2		0		0		0	
Pilot	0		0		0		0		0		0	
Total	**328**		**306**		**227**		**207**		**348**		**284**	
Pharmacy Routine Inspections												
No Deficiency	93	38%	109	49%	57	36%	53	33%	98	39%	64	33%
Deficiency	75	31%	64	29%	55	34%	47	34%	76	34%	66	34%
Deficiency & IPHCO	74	31%	49	22%	47	30%	59	37%	79	31%	63	33%
Total	**242**		**222**		**159**		**159**		**253**		**193**	

Virginia Board of Pharmacy
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Frequently Cited Deficiencies
June 2018 - October 2019

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	129
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	60
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	55
7. Change of location or remodel of pharmacy without submitting application or Board approva	32
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	28
20. Pharmacist not checking and documenting repackaging or bulk packaging	26
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	24
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	23
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	21
12. Storage of prescription drugs not in the prescription department	20
Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)	**Cumulative Total**
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	180
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	129
127. Repackaging records and labeling not kept as required or in compliance	101
123. Engaging in remote processing not in compliance	78
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	74
108. Emergency access alarm: code/key not maintained in compliance	70
130a. Compounded products not properly labeled	65
124. Labels do not include all required information	64
122. Engaging in alternate delivery not in compliance	52
130. Required compounding/dispensing/distribution records not complete and properly maintained	42

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
Routine Inspections Completed	242	222	159	159	253	193	1228	Repeat	Repeat
Total Deficiencies	123	83	60	101	123	119	609	13	245
Average Deficiencies per Inspection	0.5	0.4	0.4	0.6	0.5	0.6	0.5		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	0	1	2	0	0	5		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	9	12	6	12	14	7	60		2
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	2	7	2	5	1	4	21		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	0	1	1	0	2		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	1	0	0	2	6	10		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	1	0	0	1	0	2		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	7	3	2	5	11	4	32		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	1	1	1	1	0	0	4		1
9. Alarm not operational or not being set	1	0	0	1	0	0	2		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	1	1	0	3	2	11	18		1

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	2	1	0	4	2	7	16		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	1	1	2	3	1	9		
12. Storage of prescription drugs not in the prescription department	5	1	1	3	5	5	20		10
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	5	0	0	4	3	2	14		4
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	2	0	2	3	8	5	20	1	4
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	16	9	8	9	6	7	55		8
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	24	20	16	19	31	19	129	5	112
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	6	2	3	4	4	5	24		4
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	2	0	2	1	0	3	8		
18. Records of dispensing not maintained as required	4	2	3	2	1	4	16		1

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	1	0	1	0	2	3	7		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	4	4	0	3	10	5	26		17
20a. Pharmacist not documenting final verification of non-sterile compounding	3	3	1	5	5	1	18		4
20b. Pharmacist not documenting final verification of sterile compounding	5	3	1	3	1	3	16	3	14
21. No clean room	0	0	0	0	0	0	0		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	0	0	0	0	0	1	1		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	1	0	2	0	0	0	3		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	0	0	0		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	1	0	0	0	0	0	1		2
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	0	0	0	1	1		1

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Deficiencies 1 - 100
(Formerly Major Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	5	4	2	3	4	5	23	2	31
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	1	0	0	1	0	0	2		1
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	3	0	0	1	1	2	7		1
29. Unlawful compounding for further distribution by other entities	3	0	1	0	1	1	6		
30. Security of after-hours stock not in compliance	0	0	0	0	0	0	0		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	4	6	4	4	4	6	28	2	18
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	0	0	1	1		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	1	1	0	0	0	0	2		1

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Deficiencies Above 100
(Formerly Minor Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
Routine Inspections Completed	**242**	**222**	**159**	**159**	**253**	**193**	**1228**	**Repeat**	**Repeat**
Total Deficiencies	**228**	**160**	**160**	**150**	**238**	**239**	**936**	**30**	**335**
Average Deficiencies per Inspection	**0.9**	**0.7**	**1.0**	**0.9**	**0.9**	**1.2**	**0.8**		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	0	0	0	0	1	1		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	4	1	7	1	3	1	17		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	3	1	1	0	1	0	6		7
106. Prescription department substantially not clean and sanitary and in good repair	0	1	2	0	2	0	5		2
107. Current dispensing reference not maintained	3	1	6	4	2	2	18		10
108. Emergency access alarm code/key not maintained in compliance	15	8	8	9	20	10	70		18
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	38	24	26	23	31	38	180	2	45
110. Storage of paraphernalia/Rx devices not in compliance	0	1	0	0	0	0	1		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	1	0	1	2	0	0	4		2
112. Biennial taken late but within 30 days	1	3	2	2	2	0	10		
113. Inventories taken on time. but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	32	26	20	14	21	16	129	4	59

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Deficiencies Above 100
(Formerly Minor Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	7	2	0	0	1	2	12		
115. Other records of distributions not maintained as required	1	0	0	2	0	0	3		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	4	2	4	7	12	11	40		1
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	0	0	0	0	1	1	2		
119. Not properly documenting partial filling of prescriptions	4	4	5	3	13	10	39	1	25
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	0	1	2	0	0	0	3		
122. Engaging in alternate delivery not in compliance	16	9	6	5	3	13	52	3	10
123. Engaging in remote processing not in compliance	7	4	8	11	25	23	78		7
124. Labels do not include all required information	16	10	7	5	12	14	64	1	14
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	3	0	8	4	8	10	33	1	9
126. Special packaging not used or no documentation of request for non-special packaging	1	0	0	0	2	1	4		5
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	18	17	9	17	20	20	101	5	32
128. Unit dose procedures or records not in compliance	0	2	0	0	0	0	2		
129. Robotic pharmacy systems not in compliance	2	0	0	1	0	0	3		
130. Required compounding/dispensing/distribution records not complete and properly maintained	9	6	4	6	9	8	42	1	14
130a. Compounded products not properly labeled	10	9	9	9	14	14	65	2	15

Virginia Board of Pharmacy
Inspection Report
December 9, 2019

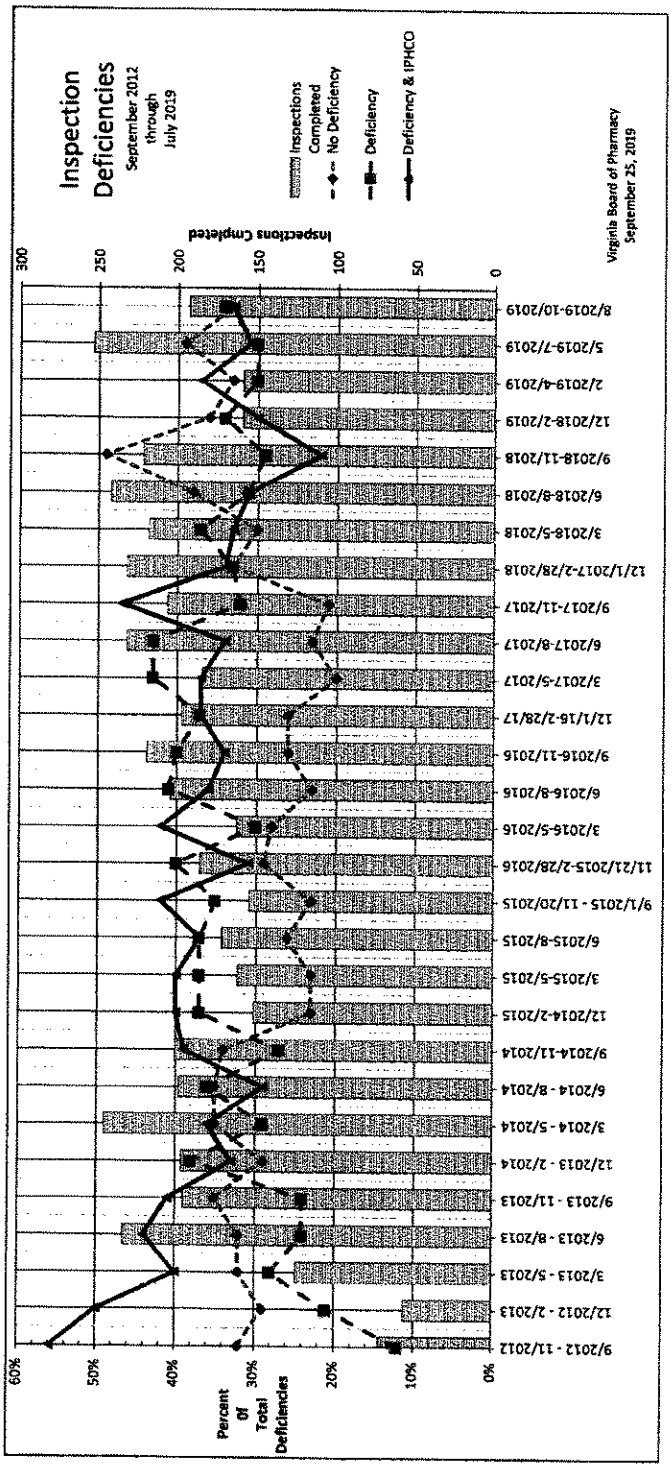
Deficiencies Above 100
(Formerly Minor Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	5	3	3	1	1	7	20		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	6	4	3	8	7	8	36	3	5
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	0	0	1	1		
Hospital specific or long-term care specific:							0		
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0	0	0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	0		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	1	1	0	0	0	1	3	1	2
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	1	4	1	3	2	3	14	1	1
139. Emergency medical services procedures or records not in compliance	0	2	0	0	1	2	5		5
140. Emergency kit or stat-drug box procedures or records not in compliance	0	1	0	1	0	3	5	1	7
141. Maintaining floor stock in a long-term care facility when not authorized	0	0	0	0	0	0	0		
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	16	10	10	10	14	14	74	4	15
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	1	0	0	0	0	0	1		

Virginia Board of Pharmacy
Inspection Report
December 9, 2019

Deficiencies Above 100
(Formerly Minor Deficiency)

	6/18-8/18	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	Total	8/19-10/19	Cumulative
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	1	0	0	0	0	0	1		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	0	0	0	0	0	0		4
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13)	0	0	0	0	0	0	0		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	1	0	1	0	0	1	3		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)	1	3	7	2	11	4	28		3


Inspection Deficiencies
September 2012 through July 2019
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Virginia Board of Pharmacy
September 25, 2019
Inspections Completed
Percent Of Total Deficiencies
300
250
200
150
100
50
0
60%
50%
40%
30%
20%
10%
0%
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019
2/2019-4/2019
5/2019-7/2019
8/2019-10/2019

Pharmaceutical Processors Report-December 9, 2019

- Coordination of pharmaceutical processor inspection schedule
- Ongoing work to establish the CBD/THC-A product registration process through the Prescription Monitoring Program and patient verification through Virginia Interactive.
- Recruitment for a program admin specialist for the Pharmaceutical Processors program continues to move forward.
- Presentations provided to the Geriatric Mental Health Partnership, the Community Coalitions of Virginia 2nd Annual Summit, and the DHP Senior Inspector Training Day.

Pharmaceutical Processors Program-By the Numbers
As of 11/22/19

Registered Practitioners	384
Registered Patients	1395
Registered Parents/Guardians	31
Pending applications for Patients	303
Pending applications for Parents/Guardians	15

Discipline Program Report

Open Cases as of 11/22/19:

	PC	APD	Investigation	FH	IFC	Pending Closure	TOTALS
Patient Care Cases	53	12	65	5	7	0	137
Non-Patient Care Cases	55	14	63	2	10	11	155
						TOTAL:	**292**

Notes:

1) Patient care cases:
   - We have fifty-three (53) patient care cases at Probable Cause compared to twenty-two (22) that were reported in September 2019. Twelve (12) of these cases are pending an IFC or FH.
   - We have twenty percent (20%) more cases compared to September 2019.
2) Non-patient care cases (inspection cases or compliance related cases)
   - The number of cases is consistent with the last report.
3) Cases greater than 250 work days: We have twenty (27) cases exceeding 250 work days. Of this number, three (3) cases are in CAP status and five (5) cases are at a status of formal/informal hearing.

Upcoming Disciplinary Proceedings:

December 10, 2019	Formal Hearings	Note Location: Westerre Conf Center
January 7, 2020	IFCs	Patricia Richards-Spruill/Glenn Bolyard
January 14, 2020	Formal Hearings	
February 5, 2020	Formal Hearings	
February 18, 2020	IFCs	Kris Ratliff/Melvin Boone
March 10, 2020	IFCs	Patricia Richards-Spruill/Glenn Bolyard
March 24, 2020	Full Board Meeting/Formal Hearings	