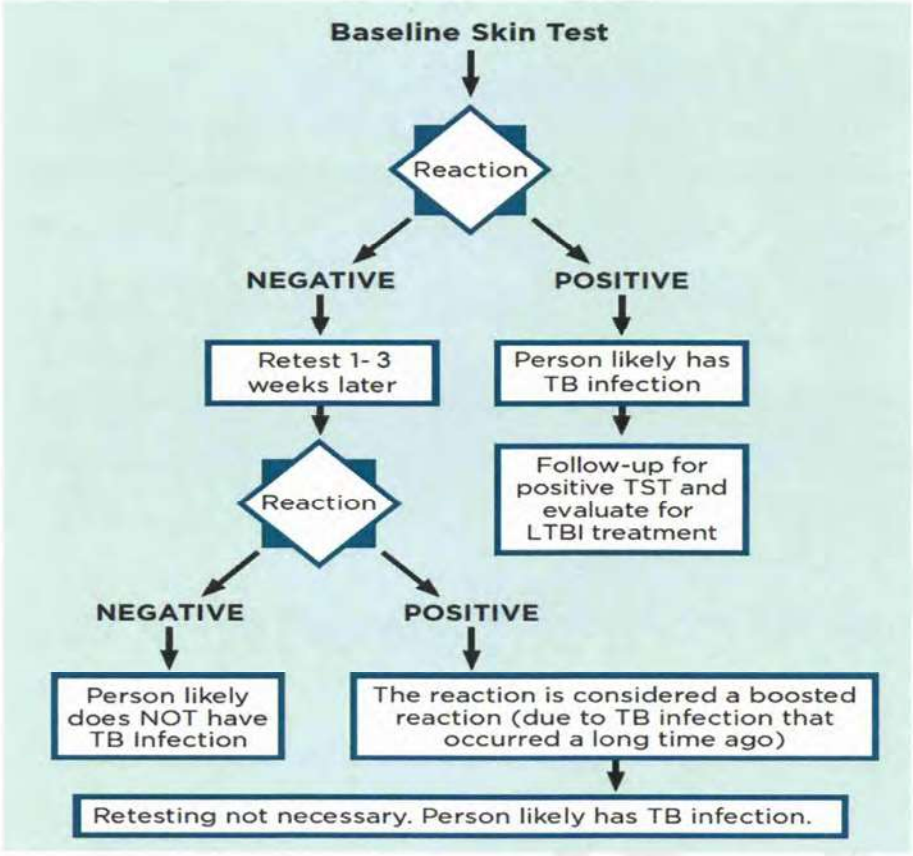

Baseline Skin Test
Reaction
NEGATIVE
POSITIVE
Retest 1- 3 weeks later
Person likely has TB infection
Reaction
Follow-up for positive TST and evaluate for LTBI treatment
NEGATIVE
POSITIVE
Person likely does NOT have TB Infection
The reaction is considered a boosted reaction (due to TB infection that occurred a long time ago)
Retesting not necessary. Person likely has TB infection.

**Agenda Item: Adoption of Proposed Regulations – Pharmaceutical processors/dispensing facilities**

**Included in your agenda package are:**

Copy of the statutory requirements for adoption of regulations as an exempt action (54.1-3446.2)

Copy of Notice of Intended Regulatory Action from a petition for rulemaking

Copy of portion of NOIRA background document

Copy of a comment on NOIRA

Copy of Draft regulatory action for Board's consideration

**Board action:**

The Board will need to adopt proposed regulations that will be posted for a 60-day comment period with final adoption at the December board meeting.

## § 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.

...N. With the exception of § 2.2-4031, neither the provisions of the Administrative Process Act (§ 2.2-4000 et seq.) nor public participation guidelines adopted pursuant thereto shall apply to the adoption of any regulation pursuant to this section. Prior to adopting any regulation pursuant to this section, the Board of Pharmacy shall publish a notice of opportunity to comment in the Virginia Register of Regulations and post the action on the Virginia Regulatory Town Hall. Such notice of opportunity to comment shall contain (i) a summary of the proposed regulation; (ii) the text of the proposed regulation; and (iii) the name, address, and telephone number of the agency contact person responsible for receiving public comments. Such notice shall be made at least 60 days in advance of the last date prescribed in such notice for submittals of public comment. The legislative review provisions of subsections A and B of § 2.2-4014 shall apply to the promulgation or final adoption process for regulations pursuant to this section. The Board of Pharmacy shall consider and keep on file all public comments received for any regulation adopted pursuant to this section.

O. The Board shall register all cannabis products that meet testing, labeling, and packaging standards.

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

**Agency** Department of Health Professions

**Board** Board of Pharmacy

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

Action: Response to petition for rulemaking

## Notice of Intended Regulatory Action (NOIRA)

Action 5611 / Stage 9081

Edit Stage | Withdraw Stage | Go to RIS Project

| Documents | | |
|---|---|---|
| Preliminary Draft Text | None submitted | Sync Text with RIS |
| Agency Background Document | 9/21/2020 | Upload / Replace |
| Governor's Review Memo | 2/5/2021 | |
| Registrar Transmittal | 2/5/2021 | |

| Status | |
|---|---|
| **Public Hearing** | Will be held at the **proposed** stage |
| **Exempt from APA** | No, this stage/action is subject to Article 2 of the *Administrative Process Act* |
| **DPB Review** | Submitted on 9/21/2020<br>Policy Analyst: Jerry Gentile<br>Review Completed: 10/1/2020 |
| **Secretary Review** | Secretary Review Completed: 12/9/2020 |
| **Governor's Review** | Review Completed: 2/5/2021<br>Result: Approved |
| **Virginia Registrar** | Submitted on 2/5/2021<br>The Virginia Register of Regulations<br>Publication Date: 3/1/2021 Volume: 37 Issue: 14 |
| **Comment Period** | Ended 3/31/2021<br>0 comments |

| Contact Information | |
|---|---|
| **Name / Title:** | Caroline Juran, RPh / *Executive Director* |
| **Address:** | 9960 Mayland Drive<br>Suite 300<br>Richmond, VA 23233 |
| **Email Address:** | caroline.juran@dhp.virginia.gov |

VIRGINIA
REGULATORY TOWN HALL

townhall.virginia.gov

# Notice of Intended Regulatory Action (NOIRA)
# Agency Background Document

| | |
|---|---|
| **Agency name** | Board of Pharmacy, Department of Health Professions |
| **Virginia Administrative Code (VAC) Chapter citation(s)** | 18VAC110-60 |
| **VAC Chapter title(s)** | Regulations Governing Pharmaceutical Processors |
| **Action title** | Petition for rulemaking |
| **Date this document prepared** | 9/11/20 |

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

## Brief Summary

*Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.*

In response to a petition for rulemaking from the Virginia Medical Cannabis Coalition, the Board of Pharmacy decided to publish a Notice of Intended Regulatory Action in order to consider the requested amendments to regulations governing pharmaceutical processors. The amendments requested are relating to requirements for pharmacy technicians, visitor policy, inventory, labeling, expiration dates on products, remediation of samples, and access for non-licensed personnel.

## Substance

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

The petitioner has requested the following amendments:

18VAC110-60-170: Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor

18VAC110-60-220(F,G): Visitors Policy: Remove the requirement that the Board must approve or waive all visitors. Also, allow younger minor children to accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues.

18VAC110-60-230(A)(1), (B): Inventory: Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct.

18VAC110-60-290: Product Label: Remove requirements for duplicative information between the product label and patient label.

18VAC110-60-290(B)(2)(e): Expiration Dates: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months

18VAC110-60-300(F): Remediation: Allow for remediation if a sample does not pass testing requirements.

18VAC110-60-310(A)(1): VCPRL: Allow non-licensed personnel to access the VCPRL to allow access to the processor.

18VAC110-60-310(C): Patient Labels: Remove requirements for duplicative information between the product label and patient label (same request as product label).

The Board has referred these specific requests for amendments to the Regulation Committee; that committee will review and recommend language for consideration at the proposed stage.

# Comments re: Notice of Intended Regulatory Action

## 18 VAC 110-60-300, Regulations Governing Pharmaceutical Processors Allowing for remediation if a sample does not pass testing requirements

Submitted by:
Jill Ellsworth, Founder & CEO
On behalf of Willow Industries

Thank you for the opportunity to comment on the Notice of Intended Regulatory Action regarding the remediation of medical cannabis. We appreciate the Virginia Board of Pharmacy considering this petition for rulemaking, as we believe that the testing and remediation of cannabis products are integral parts of any medical cannabis program.

Willow Industries works with cannabis cultivators and processors across the country, with a focus on decontaminating cannabis to remove harmful microbes. We support increasing pharmaceutical processors' ability to remediate cannabis, and have some specific recommendations for how to strengthen Virginia's testing and remediation program based on our experience in other states.

## Recommendation:

We have two major recommendations regarding the remediation of cannabis:

1. Establish definitions of "decontamination" and "remediation"
2. Allow the decontamination and remediation of cannabis for microbials, not just residual solvents

## Suggested language:

1. Oklahoma recently adopted separate definitions for "decontamination" and "remediation"[1] that would serve as a good model for Virginia to emulate.

> "Decontamination" means a process that attempts to remove or reduce to an acceptable level a contaminant exceeding an allowable threshold set forth in these Rules in a harvest batch or production batch.
>
> "Remediation" means the process by which the medical marijuana flower or trim, which has failed microbial testing, is processed into solvent-based medical marijuana concentrate and tested in accordance with these Rules.

[1] Oklahoma regulations

2. We suggest modifying the language on microbial testing in 18VAC110-60-300(F)(1), as follows:

> "For purposes of the microbiological test, a cannabis ~~oil~~ sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia. If a sample does not pass the microbial test, the batch can be decontaminated or remediated, after which the batch must be retested for microbiological contaminants."

## Reasoning:

Defining decontamination and remediation is important for giving operators clarity on regulatory intent. When states do not have definitions for these processes it can cause confusion, as when they are incorrectly used interchangeably, or when two parties use them to mean different things. Multiple states have recently added these definitions, or are currently in the process of doing so.[2]

"Decontamination" can be proactive (before testing) or reactive (due to failed testing), and can encompass a wide variety of techniques including ozone, radiation, radio frequency, or chemicals.

"Remediation" is always reactive (due to failed testing). Some states use it to mean any post-testing processing, while others define it specifically to mean processing into a concentrate. A clear definition will allow operators to easily understand regulators' intent.

As the governor recently signed legislation to allow botanical cannabis for patients in Virginia,[3] it is especially important that regulations allow operators to decontaminate cannabis. The end product of ozone and other techniques is botanical cannabis, not concentrates, so decontamination will allow operators to meet patient demand for new botanical products.

There are major economic benefits to decontamination and remediation, as destroying a batch can cost hundreds of thousands of dollars. Decontamination helps operators reduce waste, therefore reducing costs and passing on those savings to patients.

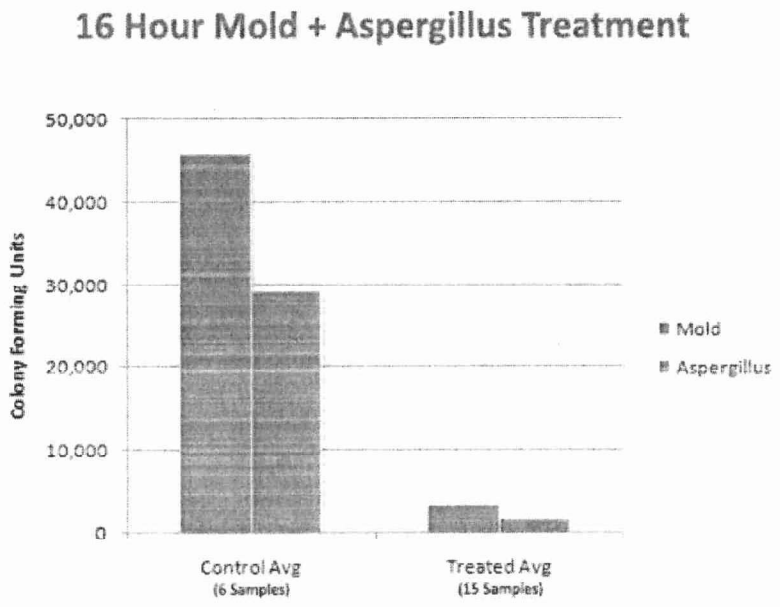
While current regulations allow remediation for residual solvents, decontamination and remediation have been shown to be effective at reducing the levels of a wide variety of contaminants, including microbials.

---

[2] Oklahoma added these definitions in late 2020, and Colorado is currently updating its definitions in a similar manner.

[3] SB 1333 and HB 2218 allow for botanical cannabis to be sold.

We have conducted multiple studies that demonstrate the effectiveness of ozone decontamination in reducing Aspergillus and Total Yeast and Mold to compliant levels, as shown in the graph below.[4]




We also have additional studies that demonstrate this treatment can effectively reduce microbial contamination without disrupting the medicinal properties of the plant.

## Conclusion:

Thank you again for your consideration of our suggestions. Please do not hesitate to contact us if you have any questions or would like additional information:

Submitted by,

Jill Ellsworth

Jill Ellsworth
Founder & CEO
Willow Industries
jill@willowindustries.com

[4] Partnering with Anresco Labs in California, we conducted a study to test the efficacy of WillowPure treatment on total yeast and mold counts, as well as Aspergillus. After 16 hours we were able to take total yeast and mold counts from an average of 45,900 CFU's to 1,388 CFU's, showing a 96.98% reduction. We also reduced Aspergillus counts from an average of 22,283 CFU's to 1,600, showing a 92.82% reduction.

## Draft Proposed changes to Pharmaceutical Processor Regulations

## Editorial changes:

**18VAC110-60-10. Definitions.**

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabis ~~oil~~ product is sold to a registered patient, parent, legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

"Perpetual inventory" means an ongoing system for recording quantities of cannabis ~~oil~~ product received, dispensed, or otherwise distributed by a cannabis dispensing facility.

**18VAC110-60-160. Grounds for action against a pharmaceutical processor permit or a cannabis dispensing facility.**

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

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

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

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

**18VAC110-60-230. Inventory requirements.**

D. The record of all cannabis products sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor or cannabis dispensing facility; the name and address of the registered patient, parent, legal guardian, or registered agent to whom the cannabis product was sold; the kind and quantity of cannabis product sold or disposed of; and the method of disposal.

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

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents~~, pesticide~~

~~chemical residue, and, for botanical cannabis, the water activity and moisture content~~; and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

5. For purposes of the active ingredient analysis, a sample of the cannabis oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

~~For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required.~~

*Note: For 300 B: "and, for botanical cannabis, the water activity and moisture content," has been included in 300 C*
*For 300 G 5 "For botanical cannabis products, only the total cannabidiol (CBD) and total tetrahydrocannabinol (THC) are required and has been included in 300 H 5.*

## Changes requested by the Va. Medical Cannabis Coalition in a petition for rulemaking and included in the Notice of Intended Regulatory Action

***Note: Some amendments have already been made as a result of legislation passed in the 2021 Session of the General Assembly. Those amendments became effective Sept. 1.***

### 1) 18VAC110-60-170: **Remove the two-year requirement for pharmacy technicians employed by a pharmaceutical processor – Already amended**

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

### 2) 18VAC110-60-220(F,G): **Visitors Policy: Remove the requirement that the Board must approve or waive all visitors. Also, allow younger minor children to**

**accompany their parent into the dispensing area and allow visitors to assist someone into the facility that might have mobility issues. - This was partially addressed in amendment to subsection F and in the adoption of Guidance document 110-40 that allows access to processors or facilities by contractors without board approval.**

18VAC110-60-220. Pharmaceutical processor or cannabis dispensing facility prohibitions.

A. No pharmaceutical processor shall:

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

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

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

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor or cannabis dispensing facility and shall return the visitor identification badge to an employee upon exiting the processor or facility.

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

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

3) 18VAC110-60-230(A)(1), (B): Inventory: **Remove requirement that a pharmacist or pharmacy technician must conduct inventory. Change to require a pharmacist or pharmacy technician to verify the inventory, not conduct. – Already amended**

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:
1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis ~~oil~~ products, at the facility. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area. The ~~inventory~~ inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, ~~or~~ pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. If a facility commences

business with no Cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory; and

4) 18VAC110-60-290: **Product Label: Remove requirements for duplicative information between the product label and patient label.** – **Not amended**

5) 18VAC110-60-290(B)(2)(e): **Expiration Dates: Set a specific expiration date range for products until stability testing is feasible. Specifically consider between 6 and 12 months –Already amended**

B. Cannabis ~~oil~~ products produced as a batch shall be:

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

2. Labeled with:

a. The name and address of the pharmaceutical processor;

b. The brand name of the cannabis ~~oil~~ product that was registered with the board pursuant to 18VAC110-20-285;

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

d. The date of testing and packaging;

e. The expiration date ~~based on~~, which shall be six months or less from the date of packaging, unless supported by stability testing;

6) 18VAC110-60-300(F): **Remediation: Allow for remediation if a sample does not pass testing requirements. Already amended**

~~F.~~ G. If a sample of cannabis oil product does not pass the microbiological, mycotoxin, heavy metal, ~~or~~ pesticide chemical residue, or residual solvent test based on the standards set forth in this subsection, the ~~pharmaceutical processor shall dispose of the entire batch from which the sample was taken~~ batch may be remediated with further processing. After further processing, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, and residual solvent, and an active ingredient analysis and terpenes profile shall be conducted.

7) 18VAC110-60-310(A)(1): VCPRL: **Allow non-licensed personnel to access the VCPRL to allow access to the processor. – Not amended; consider standard for agents who can access the PMP – see below**

**18VAC110-60-310 Dispensing of cannabis ~~oil~~ products**

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

1. Prior to the initial dispensing of cannabis ~~oil~~ products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the

registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis ~~oil~~ products to the registered patient.

**Statute for obtaining information prior to dispensing cannabis product**

§ 54.1-3408.3. Certification for use of cannabis oil for treatment

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

**Statutory standard for delegation of confidential information in the Prescription Monitoring Program**

§ 54.1-2523.2. (Effective until July 1, 2022) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to individuals who are employed or engaged at the same facility and under the direct supervision of the prescriber or dispenser and (i) are licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction or (ii) have routine access to confidential patient data and have signed a patient data confidentiality agreement.

§ 54.1-2523.2. (Effective July 1, 2022) Authority to access database.

Any prescriber or dispenser authorized to access the information in the possession of the Prescription Monitoring Program pursuant to this chapter may, pursuant to regulations promulgated by the Director to implement the provisions of this section, delegate such authority to health care professionals who are (i) licensed, registered, or certified by a health regulatory board under the Department of Health Professions or in another jurisdiction and (ii) employed at the same facility and under the direct supervision of the prescriber or dispenser.

8) 18VAC110-60-310(C): **Patient Labels: Remove requirements for duplicative information between the product label and patient label (same request as product label).** – **Not amended**

## Agenda Item: Withdrawal of regulatory actions in Chapter 60: Regulations Governing Pharmaceutical Processors

**Included in package:**

Summary of actions currently posted on Townhall and in the process of being promulgated

**Staff note:**

Subsection N of § 54.1-3442.6 was added in 2021 to authorize the adoption of regulations that are exempt from certain provisions of the Administrative Process Act provided the process of notification and public comment period are followed.

An exempt regulatory action was adopted by the Board in July, 2021. Included in that action were:

1) Amendments that were necessary to implement HB1988, HB2218 and SB1333; **and**

2) Amendments that were currently in effect as emergency regulations to include:

- Amendments that: 1) include in regulation provisions for cannabis dispensing facilities; 2) provide for patients who are temporary residents to register; 3) allow for access to cultivation areas of the processor when a pharmacist is not present; 4) set out standards for laboratories that provide testing to obtain a controlled substance registration; 5) allow for sale of devices and inert sample products; 5) provide for wholesale distribution between processors and dispensing facilities; and 6) modify other provisions as applicable to changes in the Code of Virginia pursuant to SB976 of the 2020 General Assembly.

- Amendments for 1) registration of agents for patients certified to receive cannabidiol or THC-A oil, so all sections that reference registered individuals are amended to include registered agents; and 2) wholesale distribution of oils between processors.

- Amendment to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate.

Therefore, those actions can be withdrawal since the amended language is now included in the regulation that became effective September 1, 2021.

**Board action**:

Motion to approve the withdrawal of three regulatory actions as listed in the agenda package

## 1) Action relating to changes to law in the 2020 General Assembly

| | | |
|---|---|---|
| 9100 | Emergency/NOIRA | Stage complete. This regulation became effective on 02/08/2021 and expires on 08/07/2022. |

**Chapter**

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

**Action:**

Amendments resulting from SB976 of the 2020 General Assembly

Amendments will: 1) include in regulation provisions for cannabis dispensing facilities; 2) provide for patients who are temporary residents to register; 3) allow for access to cultivation areas of the processor when a pharmacist is not present; 4) set out standards for laboratories that provide testing to obtain a controlled substance registration; 5) allow for sale of devices and inert sample products; 5) provide for wholesale distribution between processors and dispensing facilities; and 6) modify other provisions as applicable to changes in the Code of Virginia pursuant to SB976 of the 2020 General Assembly.

## 2) Action relating to wholesale distribution and registered agents

| | | |
|---|---|---|
| 8778 | Emergency/NOIRA | Stage complete. Emergency regulation was set to expire on 06/29/2021 and has been extended until 12/28/2021. |
| 8948 | Proposed | Stage complete. Comment period ended 04/30/2021. |

**Chapter**

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

**Action:**

Registered agents and wholesale distribution

SB1719 (2019) requires the adoption of emergency regulations regarding the registration of agents for patients certified to receive cannabidiol or THC-A oil, so all sections that reference registered individuals are amended to include registered agents. The bill also provides for wholesale distribution of oils between processors, so section 251 is added to establish the requirements for such distribution.

## 3) Action relating to vaping

**Chapter**

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

**Action:**

Prohibition of products for vaping or inhalation with vitamin E acetate

| | | |
|---|---|---|
| 8856 | Emergency/NOIRA | Stage complete. This regulation became effective on 08/06/2020 and expires on 02/05/2022. |
| 9166 | Proposed | Stage complete. Comment period ended 07/23/2021. |

Section 280 on cultivation and production of cannabidiol oil or THC-A oil is amended to prohibit the production of an oil intended to be vaporized or inhaled from containing vitamin E acetate.

**Agenda Item: Petition for rulemaking:**

**Included in your package are:**

Copy of petition from Courtney Fuller

Copy of Notice on Townhall

Copy of Comments on the petition

Copy of sections 460 and 490 of regulations for which amendments are requested

**Board action:**

**To deny the petition, or**

**To initiate rulemaking with publication of a NOIRA**

# 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. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.*

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

| | | |
|---|---|---|
| **Petitioner's full name (Last, First, Middle initial, Suffix,)**<br>Fuller, Courtney M | | |
| **Street Address**<br>200 Wadsworth Drive | **Area Code and Telephone Number**<br>804-267-5849 | |
| **City**<br>Richmond | **State**<br>VA | **Zip Code**<br>23236 |
| **Email Address (optional)**<br>Courtney.Fuller@HealthTrustPG.com | **Fax (optional)** | |

**Respond to the following questions:**

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

18 VAC 110-20-490(C) of the Regulations Governing the Practice of Pharmacy – requires the delivery record of drugs placed into an Automated Dispensing Device (ADD) in a hospital to include the initials of the pharmacist *at the hospital* that checked the drugs removed from the pharmacy and the delivery record for accuracy.

18 VAC 110-20-460(A) of the Regulations – requires a pharmacist to check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and to initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

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

VA Code § 54.1-3307.2 Approval of Innovative Programs – HealthTrust Supply Chain requests the review of the approved innovative pilot program which allows the distribution of *Schedule VI* drugs to certain hospitals to be placed in specific automated dispensing devices via Pharmacist Central Distribution. Pharmacist Central Distribution is a process by which a Virginia licensed pharmacist located at Central Shared Services, LLC, (central warehouse) verifies 100% of Schedule VI drugs to be placed in a ADD prior to delivery to the pharmacy department at the receiving hospital, and pharmacy technicians at the hospital load the drugs directly into the specific ADD without further verification by a pharmacist at the receiving hospital. The central warehouse shall maintain a record of all drugs distributed to each hospital to be placed in a specific ADD and shall include date, drug name, dosage form, strength, quantity, hospital name, hospital unit, and a unique identifier for the specific ADD receiving the drug, initials of the pharmacist verifying the drugs. The receiving hospital shall maintain a record of the initials of the person loading the drugs in to the ADD. An invoice shall be provided to the receiving hospital for the drugs delivered to be placed in the ADD. The central warehouse shall maintain records for a minimum of two years. The facility shall maintain at least a 90% bar code scanning rate for restocking the drugs into ADD. Barcode linking of the drug to the drug files in the hospital information system and ADD system shall be performed by the pharmacist at the central warehouse.

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.

VA Code §§ 2.2-4023 and 54.1-2400.2 as referenced in consent order for pharmacy distribution license 0216-000033.

Signature: Courtney Mueller Date: 5/5/2021

Virginia.gov Agencies | Governor


Secretariat Health and Human Resources

Agency Department of Health Professions

Board Board of Pharmacy

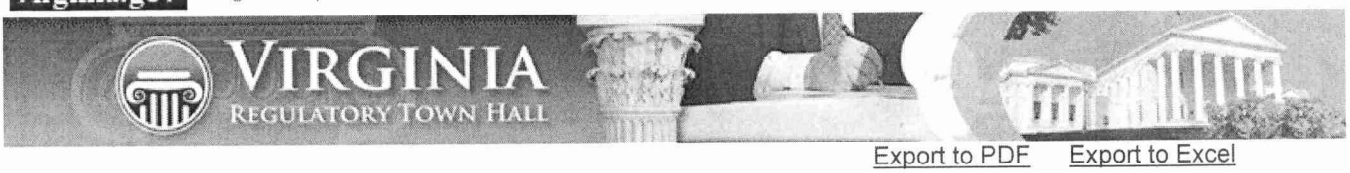
Edit Petition

Petition 344

| Petition Information | |
|---|---|
| **Petition Title** | Delivery of Schedule VI drugs to be placed in automated dispensing devices |
| **Date Filed** | 5/6/2021 [Transmittal Sheet] |
| **Petitioner** | Courtney Fuller |
| **Petitioner's Request** | To amend sections 460 and 490 to allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an ADD prior to delivery to the receiving hospital and pharmacy technicians at the hospital to load the drugs directly into the ADD without further verification by a pharmacist at the hospital. |
| **Agency's Plan** | In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on June 7, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until July 7, 2021.<br><br>Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its next meeting following the close of comment. |
| **Comment Period** | Ended 7/7/2021<br>40 comments |
| **Agency Decision** | Pending |

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

Virginia.gov Agencies | Governor




Export to PDF Export to Excel

Agency Department of Health Professions

Board Board of Pharmacy

Chapter

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

40 comments

**All good comments for this forum** Show Only Flagged

Back to List of Comments

**Commenter:** Jennifer Hill 6/10/21 2:48 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I would like to give my full support on the delivery of schedule VI drugs to be placed in automated dispensing devices. As a recipient of this process through the pilot program, I see the benefit that it provides to facilities for several reasons. As we are all experiencing unprecedented staffing shortages, having a standardized, reliable process for refilling of our ADDs that decreases the amount of time that is taken away from our facility staff is invaluable. Also, the environment that the medications are being refilled in to be delivered to the facilities is focused on this process which provides for a more focused and uninterrupted workflow which decreases errors in refilling. Lastly, the ability of the supplier (warehouse) to supply JIT and decrease the amount of medication that the facility needs to purchase and stock, and potential waste and expire, is fiscally responsible. The thought and structure that has been put into this pilot should be allowed to be considered standard practice if not best practice.

CommentID: 99086

**Commenter:** Celene Crowley, Chippenham Hospital 6/10/21 2:52 pm

**Delivery of Schedule VI Drugs to fill Pyxis**

Hello

This is a consistent and legal process and should be permitted per the regs. It allows for accuracy and duties of the hospital site to be higher level for patients. I strongly support the ability to deliver Schedule VI drugs to a facility to fill Pyxis.

Thank you Celene Crowley

CommentID: 99087

**Commenter:** Karen Dunavant, StoneSprings Hospital Center 6/11/21 7:40 am

**Delivery of Schedule VI Drugs to Automated Dispensing Devices**

I fully support the Delivery of Schedule VI drugs to automated dispensing devices amendments to section 460 and 490 of the current code. The pharmacists checking the drugs prior to delivery are thorough and safe. Benefits of this practice include but are not limited to:

- Pick process is segregated from the facility decreasing errors by improving workflow with dedicated staff and few interruptions
- The pharmacists checking the ADD orders have fewer distractions decreasing ADD filling errors
- The hospital pharmacists are able to direct their attention to direct patient care issues improving patient outcomes

This system of off-site pick and check has successfully helped and supported systems of all sizes. As such, the pilot has proved the concepts' worth and should be adopted by the state.

CommentID: 99091

**Commenter:** Denise Owczarski Henrico Doctors 6/11/21 8:22 am

**Delivery of Schedule VI drugs to Automated dispensing devices**

I would like to give my full support of the Delivery of Scheduled VI drugs to automated dispensing devices. I see the benefit of the pilot program as we get our medications from this service. It helps us with staffing so that we don't need to help pull these medications, if gives time back to our Pharmacists who are busy doing other things.

The program I feel has been successful in getting correct medications to our facilities for our staff to deliver.

CommentID: 99092

**Commenter:** Sharon Goad LewisGale Montgomery Hospital 6/11/21 8:40 am

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I would like to give my support to the Delivery of Schedule VI drugs to be placed in automated dispensing devices. Our pharmacy has benefited from this pilot program in several ways. It gives us back time when the techs do not have to pull meds everyday for the fills. As we are becoming more busy this is a huge time saver. It frees up our Pharmacists for patient care when they do not have to spend time checking medications that have been pulled.

This pilot program has worked well. Our shipments are on time and have always been correct. This program is a huge benefit for our pharmacy.

CommentID: 99093

**Commenter:** Anonymous 6/14/21 9:36 am

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

This is long overdue.

CommentID: 99097

6/14/21 9:51 am

**Commenter:** Tom Hinely Dominiopn Hospital

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

This will help hospitals be more efficient and improve work flow.

CommentID: 99098

**Commenter:** Tammie Lard Lewis Gale Hospital Montgomery 6/14/21 9:58 am

**Delivery of Schedule VI to be placed in Automated Dispensing Devices**

I fully support the Delivery of Schedule VI drugs to be placed in automated dispensing devices. Since being a part of the pilot program, I see the BIG benefits that it provides.

- Time - this is invaluable. It frees up pharmacist and pharmacy techs at the facility to focus on patient care
- Decreased errors- At a facility, there is more room for human error due to continuous activity when trying to pick and check for refills. At the warehouse, it is focused and they have a process in place JUST for picking and checking drugs to provide minimal error. They have one focus. At a hospital when picking and checking, there are MANY distractions.

The program has been very successful and it shows great teamwork and innovation to keep our patients safe and have the best care possible!

CommentID: 99099

**Commenter:** Joseph Metrick-Wheaton, HealthTrust Performance Group 6/14/21 10:29 am

**Forward Thinking: Direct Distribution to ADD Distribution Model**

HealthTrust and HCA's model to fill ADDs from a central location is a LEAN, just in time model. This model limits the number of touchpoints involved, reducing introductions for error.

Similar models have been previously utilized in VA through Cardinal Health. Cardinal's, CardinalAssist, a similar program where medications are received by the facility ready for a direct refill.

HealthTrust/ HCA's hub and spoke model is more efficient than the traditional workflows and allows Pharmacists on-site to work shoulder to shoulder with peers. HCA has been forward-thinking with this initiative and others. Moving Pharmacists one step closer to provider status.

CommentID: 99100

**Commenter:** Sarah Gaffney, Henrico Doctors' Hospital 6/14/21 11:16 am

**Support for CSC distribution fill for facilities**

I am writing to voice my strong and continued support of the CSC distribution and delivery for ADD machines. This process has multiple benefits including but not limited to: weathering of drug shortages due to size of scope, fiscal responsibility due to minimization of expired products or wasted products, time to facility technicians to focus on medication delivery and other patient centric activities, time for facility pharmacist to focus on clinical activities and patient centric activities, reduced errors with picking medications due to interruptions in the pharmacy. This

program is highly supporting the facilities and should be expanded to other healthcare systems. Please vote in support of this pilot.

CommentID: 99101

**Commenter:** April Cross 6/14/21 11:34 am

**Petition for Rulemaking**

I fully support the Delivery of Schedule VI drugs to automated dispensing devices amendments to Section 460 and 490 of the current code.

- Helps each facility to decrease amount of time needed for safe patient care
- It definitely helps with purchasing more than needed items for each facility which can create more expired product and waste
- Helps out short staff hospital pharmacies to have our supplier (warehouse) fill our automated devices in advanced and checked by a pharmacist which gives quicker patient care service at each facility

I feel that the offsite pick and delivery has been very successful therefore should be recognized by the state

CommentID: 99102

**Commenter:** Trey Akridge 6/14/21 11:56 am

**Centralized Distribution of CVI Drugs for Placement in ADCs**

I would like to publicly voice my support of centralized distribution of Schedule VI medications for facility ADCs. Consolidation of distributive pharmacy services into a hub and spoke model has benefited my current hospital significantly. We have been able to take advantage of break bulk packaging, resulting in significant decreases in on-hand inventories. Centralized fill of ADCs has freed additional pharmacist and technician time at the facility, thus allowing more time to focus on quality patient care. The model has also allowed us to leverage technology, such as bar coding, to improve patient safety. I encourage the Board to give a great deal of consideration to adding this process to the current regulations.

CommentID: 99103

**Commenter:** Danielle Williams 6/14/21 12:38 pm

**Delivery of Schedule VI to be placed in Automation Dispensing Devices**

I would like to voice my support in the amendment to permit the delivery of Schedule VI medications pulled from a central location. This process has many benefits that includes but not limited to:

1. Provides an environment with minimal distractions for medications to be picked/checked for fill in an ADD. This helps with patient safety within hospitals.
2. Permits medication purchases to be streamlined to a location which can then distribute them as needed in a just in time manner which reduces overall pharmacy overhead and reduces waste/expired medications.
3. Getting through critical or long term shortages can be centrally managed by one group opposed to multiple (at each facility). This helps minimize hoarding at each facility which

in turn helps contribute to improve all's ability to get through shortage situations and have necessary drugs for patient care.

4. Improves pharmacy workflow as it eliminates hours from Pharmacy Technician's day, that is historically spent picking medications, as well as from Pharmacist's day that is historically spent checking these medications for refill. This allows that time to be spent focused on more clinical, medication delivery and nursing support tasks.

CommentID: 99105

**Commenter:** Jennifer Bendura Henrico Doctors Hospital 6/14/21 12:40 pm

**Delivery of Schedule VI to be placed in Automated Dispensing Devices**

I would like to give my full support of the Delivery of Scheduled VI drugs to automated dispensing machines. I see the benefit of the pilot program as we get our medications from this service. It helps us with staffing so that we do not need help pulling majority of the medications for these machines. It allows our Pharmacist time back so that they do not have to take time to check the fills that come from Delivery allowing them more time to work on getting other medications and IV's to the patients.

The program has been very successful in getting correct medications in a timely manner to our facilities for our staff to deliver to the devices.

CommentID: 99107

**Commenter:** Gill Abernathy 6/14/21 12:52 pm

**Support Petition 344**

This is to support the practice of pharmacist check of automated dispensing dispense fills at the centralized services center where the fill is done (as opposed to by pharmacist at the receiving hospital). It's logical to do the check where the fill is done, keeping oversight and responsibility directly connected to the work done. The receiving hospitals are attesting to the success of the pilot and their great desire to make it permanent. The Board setting the required safety standards while giving the impacted health system flexibility to best determine where the work is done, also makes sense.

Gill B. Abernathy, MS, RPh.

CommentID: 99108

**Commenter:** Frank Shen, Reston Hospital Center 6/15/21 9:43 am

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

Reston Hospital Center has greatly benefitted from this practice. Out pharmacists have been able to focus on clinical interventions and patient care rather than spending time checking medications to be loaded or refilled to the ADMs. Whether done in house or from a central location, picks are checked by authorized team members. For a hospital of our size, it also saves technician time to allow faster delivery of first doses as the technicians are not burdened by the routine refilling of the "fast mover" medications. I strongly support this practice.

CommentID: 99111

**Commenter:** Jerry Martin, Spotsylvania Regional Medical Center 6/15/21 11:45 am

**Petition 344**

I am in full support of the process of Pharmacist verification of non-narcotic (schedule VI) medications prior to dispensing from a central warehouse location, versus requiring a pharmacist to verify upon arrival on site, given that the verifying pharmacist is the terminal person to verify the medication(s) prior to application of tamper-proof seals and where final destination being placed in ADDs (i.e. Pyxis, AcuDose, Omnicel) via scanning/bar-code technology us being utilized by registered pharmacy technicians.

CommentID: 99113

**Commenter:** Rungaroon Sihavong, StoneSprings Hospital Center 6/16/21 12:20 pm

**Delivery of Schedule VI drugs to automated dispensing devices**

I strongly support this practice because it allows the on site Pharmacists to focus on patient care and clinical interventions instead of checking meds. Whether the checking is done on site or from central location, the medications are being checked by licensed Pharmacists.

CommentID: 99161

**Commenter:** Anonymous 6/17/21 9:32 am

**A comment in support of conituning this**

It is very time efficient to have the orders already checked and delivered instead of having to get the staff pharmacist to check everything

CommentID: 99182

**Commenter:** Emily Chambers 6/17/21 12:05 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I support the centralized distribution of Schedule VI medications for facility ADCs. As a practicing pharmacist in Virginia, I see many benefits to this delivery model. It advances the practice of pharmacy and streamlines distribution. I fully support this addition to VA Regs.

CommentID: 99195

**Commenter:** Bradley Jobe - Henrico Doctors' Hospital 6/17/21 8:05 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I fully support the petition for Delivery of Schedule VI drugs to be placed in automated dispensing devices. It saves Pharmacists and Pharmacy Technicians valuable time and resources that are needed to provide the best patient care we can.

CommentID: 99207

**Commenter:** David Bailey 6/17/21 8:29 pm

**Deliver of Schedule VI drugs to be placed in automated dispensing devices**

I work in a setting that utilizes this process. It is efficient from an economic standpoint as well as a work-flow standpoint. It frees up valuable time for the pharmacists and technicians to concentrate their efforts on patient care, as well as decreasing distractions.

CommentID: 99208

**Commenter:** Rebecca Gonzalez-Goad 6/18/21 8:31 am

**Delivery of Schedule VI drugs to be placed in automated dispensing device**

I support the delivery of schedule VI drugs to be placed in the automated dispensing devices. This saves valuable time and resources for our facility.

CommentID: 99210

**Commenter:** Christina (Whitehill) Fox - Henrico Doctors' Hospital 6/18/21 4:32 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I support the centralized distribution of Schedule VI medications for refill of facility ADCs. This expansion streamlines distribution to allow facility pharmacist efforts to be redirected to providing lifesaving medications and other important patient care activities. ADC's have barcode scanning and thus once checked by a pharmacist at distribution, I believe it is appropriate to be sent directly to the ACD, a second pharmacist is a redundancy. We should take every opportunity to stream line medication delivery. I support 18 VAC 110-20, Delivery of Schedule VI medications to be placed in ACD.

CommentID: 99213

**Commenter:** Melissa Moore HCA 6/22/21 3:54 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I give my full support of centralized distribution of Schedule VI medications to be placed in ACDs, 18 VAC 110-20. This affords our pharmacists and technicians at the facilities time to provide the very best patient care. This process overall makes for a safer process for medication filling, checking and drug shortage management as well.

CommentID: 99233

**Commenter:** Judy Houston 6/23/21 5:26 am

**Delivery of Schedule VI Drugs to be Placed in Automated Dispensing Devices**

As one of the pharmacists that will be performing this new task, I believe this will afford us the ability to decrease the time that a medication is out of stock. This will allow a cost savings to the hospitals, whereas they will be able to receive items from the warehouse instead of from a third party.

CommentID: 99239

**Commenter:** Natalie Nguyen, Virginia Society of Health-System Pharmacists 6/23/21 10:38 am

**Support Petition for Delivery of Schedule VI drugs to be Placed in Automated Dispensing Devices**

We support the centralized distribution model that permits delivery of medications by pharmacy technicians at the receiving hospital. Checks and balances regarding medication safety are still maintained within the medication use system by leveraging the additional technology such as bar coding within the ADCs by pharmacy team members and nursing to ensure patient safety.

CommentID: 99242

**Commenter:** Mary Kay Burnett 6/24/21 3:08 pm

**Delivery of schedule VI drugs to be placed in ADD**

I support the centralized distribution of schedule VI medications for refill of facility Automatic Dispensing devices. This process streamlines distribution to allow facility pharmacists to be available for checking and evaluating new orders with the precious time needed to ensure the orders are correct. The centralized orders are checked at a central location by a pharmacist and are transported to facilities clearly labeled for each individual machine. The only additional step is that the meds are then transported to the various hospitals for final delivery into the machines. This is really no different than having meds checked on site and then taken to machines. In a really big institution, the time it takes for these checked meds to get to the ADD may be just as long as the short car ride they take from a central warehouse. The barcode scanning ensures safety all the way through the process. Thank you for your consideration of this request

CommentID: 99252

**Commenter:** Caroline Duvall 6/24/21 3:13 pm

**Support Delivery of Schedule VI Medications to Automatic Dispensing Device**

I support this petition to have centralized delivery of schedule VI medications to an automatic dispensing device at a facility. This process saves valuable time at a facility by freeing up technicians and pharmacists to concentrate on maximizing patient care.

CommentID: 99253

**Commenter:** Jeffery Edwards LewisGale Hospital Pulaski 6/24/21 3:45 pm

**Delivery of Schedule VI to be placed in Automated Dispensing Devices**

I would like to voice my support of the centralized distribution of Schedule VI medications for facility automated dispensing machines. This process has benefited my current facility in many ways. The biggest benefit it has provided is to increase patient care at the facility. The process provides additional time for both the pharmacists and pharmacy technicians to provide direct patient care instead of spending that time to pull and verify medications. I personally feel like it decreases errors associated with pulling medications at the facility. The sole job of the people at the distribution warehouse is to pull the medications whereas we at the facility level can be distracted by phone calls and other distractions. This program is a huge benefit to our pharmacy, our hospital and our patients and I believe other healthcare organizations should have the opportunity to see the benefit it provides.

CommentID: 99255

**Commenter:** Megan Bennett 6/24/21 3:56 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I support the petitioner's request to amend regulations concerning delivery of schedule VI drugs to be placed in hospital ADDs having been verified by a pharmacist at a central distribution company. A centralized pharmacist verifying orders can operate in a more streamlined environment with less distractions as compared to an on-site pharmacist. A centralized pharmacist also scans and links product barcodes to appropriate entries within hospital information systems. This results in less errors, improved patient safety, and allows more time for on-site staff to focus on clinical and interdisciplinary tasks. Centrally managed inventory assists sites with shortage and out of stock issues, as well as a reduction in wasted and expired meds, helping with cost savings and reducing potential delays in therapy for patients.

CommentID: 99256

**Commenter:** Linda Evans, HDH - Forest 6/25/21 2:28 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I fully support this effort, it will help to streamline the workload, reduce duplicated orders and so make the entire pharmacy run more efficiently.

CommentID: 99262

**Commenter:** Randy Duvall 6/26/21 10:37 am

**Petition 344**

I fully support petition 344 of a centralized pharmacy distribution center of schedule VI medications. A centralized system is more efficient, productive, safe and cost effective.

CommentID: 99265

**Commenter:** Anonymous 6/28/21 4:57 pm

**Petition 344**

I write to offer comment in support of petition 344 regarding central distribution and pharmacist verification of schedule VI drugs being delivered directly to receiving hospital automated dispensing devices. Hospitals are continually forced to find more efficient, yet clinically sound, methods for providing care to patients. It is an ongoing battle to optimize great patient care with reliable operations, both competing for time, manpower and other resources. Distributing medications using a just-in-time model of distribution has allowed facilities to dramatically improve their economic performance by reducing inventory stored on the shelf at any given time, increase inventory turnover to keep fresh stock, and virtually eliminate waste through expiry. Additionally, centralization has allowed for focused checking of the drug supply by dedicated distribution pharmacists, thereby allowing facility pharmacists to focus on the bedside patient care and support of the multidisciplinary care team. This is the way of the future, supporting pharmacists to work a the top of their license and allowing the dedicated distributive staff to focus on their main objective to deliver cost efficient and accurate drug supply.

CommentID: 99278

**Commenter:** Jason Hoffman - Carilion 6/29/21 12:21 pm

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I fully support this petition concerning the delivery of schedule VI medications to an automated dispensing machine. This would free up significant time to allow for additional focus on patient care within the facility while still maintaining patient safety as a top priority.

CommentID: 99290

**Commenter:** Ahmed El Kority 6/29/21 12:32 pm

**Pharmacy central processing**

This process is very effective in improving efficiency and allowing more pharmacist time dedicated towards direct patient care.

CommentID: 99291

**Commenter:** Chad Alvarez-Carilion Clinic 6/29/21 1:49 pm

**: Delivery of Schedule VI drugs to be placed in automated dispensing devices**

I support the petition of delivery of Schedule VI drugs to be placed in automated dispensing devices. Significant safety advantages are in place today along with an initial pharmacist check at the central distribution site that make an additional check unnecessary. The elimination of a redundant second check will allow the Pharmacist time to be re-focused on direct patient care activities that provide positive patient outcomes.

CommentID: 99296

**Commenter:** Katherine Olson 6/29/21 1:57 pm

**Delivery of Schedule VI Drugs to be Placed in Automated Dispensing Devices**

As someone who has worked both in the pharmacies receiving this service and in the facility providing it, I would like to offer my support of this pilot program. The hospital pharmacy staff gains much needed time from this service that can be directed towards patient care. The facility providing this service has the advantage of minimal interruptions when pulling drugs for the ADD's.

CommentID: 99297

**Commenter:** Derrick Botkins 7/2/21 1:34 pm

**Centralized Distribution of CVI Drugs for Placement in ADCs**

I would like to take a moment to voice my support of the centralized distribution of Schedule VI medications for facility automated dispensing machines (ADC). This program has benefited the facility by removing the task of pulling and verifying medications locally and sourcing it to individuals that can solely focus on this task. What this means for the patients is locally more time and attention to pharmaceutical patient care. In addition to having more time for patient care, I believe the final delivery using this process to be more accurate as the individuals pulling and verifying can focus on a single task vs. the distractions that working in a facility presents.

CommentID: 99341

**Commenter:** Trina Epperly 7/6/21 10:16 am

**Delivery of Schedule VI drugs to be placed in automated dispensing devices**

We support delivery of Schedule VI drugs to automated dispensing devices from Central Distribution areas. In our practice, a medication from the Central Distribution department is barcode scanned six times before it reaches a patient. These six scans include: medication barcode validation in EPIC, scan into drug storage carousel by technician, out of carousel by technician, medication accuracy scan by pharmacist, scan by hospital technician loading to automated cabinet and scan at bedside by nurse. We are also researching the possibility of a future tech-check-tech model for this area due to significant amount of barcode scans. Advances in technology and the extensive barcode scanning protocols in place help to significantly reduce errors and allow for increased efficiencies across our system.

CommentID: 99344

# 18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI 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. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

Statutory Authority

§ 54.1-2400 and Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 10.4, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21,

eff. August 9, 1995; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009.

# 18VAC110-20-490. Automated devices for dispensing and administration of drugs.

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated dispensing device shall have a specific access code that records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device. The delivery record shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for ensuring reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue or maintained electronically.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or

resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures that are consistent with § 54.1-3434.02 A of the Drug Control Act for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drug recorded as removed from the pharmacy was diverted rather than placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software that provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity, which includes usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs, and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

1. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

2. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

3. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

4. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedules II through V distribution and delivery records may also be stored off site or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Statutory Authority

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 10.7, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 14, Issue 8, eff. February 4, 1998; Volume 15, Issue 21, eff. August 4, 1999; Volume 20, Issue 23, eff. August 25, 2004; Volume 25, Issue 24, eff. September 2, 2009; Volume 27, Issue 11, eff. March 17, 2011; Volume 30, Issue 10, eff. February 12, 2014; Volume 36, Issue 6, eff. December 11, 2019.

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

**Repealing part of Section 322 - Scheduling Chemicals in Schedule I -**

**Included in agenda package:**

Amendments to regulation: 18VAC110-20-322

**Staff Note:**

All of the chemicals scheduled by Board action listed in subsections A through C have now been scheduled in the Drug Control Act, so they can now be removed in regulations.

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

**Board action:**

Adoption of final regulation in section 322

## Board Of Pharmacy

## Deletion of chemicals now scheduled in Code

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

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

~~1. Synthetic opioids.~~

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

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

~~2. Research chemicals.~~

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

~~b. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), its optical, position, and geometric isomers, salts, and salts of isomers~~

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

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

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

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

3. Cannabimimetic agents.

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

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

~~The placement of drugs listed in this subsection shall remain in effect until June 10, 2021, unless enacted into law in the Drug Control Act.~~

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

~~1. Synthetic opioids.~~

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

~~b. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), 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. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-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.~~

~~b. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-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.~~

~~c. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone), 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. 1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone), 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. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), 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. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB-2201), 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-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

d. 1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until February 4, 2022, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids.

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

b. N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene), 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. (2-ethylaminopropyl)benzofuran (other name: EAPB), 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. 2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence

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

~~c. 4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH), 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. 4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT), 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. N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~f. 1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD), 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.~~

~~g. 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA), 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. Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo] 3,3-dimethylbutanoate (other name: MDMB-4en-PINACA), 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. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-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.~~

~~c. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA), 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.~~

~~d. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names: MMB-FUBICA, AMB-FUBICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until May 24, 2022, unless enacted into law in the Drug Control Act.~~

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

1. Synthetic opioid. N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene), 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. Compounds expected to have hallucinogenic properties.

a. 4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

c. N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

d. 4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

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

f. 3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers (optical, position, and geometric), and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties.

a. Bromazolam, 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. Deschloroetizolam, 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.

c. 7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA), 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. Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 27, 2022, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids.

a. 1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

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

c. 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

d. N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene), 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. Depressant.

5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam), 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.

3. Cannabimimetic agent.

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

The placement of drugs listed in this subsection shall remain in effect until December 23, 2022, unless enacted into law in the Drug Control Act.

**Agenda Item: Amendments to Guidance documents**

***Staff Note:***

Guidance documents 110-1, 110-5, 110-9, 110-30, 110-31 and 110-44 need to be revised

Guidance document 110-50 can be repealed/deleted

***Board action:***

To revise the guidance documents as presented in the agenda package and to delete guidance document 110-50

Revised: September 24, 2021
Effective: November 25, 2021

# VIRGINIA BOARD OF PHARMACY

## CATEGORIES OF FACILITY LICENSURE

**PHARMACY:** This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. Federal law allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

**NONRESIDENT PHARMACY:** This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

**MEDICAL EQUIPMENT SUPPLIER:** This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

**NONRESIDENT MEDICAL EQUIPMENT SUPPLIER:** This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

**WHOLESALE DISTRIBUTOR:** This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**NONRESIDENT WHOLESALE DISTRIBUTOR:** This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors. This registration does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**WAREHOUSER:** This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements. This permit may be preferable to the wholesale distributor license for those entities which distribute prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**NONRESIDENT WAREHOUSER:** This registration is for those entities located outside of the Commonwealth which distribute prescription drugs and/or prescription devices, but are exempted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only distribution of drug samples, or only distribution of medical gases. This registration is also for those entities which only distribute prescription devices and no prescription drugs. This registration does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**NON-RESTRICTED MANUFACTURER:** This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**RESTRICTED MANUFACTURER:** This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use. This permit does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**NONRESIDENT MANUFACTURER:**
This registration authorizes any manufacturer located outside the Commonwealth to ship prescription drugs into the Commonwealth. This registration does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**CONTROLLED SUBSTANCES REGISTRATION (CSR):** This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouser, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration to

dispense injectable naloxone and syringes without charge or compensation. An entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedule II through VI controlled substances may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

**OUTSOURCING FACILITY:** This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite, the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

**NONRESIDENT OUTSOURCING FACILITY:** This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

**PRACTITIONER OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCE FACILITY PERMIT:** This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

**LIMITED USE PRACTITIONER DISPENSING PERMIT:** This permit authorizes a nurse practitioner or a physician assistant who is licensed by the Board of Pharmacy and practicing in a nonprofit facility, to dispense Schedule VI controlled substances (excluding the combination of misoprostol and methotrexate) and hypodermic syringes and needles for the administration of prescribed controlled substances. The nurse practitioner or physician assistant must also obtain a Limited Use Practitioner Dispensing License.

**THIRD-PARTY LOGISTICS PROVIDER:**
This permit authorizes the permit holder, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device. This permit does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

**NONRESIDENT THIRD-PARTY LOGISTICS PROVIDER:** This registration authorizes a facility outside of the Commonwealth, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, warehouse or dispenser of the drug or device. This registration does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

* § 54.1-3455. Schedule VI.
**The following classes of drugs and devices shall be controlled by Schedule VI:**

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.
2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

**DRAFT**

# Virginia Board of Pharmacy
# Theft or Loss of Drugs

Virginia law requires the reporting of any theft or unusual loss of any Schedule I – V controlled substances to the Board of Pharmacy, as follows:

***from Code of Virginia, Drug Control Act***
***§54.1-3404***

...

*E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within thirty days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.*

...

## *Board guidance on reporting theft or unusual loss*

The Drug Control Act in §54.1-3404 requires a registrant or licensee who discovers a theft or any other unusual loss of a drug in Schedules II, III, IV, or V to immediately report the theft or loss to the Board. Similarly, Title 21 Code of Federal Regulations (CFR) §1301.74 states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." In addition to the notification requirement, a registrant or licensee must furnish the Board with a listing of the kind, quantity, and strength of such drugs lost within 30 days after the discovery of the loss. Submission of a copy of Drug Enforcement Administration (DEA) Form 106 is acceptable for complying with the Board's reporting requirement.

While it is clear that a "theft" of any quantity of drug in Schedules II-V must be reported to the Board and DEA, there is occasionally confusion regarding the reporting requirements for a loss when it is unclear whether the loss constitutes an "unusual" or "significant" loss. While the terms "unusual loss" as used in the Drug Control Act and "significant loss" as used in the federal regulation are not defined in state or federal rules, DEA does offer guidance in rule and the *Pharmacist's Manual* for determining if a loss constitutes a "significant loss." It is suggested that pharmacists and pharmacy technicians follow DEA's guidance for satisfying the state and federal reporting requirements for both unusual and significant drug losses. To determine whether a loss is "significant," Title 21 CFR §1301.74 states:

> . . . a registrant should consider, among others, the following factors:
> 1. The actual quantity of controlled substances lost in relation to the type of business;
> 2. The specific controlled substances lost;
> 3. Whether the loss of the controlled substances can be associated with access to those controlled
> substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;

4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
5. Whether the specific controlled substances are likely candidates for diversion;
6. Local trends and other indicators of the diversion potential of the missing controlled substance.

Furthermore, DEA's 2010 edition of the *Pharmacist's Manual* states:

> Although the [Controlled Substances Act] regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer. Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

In accordance with §54.1-3404 of the Drug Control Act, if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he or she shall immediately make a complete inventory of all Schedule II-V drugs. Also, if after the initial notification of a theft or loss to the Board or DEA the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, then a complete listing and the DEA Form 106 is not required to be filed. However, the licensee or registrant should notify the Board and DEA in writing of this fact in order to resolve the initial report.

If it is determined that a loss occurred, but it is not significant, DEA indicates in the *Pharmacist's Manual* that " . . . the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion." Lastly, as indicated in the *Pharmacist's Manual* and supported by the Board, if there is a question as to whether a theft has occurred or a loss is significant, a licensee or registrant should err on the side of caution and report it to DEA and the Board.

## *Procedure for reporting a theft or loss*

Please use DEA 106 form for the complete reporting of theft or loss of drugs. The form may be found on DEA's website as follows:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

If, after a breaking or suspected loss of drugs, it is determined that no drugs were taken, the above form does not need to be completed.

Distribute copies and keep a copy as follows:

1 Copy: Virginia Board of Pharmacy
Fax: 804-527-4472
Email: pharmbd@dhp.virginia.gov

~~9960 Mayland Drive, Suite 300~~
~~Richmond, VA 23233~~
~~804/367-4456~~

~~2 Copies~~
1 Copy: Drug Enforcement Administration
Submit either via electronic submission or mail to local DEA office. If submitting electronically, be sure to print a copy for your records and to send to the Board.
~~Techworld Plaza~~
~~ATTN: Drug Diversion~~
~~800 K Street, N.W., Suite 500~~
~~Washington, DC 20001~~
~~202/305-8888~~
**The DEA Form 106 can be completed via Theft/Loss Reporting Online (TLR) [apps2.deadiversion.usdoj.gov] or download the fillable PDF [deadiversion.usdoj.gov] version and submit to your Local Diversion Field Office [apps2.deadiversion.usdoj.gov].**

1 Copy: To be maintained at location of drug stock for your records

~~*You may submit your DEA form via the online submission process on DEA's website. You will need to print a copy for your records and the Board of Pharmacy~~

# Virginia Board of Pharmacy
# Pharmacy Inspection Deficiency Monetary Penalty Guide

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location | 54.1-3434 and 18VAC110-20-110 | must have documentation | 2000 |
| 2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe | 54.1-3434 and 18VAC110-20-110 | | 1000 |
| 3. Unregistered persons performing duties restricted to pharmacy technician without first becoming registered as a pharmacy technician trainee | 54.1-3321 and 18VAC110-20-111 | per individual | First documented occurrence = no penalty<br>Repeat = $ penalty<br>250 |
| 4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration | 18VAC110-21-60, 18VAC110-21-110, and 18VAC110-21-170 | per individual | First documented occurrence = no penalty<br>Repeat = $ penalty<br>100 |
| 5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists | 54.1-3320 18VAC110-20-112 | | 500 |

## Other Deficiencies

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

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 101. Repealed 6/2011 | | |
| 102. Special/limited-use scope being exceeded without approval | 18VAC110-20-120 | |
| 103. Repealed 12/2013 | | |
| 104. Sink with hot and cold running water not available within the prescription department. | 18VAC110-20-150 | |
| 105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit. Temperature not being recorded daily or record of such not maintained properly. | 18VAC110-20-150 and 18VAC110-20-10 | determined using inspector's calibrated thermometer |
| 106. Prescription department substantially not clean and sanitary and in good repair | 18VAC110-20-160 | must have picture documentation |
| 107. Current dispensing reference not maintained | 18VAC110-20-170 | |
| 108. Emergency access alarm code/key not maintained in compliance | 18VAC110-20-190 | |
| 109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs | 54.1-3457<br>18VAC110-20-200 | 10% threshold |

# Virginia Board of Pharmacy

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

The Board of Pharmacy provides the following guidance regarding drugs maintained and administered within an animal shelter or pound.

1. Pursuant to §54.1-3423 E, an animal shelter or pound may obtain a controlled substances registration (CSR) certificate from the Board of Pharmacy for purchasing, possessing, and administering drugs for two purposes: euthanasia of injured, sick, homeless and unwanted domestic pets and animals; and prevention, control, and treatment of certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. These drugs shall only be stored and administered at the address of the humane society or shelter and shall not be taken off-site for administration. Additionally, the training requirements for persons to administer drugs for these two purposes differ and are highlighted below.

2. Pursuant to the Virginia Department of Wildlife Resources Director Policy to Capture, Possess, Transport, Release, or Humanely Dispatch Wildlife by Animal Control Officers and Local Animal Shelters in Accordance with 4VAC15-30-50, an animal shelter or pound may obtain a CSR or amend its existing CSR from the Board of Pharmacy for purchasing, possessing, and administering drugs to chemically immobilize wildlife for the purpose performing humane dispatch in a manner that prioritizes public safety and animal welfare. Such drugs must be administered by trained animal control officers or trained animal shelter staff at the address of the animal shelter in accordance with the Policy of the Director of the Department of Wildlife Resources (DWR).

~~Lastly, this guidance document does not apply to the purchase, possession, or administration of drugs for the purpose of chemical capture of animals in accordance with the State Veterinarian's directive concerning such.~~

## Drugs for Euthanasia

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

**Training for administering drugs for euthanasia**

The training for persons administering drugs to domestic animals in accordance with protocols established by the State Veterinarian for euthanasia shall be approved by the State Veterinarian. A current certification of competency signed by the supervising veterinarian for the facility shall be maintained at the facility for each person administering drugs and must be retained for not less than two years after the person ceases administering. To access the most recent State Veterinarian's directive on Methods Prescribed or Approved for Animal Euthanasia and Competency Certification Requirements (Directive 79-1) click on: http://www.vdacs.virginia.gov/pdf/euthansiadirective.pdf

The training for persons administering drugs to wildlife shall be in accordance with the DWR Director Policy.

## Drugs for Communicable Disease Prevention, Control and Treatment

Only certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound may be purchased, possessed, or administered unless prescribed to a specific domestic animal by a licensed veterinarian. These drugs shall not be used for the treatment of a non-transmissible malady or condition such as an injury; controlled substances required for the treatment of such conditions must be prescribed to a specific animal by a licensed veterinarian. The drugs shall also not be used for administration to wildlife.

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

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

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

**Training for administering certain Schedule VI for communicable diseases**

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

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

## Controlled Substances Registration Certificate

The application for a controlled substances registration certificate for an animal shelter or pound handling only domestic animals requires the designation and signature of a responsible party and supervising practitioner.

- **Responsible party**

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

- **Supervising practitioner**

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

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

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

Animal pounds or shelters intending to handle both domestic animals and wildlife shall adhere to the information for how to obtain a controlled substances registration as indicated in the DWR Director Policy.

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

***from the Code of Virginia***

**§54.1-3423**

*E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II through VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals and to purchase, possess, and administer certain Schedule VI drugs and biological products for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. Controlled substances used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs and biological products used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs and biological products shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs and biological products, written protocols for administering, and training records of those persons administering drugs and biological products on the premises of the shelter.*

***from Regulations Governing the Practice of Pharmacy***

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

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

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

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

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

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

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

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

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

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

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

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

*B. Persons or entities that may be registered by the board shall include hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.*

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

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

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

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

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

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

*D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.*

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

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

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

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

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

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

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

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

*3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.*

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

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

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

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

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

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

*C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation; or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.*

*D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.*

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

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

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

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

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

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

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

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

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

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

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

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

*6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.*

**18VAC110-20-720. Requirements for recordkeeping.**

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

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

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

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

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

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

DRAFT

## Virginia Board of Pharmacy

## Guidance on

# APPROVED CAPTURE DRUGS AND DRUG ADMINISTERING EQUIPMENT

Animal control officers and other officials as defined in §3.1-796.66 of the Comprehensive Animal laws may possess drugs and drug administering equipment which are approved by the State Veterinarian for use in the capture of companion animals. Such drugs and drug administering equipment may also be possessed by trained animal control officers or trained animal shelter staff at the address of the animal shelter for chemically immobilizing wildlife for the purpose performing humane dispatch in a manner that prioritizes public safety and animal welfare. Click below to access the most recent State Veterinarian's directive for Approved Capture Drugs and Drug Administering Equipment.

http://www.vdacs.virginia.gov/animals-animal-care.shtml

# Virginia Board of Pharmacy

## Naloxone Protocols

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

***§54.1-3408***

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

*Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal other than naloxone in an injectable formulation with a hypodermic needle or syringe in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.*

*Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and*

*administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.*

*For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.*

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

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

a. **Authorized Dispensers**

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

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

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- School nurses,

- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services,
- Firefighters, and
- Employees or other persons acting on behalf of a "public place" which means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest

**b. Required Training**

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

**c. Required Order**

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.

ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:

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

| Intranasal | Auto-Injector | Intranasal | Intranasal |
|---|---|---|---|
| Naloxone 2mg/2ml prefilled syringe, # 2 syringes<br><br>Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br><br>Mucosal Atomization Device (MAD) # 2 | Naloxone 2 mg #1 twin pack<br><br>Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. | ~~Narcan~~ Naloxone Nasal Spray 4mg, #1 twin pack<br><br>Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. | Naloxone nasal spray 8mg, #1 twin pack<br><br>Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. |

| | | | |
|---|---|---|---|
| SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration. | | | |

d. **Required Labeling and Recordkeeping**

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

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

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

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

e. **Required Instruction**

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

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

a. **Authorized Dispensers**

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

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

**b. Training**

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

**c. Required Order**

i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:

1. Name of organization authorized to dispense naloxone pursuant to standing order;
2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
4. Prescriber's signature;
5. Date of issuance; and
6. Amount of time, up to two years from date of issuance, for which the order is valid.

| Intranasal | Auto-Injector | Intranasal | Injection* | Intranasal |
|---|---|---|---|---|
| Naloxone 2mg/2ml prefilled syringe, # 2 syringes<br><br>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br>Mucosal Atomization Device (MAD) # 2<br>SIG: Use as directed for naloxone administration.<br>Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration. | Naloxone 2 mg #1 twin pack<br><br>SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. | ~~Narcan~~ Naloxone Nasal Spray 4mg, #1 twin pack<br><br>SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. | Naloxone 0.4mg/ml #2 single-use 1ml vials<br><br>SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response.<br><br>#2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles<br>SIG: Use as directed for naloxone administration.<br>Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration. | Naloxone nasal spray 8mg, #1 twin pack<br><br>SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. |

**d. Registration**

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

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

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

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

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

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

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

f. **Required Instruction**

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

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

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

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

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

ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or

iii. Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person

dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

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

## IV. Resources

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

Repealed: September 24, 2021
Effective: November 25, 2021

# VIRGINIA BOARD OF PHARMACY

## Use of Telemedicine by Registered Practitioners of Cannabis Oil

The following guidance is provided to assist registered practitioners of cannabis oil in complying with requirements when employing the use of telemedicine, consistent with federal requirements for the prescribing of Schedule II through V controlled substances:

- The registered practitioner of cannabis oil should maintain a DEA registration as a practitioner, unless exempted under federal requirements;
- The patient being examined or treated via telemedicine should be in the physical presence of a DEA-registered practitioner or be physically located in a hospital or clinic that maintains a DEA registration.
- The telecommunication system used is consistent with that which is required under federal requirements for the prescribing of Schedule II-V controlled substances.

***Code of Virginia (Effective July 1, 2020):***

*§ 54.1-3408.3. Certification for use of cannabis oil for treatment.*

*A. As used in this section:*

*"Cannabis oil" means any formulation of processed Cannabis plant extract or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and no more than 10 milligrams of tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.*

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

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

*B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.* ***The practitioner shall use his professional judgement to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances.***

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

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

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

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

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

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

*I. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House Committee for Courts of Justice and the Senate Committee on the Judiciary, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed practitioners or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor or cannabis dispensing facility involved in the treatment of a registered patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated*

*adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.*

Repealed

**Agenda Item: Adoption of New Guidance Documents**

***Staff Note:***

Enclosed are new guidance documents for:

- Background checks for cannabis dispensing facilities
- Use of automated dispensing devices in certain DBHDS facilities
- Emergency Medical Services Drug Kits

***Board action:***

To adopt the new guidance documents as presented in the agenda package or as revised by the Board

Adopted: September 24, 2021
Effective: November 25, 2021

# VIRGINA BOARD OF PHARMACY

## Criminal Background Checks of Material Owners for Pharmaceutical Processor or Cannabis Dispensing Facility Permits

The Board provides the following guidance for a material owner of an applicant for a pharmaceutical processor or cannabis dispensing facility permit who is also a material owner of another permitted pharmaceutical processor or cannabis dispensing facility and was previously subject to a criminal background check. Upon submission of an application for change of ownership of an existing pharmaceutical processor or cannabis dispensing facility or new application, the material owner(s) shall complete a background check if it has been more than 90 days since the previous background check was conducted. Board staff will provide the material owner(s) with the necessary documentation to complete the background check.

***Code of Virginia (Effective July 1, 2021)***

***§ 54.1-3442.6. Permit to operate pharmaceutical processor or cannabis dispensing facility.***

*G. The Board shall require the material owners of an applicant for a pharmaceutical processor or cannabis dispensing facility permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant's material owners. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity. A pharmaceutical processor shall maintain evidence of criminal background checks for all employees and delivery agents of the pharmaceutical processor. Criminal background checks of employees and delivery agents may be conducted by any service sufficient to disclose any federal and state criminal convictions.*

Adopted: September 24, 2021
Effective: November 25, 2021

# VIRGINIA BOARD OF PHARMACY

## Use of Automated Dispensing Devices in Certain Facilities

The Board interprets "Hospitals licensed pursuant to Title 32.1 or Title 37.2" as found in § 54.1-3434.02(A) to include facilities licensed by the Department of Behavioral Health and Developmental Services as "inpatient" or "partial hospitalization" and which only use licensed health care professionals authorized in law to administer medications. Such facilities may use automated dispensing devices in compliance with § 54.1-3434.02.

***From the Code of Virginia, July 1, 2021:***

*§ 54.1-3434.02. Automated drug dispensing systems.*

*A. Hospitals licensed pursuant to Title 32.1 or Title 37.2 may use automated drug dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:*

*1. Drugs are placed in the automated drug dispensing system in a hospital and are under the control of a pharmacy providing services to the hospital;*

*2. The pharmacist-in-charge of the pharmacy providing services to the hospital has established procedures for assuring the accurate stocking and proper storage of drugs in the automated drug dispensing system and for ensuring accountability for and security of all drugs utilized in the automated drug dispensing system until the time such drugs are removed from the automated drug dispensing system for administration to the patients;*

*3. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;*

*4. Adequate security for automated drug dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;*

*5. Accountability for drugs dispensed from automated drug dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to the hospital;*

*6. Filling and stocking of all drugs in automated drug dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into an automated drug dispensing system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in*

*accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system.*

*B. Drugs placed into and removed from automated drug dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging, other than those administered orally, may be placed in such a device if approved by the pharmacist-in-charge in consultation with a standing hospital committee comprised of pharmacy, medical, and nursing staff.*

*C. The pharmacist-in-charge in a pharmacy located within a hospital or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the hospital and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.*

*D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from automated drug dispensing systems and for reviewing the operation and maintenance of automated drug dispensing systems.*

# Virginia Board of Pharmacy

## Emergency Medical Services Drug Kits

Multiple models currently exist for how emergency medical services (EMS) may obtain and store prescription drugs for patient administration. This guidance document summarizes these models and highlights certain requirements under current law and regulation. The models described within this document are the only legally acceptable models for obtaining drugs.

### I. Hospital Pharmacy Drug Exchange Models:

#### Kit for Kit Exchange

Historically, the most common practice in Virginia for EMS to obtain drugs for patient administration has been via a kit for kit exchange with participating local hospitals. Pursuant to Regulation 18VAC110-20-500, a hospital pharmacy may prepare a drug kit for a licensed EMS agency. The kit usually contains drugs in Schedules II through VI. The kit must be sealed, secured and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection of theft or loss. The hospital pharmacy must have a method of sealing the kits such that once the seal is broken, it cannot be reasonably resealed without the breach being detected. If a seal is used, it must have a unique numeric or alphanumeric identifier to preclude replication or resealing. The pharmacy is required to maintain a record of the seal identifiers when placed on a kit for a period of one year. 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. EMS personnel should not break the seal or open the kit until a drug is needed for administration.

When the drug kit has been opened, the kit must be returned to a participating hospital pharmacy and exchanged for an unopened kit. The record of the drugs administered must accompany the opened kit when exchanged. An accurate record must be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse must reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. The theft or any other unusual loss

of any Schedule II, III, IV, or V controlled substance must be reported by the hospital pharmacy in accordance with § 54.1-3404 of the Code of Virginia. In lieu of exchange by the hospital pharmacy, the pharmacist-in-charge of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department must only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

The drug kit must remain secured in the ambulance at appropriate temperatures at all times. These kits are not intended to be stored within the EMS facility.

**One-to-One Exchange of Schedule VI Drugs**

To reduce the workload burden of hospital staff in reconciling the contents of the entire drug kit and facilitate efficiency in the kit exchange process when only a Schedule VI drug is removed from the kit for administration, Regulation 18VAC110-20-500 authorizes an EMS agency or multiple agencies within a single county to obtain a controlled substances registration (CSR) for the purpose of participating in a one-to-one exchange of the Schedule VI drug administered. Under this exchange model, the drugs in Schedules II-V must remain in a separate, sealed container. For example, if an epinephrine auto injector is removed from the kit for patient administration, the EMS personnel would unseal only the area of the kit or container storing the Schedule VI drugs. Then, instead of exchanging the entire drug kit for a sealed drug kit at the hospital, the EMS personnel would simply provide the hospital pharmacy or emergency department with the used epinephrine auto injector and receive a new auto injector to place into the area of the kit storing the Schedule VI drugs. EMS personnel should then reseal the Schedule VI container in a manner that will deter theft or loss of drug and aid in detection of theft or loss. The drugs in Schedules II-V shall remain in a separate, sealed container. Any time the container of Schedule II-V drug is unsealed, the entire container storing all Schedule II-V drugs must be exchanged for an unsealed container. A one-to-one exchange of drugs in Schedules II-V is not allowed.

Examples of drugs in Schedules VI include epinephrine, lidocaine, albuterol, amiodarone, atropine, insulin, diphenhydramine, furosemide, haloperidol, ketorolac, methylprednisolone, and intravenous or irrigation fluids with no added drug. Consult a

current drug reference source for additional information regarding drug schedules. A drug in Schedule VI is often referenced as "Rx". If the drug is placed into a Schedule II, III, IV, or V, it will usually be referenced as "CII", "CIII", "CIV", or "CV".

**Applying for a CSR for One-to-One Exchange of Schedule VI Drugs**

A CSR is issued for a specific purpose or type of activity. An EMS agency may apply for a CSR for this purpose or multiple agencies within a single county may submit a single CSR application for all agencies listed on the application. If submitting one CSR application for multiple EMS agencies within a single county, attach an addendum to the application listing the names and addresses of all EMS agencies within the county that intend to participate in the one-to-one exchange of Schedule VI drugs. For the "Type of Activity", choose "EMS agency". For "Controlled Substances Schedules Requested", check the "VI" box only. As noted in the footnotes on the application, a written description of the processes/business practices for which the registration is being sought must be submitted with the application. In the description of business, indicate that the CSR is being obtained for one-to-one exchange of Schedule VI drugs and that no drugs will be stored within the building. No inspection is required prior to being issued a CSR for this purpose. Any change in location of the EMS agency must be updated with the Board of Pharmacy. The responsible party on the application must be someone authorized to administer medications and should be able to provide daily oversight of the drug security, recordkeeping, and compliance. The supervising practitioner must be an endorsed EMS physician. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party must inform the board and submit an application indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

**Storage of Intravenous and Irrigation Solutions**

As a Schedule VI drug, an EMS agency may obtain intravenous and irrigation solutions from a hospital pharmacy also through a kit for kit or one-to-one exchange process. Due to size, these solutions may be stored outside of the kit. However, the solutions should be securely stored on the ambulance at appropriate temperature at all

times. If solutions must be stored within the EMS facility, the agency must first obtain a CSR for the purpose of storing these solutions in the EMS facility at the address on the application. Pursuant to 18VAC110-20-710, an alarm system is not required for an EMS agency stocking only intravenous fluids with no added drug. If an agency already has a CSR for the purpose of one-to-one exchange of Schedule VI drugs, the EMS agency may submit a new CSR application without fee, along with an addendum requesting that the existing CSR be amended to include this allowance for storing solutions within the facility.

## II. EMS Preparation of its Own Kits Model:

### Storage of Schedule II-VI Drugs within EMS Facility for Preparation of Drug Kits

In lieu of obtaining drugs through a drug exchange model with a hospital pharmacy, an EMS agency may obtain a CSR and corresponding DEA registration for the purpose of ordering and stocking drugs for the preparation of its own drug kits. This may include the preparation of Rapid Sequence Intubation (RSI) kits. Under this model, the EMS facility is solely responsible for preparing and securely storing drug kits for its own use, and replacing drugs within the kits as used for patient administration. The EMS agency does not exchange kits or drugs with a hospital pharmacy. The EMS agency is also responsible for reconciling the accuracy of the kit contents when kits have been unsealed, identifying thefts or losses, and reporting such thefts or losses to the Board of Pharmacy and DEA. The supplier of the drugs, e.g., pharmaceutical manufacturer, wholesale distributor, or third party logistics provider, will provide the EMS agency with an invoice of receipt and these invoices shall be maintained in accordance with 54.1-3404. An initial inventory of all stocks on hand of Schedules II through V drugs must be taken and at least every two years.

Prepared drug kits may not be stored in an EMS agency facility other than the agency listed on the CSR and DEA registration. Should the prepared kits be intended for another EMS agency, that agency may retrieve the kit from the agency at the address listed on the CSR and DEA registration. When the kit is unsealed for drug administration, the ambulance must return the unsealed kit to the original EMS facility to obtain a sealed drug kit. Drug kits should be securely stored in ambulances at appropriate temperatures and may not be

stored within an EMS facility that does not have a CSR and DEA registration authorizing the storage of drugs in Schedules II-VI.

A CSR is not required for the ordering and storing of over-the-counter (OTC) drugs. However, as with the drugs in Schedules II-VI, the OTC drugs should not be administered to patients except in accordance with an oral or written order or standing protocol issued by the EMS physician.

***Applying for a CSR for Obtaining and Storing Drugs within the EMS Facility***

Prior to an EMS agency ordering drugs from a permitted pharmaceutical manufacturer, wholesale distributor, or third-party logistics provider, the EMS agency must apply for a CSR from the Board of Pharmacy and a registration from the DEA. On the CSR application, for the "Type of Activity", choose "EMS agency". For "Controlled Substances Schedules Requested", check the box for all schedules the agency intends to stock. This may include drugs in Schedules II, III, IV, V, and VI. As noted in the footnotes on the application, a written description of the processes/business practices for which the registration is being sought must be submitted with the application. In the description of business, indicate that the EMS agency intends to order and store drugs for the preparation of its own drug kits. An alarm system is required unless the facility is staffed 24 hours a day. If it's possible that all EMS personnel will leave the building simultaneously to address patient needs, then the facility is not staffed 24 hours a day and an alarm system compliant with 18VAC110-20-710 is required. The responsible party on the application shall be someone authorized to administer medications and should able to provide daily oversight of the drug security, recordkeeping, and compliance. The supervising practitioner must be the endorsed EMS physician. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner. An inspection of the drug storage location within the building will be performed prior to the issuance of the CSR. Any deficiencies identified during the inspection must be corrected prior to issuance. DEA

generally prefers for the state CSR to be issued prior to issuance of a DEA registration. No drugs may be ordered or stored in the building for this purpose prior to the issuance of both the CSR and DEA. Any EMS agency wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall submit a CSR application to the Board for the change of location or remodel and be inspected. No drugs may be stored in the remodeled space or new location until approved by the Board and DEA.

DRAFT

**Agenda Item: Legislation relating to MOU with FDA**

**Included in package:**

- Copy of legislation that would require reporting of information to NABP by compounding pharmacies that ship to patients out of state

Staff note:

- The legislative proposal was included in the package of proposals sent by DHP to the Secretary and the Governor. There is no information at this time about whether the bill will be approved for submission.
- No board action is required.

# Department of Health Professions
# 2022 Session of the General Assembly

A BILL to amend the *Code of Virginia* by amending § 54.1-3410.2 to require all pharmacies that compound drugs for human use which are then distributed out-of-state to report certain information on annual basis.

**Be it enacted by the General Assembly of Virginia:**

**That § 54.1-3410.2 of the *Code of Virginia* is amended and reenacted as follows:**

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

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

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

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

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

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

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when

timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

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

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

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

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

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

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

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

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

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

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

H. Pharmacists shall not engage in the following:

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

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

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

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

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

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic

name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

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

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

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

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

L. Between January 1 and March 31 of each year, every pharmacist-in-charge or owner of a permitted pharmacy that has dispensed or distributed any compounded drug for human use out-of-state during the immediately preceding calendar year shall report to the National Association of Boards of Pharmacy the information required by the memorandum of understanding addressing certain distributions of compounded human drug products between the Department of Health Professions and the United States Food and Drug Administration.

Virginia Board of Pharmacy
September 24, 2021
Licenses Issued

| | 2/1/20-4/30/20 | 5/1/20-7/30/20 | 8/1/20-10/31/20 | 11/1/20-1/31/21 | 2/1/21-4/30/21 | 5/1/21 - 7/31/21 | License Count 8/24/2021 |
|---|---|---|---|---|---|---|---|
| Business CSR | 25 | 28 | 23 | 8 | 25 | 44 | 1,472 |
| CE Courses | 0 | 2 | 0 | 0 | 1 | 1 | 9 |
| Limited Use Pharmacy Technician | 0 | 0 | 0 | 0 | 0 | 0 | 8 |
| Medical Equipment Supplier | 4 | 5 | 4 | 8 | 5 | 1 | 227 |
| Nonresident Manufacturer | 7 | 6 | 3 | 1 | 6 | 6 | 204 |
| Nonresident Medical Equipment Supplier | 9 | 5 | 11 | 9 | 8 | 6 | 356 |
| Non-resident Outsourcing Facility | 0 | 3 | 2 | 0 | 1 | 1 | 35 |
| Non-resident Pharmacy | 33 | 22 | 29 | 31 | 37 | 17 | 874 |
| Non-resident Third Party Logistics Provider | 14 | 5 | 12 | 15 | 10 | 9 | 184 |
| Non-resident Warehouser | 19 | 5 | 11 | 9 | 12 | 5 | 95 |
| Non-resident Wholesale Distributor | 8 | 11 | 5 | 10 | 20 | 18 | 642 |
| Non-restricted Manufacturer | 1 | 1 | 0 | 0 | 1 | 0 | 29 |
| Outsourcing Facility | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Permitted Physician | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharmaceutical Processor | 1 | 1 | 1 | 0 | 0 | 0 | 4 |
| Pharmacist | 120 | 309 | 301 | 178 | 175 | 275 | 16,090 |
| Pharmacist Volunteer Registration | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Pharmacy | 10 | 12 | 7 | 8 | 11 | 10 | 1,769 |
| Pharmacy Intern | 160 | 76 | 177 | 99 | 107 | 59 | 1,413 |
| Pharmacy Technician | 345 | 333 | 447 | 482 | 424 | 460 | 13,507 |
| Pharmacy Technician Trainee | | | | 149 | 1256 | 1414 | 2,914 |
| Pharmacy Technician Training Program | 0 | 2 | 7 | 2 | 7 | 3 | 139 |
| Physician Selling Controlled Substances | 28 | 22 | 24 | 16 | 7 | 19 | 600 |
| Physician Selling Drugs Location | 6 | 5 | 4 | 2 | 4 | 4 | 168 |
| Pilot Programs | 0 | 1 | 0 | 1 | 0 | 0 | 15 |
| Registered Physician For Medical Cannabis | 58 | 68 | 106 | 140 | 122 | 162 | 881 |
| Repackaging Training Program | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| Restricted Manufacturer | 1 | 1 | 0 | 0 | 1 | 0 | 41 |
| Third Party Logistics Provider | 1 | 0 | 0 | 0 | 1 | 0 | 7 |
| Warehouser | 2 | 1 | 4 | 1 | 5 | 0 | 121 |
| Wholesale Distributor | 0 | 2 | 1 | 0 | 1 | 1 | 65 |
| **Total** | **852** | **926** | **1,179** | **1,169** | **2,245** | **2,515** | **41,871** |

# Inspection Update:

- Training continues / NABP Sterile Compounding training completed

## Date Range: 04/01/2021 Ending 06/30/2021

## Number of Inspections Completed by License Type:

| Count of Result | | Insp Type | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Insp Status | License Type | Change of Location | Compliance | Focus | New | Pilot | Reinspection | Remodel | Routine | Grand Total |
| Completed | Business CSR | 8 | | | 19 | | 2 | 1 | 55 | 85 |
| | Medical Equipment Supplier | | | | 1 | | | | 9 | 10 |
| | Non-restricted Manufacturer | 1 | | | | | | | | 1 |
| | Pharmaceutical Processor Pe | 1 | | | | | | 2 | 4 | 7 |
| | Pharmacy | 4 | 4 | 1 | 16 | | 1 | 40 | 162 | 228 |
| | Physician Selling Drugs Location | | | | 3 | | 1 | | 10 | 14 |
| | Pilot Programs | | | | | 1 | | | | 1 |
| | Restricted Manufacturer | | | | 1 | | | | | 1 |
| | Third Party Logistics Provider | | | | | | | | 1 | 1 |
| | Warehouser | 3 | | | 1 | | 2 | 1 | 7 | 14 |
| | Wholesale Distributor | 2 | | | 1 | | | 1 | 2 | 6 |
| Completed Total | | 19 | 4 | 1 | 42 | 1 | 6 | 45 | 250 | 368 |
| Completed Vir | Business CSR | 3 | | | 20 | | 1 | 2 | 21 | 47 |
| | Medical Equipment Supplier | | | | 1 | | | | | 1 |
| | Pharmacy | | | 1 | | | 4 | 6 | | 11 |
| | Physician Selling Drugs Location | | | | | | | | 2 | 2 |
| | Warehouser | | | | | | 1 | | | 1 |
| | Wholesale Distributor | | | | | | 1 | | | 1 |
| Completed Virtual Total | | 3 | | 1 | 21 | | 7 | 8 | 23 | 63 |
| Grand Total | | 22 | 4 | 2 | 63 | 1 | 13 | 53 | 273 | 431 |

# Inspection Update:

## Routine Inspections, Deficiencies by License Type:

| Count of InspStatus | Result | | | |
|---|---|---|---|---|
| LicenseType | Deficiency | Deficiency & IPHCO | No Deficiency | Grand Total |
| Business CSR | 84 | | 37 | 121 |
| Medical Equipment Supplier | 5 | | 5 | 10 |
| Pharmaceutical Processor Permit | 16 | | | 16 |
| Pharmacy | 151 | 240 | 47 | 438 |
| Physician Selling Drugs Location | 22 | | 3 | 25 |
| Third Party Logistics Provider | 5 | | | 5 |
| Warehouser | 3 | | 6 | 9 |
| Wholesale Distributor | 3 | | 1 | 4 |
| Grand Total | 289 | 240 | 99 | 628 |

** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

*** Multiple deficiencies can occur at one site.*

# Inspection Update:

**Categories of Deficiencies for Occurrences Recorded >20 Times with Examples:**

| Description | Total |
|---|---|
| 110-20-190 | 20 |

Deficiency 108: Emergency access alarm code/key not maintained in compliance.
Deficiency 12: Storage of prescription drugs not in the prescription department
Deficiency 10: Unauthorized access to locking device to the prescription department

| | |
|---|---|
| 110-20-240 | 26 |

Deficiency 15: Schedule II perpetual inventory
Deficiency 113: Inventories taken on time, but not in compliance
Deficiency 14: The Pharmacist-in-Charge inventory was taken 3 days prior to the effective date of change

| | |
|---|---|
| 110-20-275 | 21 |

Deficiency 122: Engaging in alternate delivery not in compliance

# Inspection Update:

Policy for the return of medications states the medications may be returned to pharmacy
Each entity using this delivery system does not maintain a policy and procedure manual
Facility has not been keeping record of returned prescriptions

| | |
|---|---|
| 110-20-276 | 23 |

Deficiency 123: Engaging in remote processing not in compliance

| | |
|---|---|
| 110-20-700 | 23 |

Approval by the Supervising Veterinarian of a list of drugs which may be ordered by the facility could not be verified during this inspection
The supervising practitioner has not approved the list of drugs which may be ordered by the holder of
the controlled substances registration
Access to the controlled substances is not limited to the supervising practitioner

| | |
|---|---|
| 54.1-3404 | 60 |

Biennial inventory had not been done within the last two years
Deficiency 112: Biennial taken late but within 30 days

# Inspection Update:

Deficiency 16: Unusual loss of drugs not reported to the Board as required
Deficiency 148: Theft/unusual loss of drugs reported to board but report not maintained by pharmacy
Deficiency 13: Biennial inventory substantially incomplete, i.e., did not include all drugs in Schedules II-V
Deficiency 16: Theft/unusual loss of drugs not reported to the Board as required
After the initial inventory is taken, every person described herein has not taken a new inventory
Deficiency 116: Prescriptions do not include required information
Deficiency 124: Labels do not include all required information
Deficiency 131: Viable air sampling was due every 6 months

| | |
|---|---|
| 54.1-3410.2 | 163 |

800: Assessment of risk has been performed
Deficiency 130: Records for products compounded when bulk drug substances are used did not include
the manufacturer of each component
Deficiency 123: Engaging in remote processing not in compliance
Deficiency 26: No documentation of initial media-fill testing or gloved fingertip testing for persons

# Inspection Update:

performing low and medium-risk level compounding

Deficiency 22: Certification of the direct compounding area (DCA) for compounded sterile preparations

indicating ISO Class 5 not performed by a qualified individual

Deficiency 23: Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8

Deficiency 32: Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.

Deficiency 29: Unlawful compounding for further distribution by other entities

Deficiency 132: Personnel preparing compounded sterile preparations do not comply with garbing

requirements

Deficiency 130a: Compounded products not properly labeled

Deficiency 20a: Pharmacist not documenting verification of accuracy of non-sterile compounding

process and integrity of compounded products

Deficiency 33: Low or medium-risk compounded sterile preparations assigned inappropriate beyond use

date (BUD)

Deficiency 27: Compounding using ingredients in violation

# Inspection Update:

| 54.1-3434 | 21 |
|---|---|

Deficiency 14: No incoming change of Pharmacist-in-Charge inventory

Deficiency 1: Pharmacist-In-Charge not fully engaged in practice at the pharmacy location.

Deficiency 2: Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe

# Inspection Update:

## Two Year Review: 06/30/2019 Ending 06/30/2021

## Number of Inspections Completed by License Type:

| Count of Result | | Insp Type | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Insp Status | License Type | Change of Location | Compliance | Fed Agency | Focus | New | Pilot | Reinspection | Remodel | Routine | Grand Total |
| Completed | Business CSR | 49 | | | | | 127 | | 7 | 25 | 523 | 731 |
| | Medical Equipment Supplier | 20 | | | | | 23 | | | 1 | 104 | 148 |
| | Non-restricted Manufacturer | 1 | | | | | 4 | | 1 | 1 | 1 | 8 |
| | Pharmaceutical Processor Permit | 1 | | | | | 10 | | 8 | 4 | 16 | 39 |
| | Pharmacy | 31 | 7 | 20 | | 13 | 70 | 1 | 53 | 262 | 1053 | 1510 |
| | Physician Selling Drugs Location | 6 | | | | 2 | 23 | | 11 | 3 | 94 | 139 |
| | Pilot Programs | | 1 | | | | | 7 | | | | 8 |
| | Restricted Manufacturer | 2 | | | | | 4 | | | | 1 | 7 |
| | Third Party Logistics Provider | | | | | | 1 | | 2 | | 6 | 9 |
| | Warehouser | 11 | | | | | 12 | | 3 | 5 | 53 | 84 |
| | Wholesale Distributor | 2 | | | 1 | 1 | 7 | | 2 | 3 | 28 | 44 |
| Completed Total | | 123 | 8 | 21 | | 16 | 281 | 8 | 87 | 304 | 1879 | 2727 |
| Completed Virtu | Business CSR | 21 | 1 | | | | 77 | | 4 | 12 | 344 | 459 |
| | Medical Equipment Supplier | 5 | | | | | 5 | | | 2 | 42 | 54 |
| | Pharmacy | 11 | | | | 1 | 11 | | 14 | 45 | 1 | 83 |
| | Physician Selling Drugs Location | 1 | | | | | 15 | | 3 | | 7 | 26 |
| | Pilot Programs | | | | | | | 12 | | | | 12 |
| | Third Party Logistics Provider | | | | | | 1 | | | | | 1 |
| | Warehouser | 1 | | | | | 3 | | 1 | 1 | 27 | 33 |
| | Wholesale Distributor | | | | | | 1 | | 2 | 1 | 12 | 16 |
| Completed Virtual Total | | 39 | 1 | | | 1 | 113 | 12 | 24 | 61 | 433 | 684 |
| Grand Total | | 162 | 9 | 21 | | 17 | 394 | 20 | 111 | 365 | 2312 | 3411 |

# Inspection Update:

## Routine Inspections, Deficiencies by License Type:

| Count of InspStatus | Result | | | | |
|---|---|---|---|---|---|
| LicenseType | Deficiency | Deficiency & IPHCO | Deficiency-Response Required | No Deficiency | Grand Total |
| Business CSR | 859 | | 4 | 435 | 1298 |
| Medical Equipment Supplier | 71 | | | 106 | 177 |
| Non-restricted Manufacturer | | | | 2 | 2 |
| Pharmaceutical Processor Permit | 47 | | | 3 | 50 |
| Pharmacy | 954 | 1446 | | 341 | 2741 |
| Physician Selling Drugs Location | 243 | | | 12 | 255 |
| Restricted Manufacturer | | | | 1 | 1 |
| Third Party Logistics Provider | 10 | | | 3 | 13 |
| Warehouser | 21 | | | 67 | 88 |
| Wholesale Distributor | 40 | | | 22 | 62 |
| Grand Total | 2245 | 1446 | 4 | 992 | 4687 |

** Deficiency-Response required is no longer used result type in our database*

*** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

**** Multiple deficiencies can occur at one site.*

## Pharmaceutical Processors Report-September 24, 2021

- All four currently permitted pharmaceutical processors are now submitting medical cannabis products for approval.
- A cannabis dispensing facility has been permitted in Health Service Area III (Salem).
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the application review process continues to be on hold due to a court order.
- The Board is receiving, on average, 1000-1200 patient applications per week.
- In addition to two full time administrative specialist and two temporary administrative staff, the Board is recruiting for three additional temporary staff to assist with processing the high volume of applications.
- Board and agency staff have begun to develop specific components of a new patient registration platform.
- The Regulations Governing Pharmaceutical Processors approved by the Board at the July 6, 2021 full board meeting became effective on September 1, 2021

Pharmaceutical Processors Program-By the Numbers
As of 9/1/2021

| | |
|---|---|
| Registered Practitioners | 884 |
| Registered Patients | 30,952 |
| Registered Parents/Guardians | 202 |
| Registered Agents | 135 |
| Registered Cannabis Oil Products (cumulative) | 500 |

# Discipline Program Report

Open Cases as of 9-10-2021:

| | Entry | PC | APD | Investigation | FH | IFC | Pending Closure | Total # |
|---|---|---|---|---|---|---|---|---|
| **Patient Care Cases** | 3 | 91 | 4 | 81 | 2 | 8 | 0 | 189 |
| **Non-Patient Care Cases** | 2 | 99 | 15 | 18 | 1 | 8 | 19 | 162 |
| | | | | | | | **Total:** | **351** |

- There are 91 patient care cases at Probable Cause compared to 89 reported for June 2021. The number of patient care cases at Investigation has increased by 20.

- Overall case load has increased by 51 cases since last reported.

**Upcoming Disciplinary Proceedings:**

| | | |
|---|---|---|
| October 5, 2021 | IFC-A | Ratliff/StClair (sub for Henderson) |
| October 13, 2021 | Formal Hearings | All Board Members |
| October 18, 2021 | IFC-B | StClair/Bolyard |
| November 9, 2021 | IFC-C | Richards-Spruill/Lee |
| November 15, 2021 | IFC-A | Ratliff/Henderson |
| November 22, 2021 | Formal Hearings | All Board Members |
| December 7, 2021 | Formal Hearings | Full Board Meeting |
| December 17, 2021 | IFC-B | StClair/Bolyard |

**Disciplinary Proceedings 2022:**

| | | |
|---|---|---|
| January 6, 2022 | IFC-C | Richards-Spruill/Lee |
| January 26, 2022 | IFC-A | Ratliff/Henderson |
| February 16, 2022 | IFC-B | StClair/Bolyard |
| March 2, 2022 | IFC-C | Richards-Spruill/Lee |
| March 29, 2022 | IFC-A | Ratliff/Henderson |
| April 19, 2022 | IFC-B | StClair/Bolyard |
| May 12, 2022 | IFC-C | Richards-Spruill/Lee |
| May 25, 2022 | IFC-A | Ratliff/Henderson |
| June 14, 2022 | IFC-B | StClair/Bolyard |

**Executive Director's Report** – September 24, 2021

*Staffing:*

- Sorayah Haden hired as new executive assistant
- Recruitment for vacant licensing administrative assistant ongoing
- Requesting ability to fill a new licensing administrative assistant position
- Jevon Carter hired as new licensing administrative assistant for cannabis program
- Recruitment for three new temporary licensing positions for cannabis program ongoing
- Ongoing training for Ryan Logan and Sorayah Haden; Logan participated in NABP program review training in June

*Operations:*

- Continuing to telework with limited hours on-site; DHP receptionist desk has resumed daily operations
- Budget projections for 2023-2024 submitted

*Projects:*

- MPJE item review completed – O'Halloran, Logan, Shinaberry, Juran
- EMS guidance
- Wildlife, animal shelter guidance
- E-newsletter copy submitted for October publishing
- New licensing software for cannabis program
- Cubicle reconfiguration completed

*Recent Meetings Attended:*

- July 13th – Board Administrator Workshop hosted by Secretary of Commonwealth
- July 22nd – NABP Executive Committee conference call
- July 27th – Pharmacy Technician Symposium – presentation by Ryan Logan
- August 9th and 16th, Statewide protocol work group meetings
- August 13th, VPhA Virtual Convention, Law Update Presentation
- August 19-22, NABP Strategic Planning and Retreat
- August 25-26, NABP Satellite Media Tour
- August 30-31, NABP/AACP Districts 6, 7, 8 meeting
- September 6-9, NABP/AACP Districts 1, 2 meeting
- September 16, New Board Member Orientation
- September 20-21, NABP Drug Importation Task Force
- September 23, Pharmacy Technician Duties Work Group
- Daily BOP staff huddles, tier cases, review applications
- Monthly staff meetings with deputies; BOP staff; executive directors, DHP executive leadership team