COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

Tentative Agenda of Full Board Meeting
December 17, 2024
9AM

TOPIC **PAGES**

Call to Order of Public Hearing: Cheri Garvin, RPh, Chairman
- Welcome & Introductions

Public Hearings:
- Placing Certain Chemicals into Schedule I **3-12**
- Proposed Stage of Regulatory Amendments related to Pharmacy Working Conditions **13-19**
- Proposed Stage of Regulations for Fee Increases **20-31**

Adjournment of Public Hearings

Call to Order of Full Board Meeting: Cheri Garvin, RPh, Chairman
- Approval of Agenda

Approval of Previous Board Meeting Minutes:
- Full Board Meeting, June 25, 2024 **32-41**
- Public Hearings, June 25, 2024 **42-44**
- Formal Hearing, June 25, 2024 **45-47**
- Full Board Meeting, September 24, 2024 **48-55**
- Public Hearing for Scheduling of Chemicals in Schedule I, September 24, 2024 **56-57**
- Public Hearing for Scheduling of Drugs in Schedule I Pursuant to Federal Scheduling Changes , September 24, 2024 **58-59**
- Public Hearing for Prescription Accommodations, September 24, 2024 **60-61**
- Telephone Conference Call, October 31, 2024 **62-63**
- Summary Suspension Presentation, November 12, 2024 **64-65**
- Regulation Committee Meeting, November 12, 2024 **66-71**
- Innovative Pilot Program, December 3, 2024 **72**

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

DHP Director's Report: Arne Owens

Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh
- Chart of Regulatory Actions **73-77**
- Legislative Update **Verbal**
- Adoption of Proposed Stage Regulatory Amendments regarding Allowances for Emergency Drugs by EMS Agencies **78-114**

- Consideration of Resubmission of Final Action for Exemption of Automated Dispensing Devices Stocked Solely with Emergency or Stat-Use Medications from Certain Requirements of 18VAC110-20-555 **115-121**
- Adoption of Proposed Regulations for Crisis Stabilization Units and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems **122-147**
- Adoption of Exempt Regulation to Place Certain Chemicals into Schedule I **148-156**
- Adoption of Fast-Track Regulatory Action to Update Scheduling Regulation Consistent with Statutory Changes **157-160**
- Adoption of Guidance Document *Dispensing Medications to Blind or Low-Vision Patients* **161-163**
- Consideration of Request from Gates Healthcare Associates, Inc. to Recognize its Pharmacy Inspection Report **163B**
- Amend Guidance Document 110-38 *Requirement for Non-resident Pharmacies and Outsourcing Facilities to Submit Current Inspection Report* **164-167**
- Amend Coronavirus Testing and Vaccine Statewide Protocols **168-183**

New Business:

- Presentation of Recognition Plaques to Former Board Members Dale St. Clair, PharmD and Sarah Melton, PharmD
- Overview Presentation of Health Practitioner Monitoring Program - Julia Bennett, Deputy Director Administrative Proceedings Division
- Consideration of Convening a Retreat **184-191**

Reports:

- Chairman's Report – Cheri Garvin, RPh
- Report on Licensure – Ryan Logan, RPh **192-195**
- Report on Inspection Program – Beth O'Halloran, RPh **196-198**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **199-205**
- Executive Director's Report – Caroline D. Juran, RPh **206**

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

Adjourn

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

Project 8124 - None

Board of Pharmacy

December 2024 scheduling of chemicals in Schedule I

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 opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), 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. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), 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.

3. Compounds expected to have depressant properties. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), 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.

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), 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)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-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 July 31, 2024, 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 opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), 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. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), 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. Compound expected to have depressant properties. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), 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.

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), 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 12, 2024, 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. 2-(4-isopropoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other name: N-Pyrrolidino 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.

b. 5-nitro-2-(4-propoxybenzyl)-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other names: N-Pyrrolidino Protonitazene, Protonitazepyne), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl 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.

2. Synthetic compounds.

a. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

3. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), 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. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), 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. Compounds expected to have depressive properties:

a. 6-(4-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: 4'-chloro Deschloroalprazolam, 4'Cl-Deschloroalprazolam), 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. 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam), 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.

5. Central nervous system stimulant. 2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine), its salts, isomers (optical, position, and geometric), and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until March 27, 2025, 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.

a. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other name: N-desethyl 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.

b. 7-[(3-chloro-6-methyl-5,5-dioxo-11H-benzo[c][2,1]benzothiazepin-11-yl)amino]heptanoic acid (other name: Tianeptine), its isomers, esters, ethers, salts,

and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Cannabimimetic agent. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-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.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2025, unless enacted into law in the Drug Control Act.

E. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following compounds expected to have hallucinogenic properties in Schedule I of the Drug Control Act:

1. 1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA, 3C-P, 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), 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.

2. 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), 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.

The placement of drugs listed in this subsection shall remain in effect until August 28, 2025, unless enacted into law in the Drug Control Act.

F. 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. Compounds expected to have hallucinogenic properties:

a. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), 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. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), 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.

c. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), 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.

2. Compound classified as a cannabimimetic agent. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), 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 April 8, 2026, unless enacted into law in the Drug Control Act.

G. 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. The following compounds expected to have hallucinogenic properties:

a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine), 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. 4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP), 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.

c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), 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.

2. The following cannabimimetic agent: Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 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 April 8, 2026, unless enacted into law in the Drug Control Act.

H. 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. The following compounds classified as synthetic opioids:

a. **2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)benzimidazole (other names: metonitazepyne, N-pyrrolidino 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.

b. **2-[2-[(4-ethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N-ethylethanamine (other name: N-desethyl etonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

c. **N-(2-methylphenyl)-N-[1-(2-phenethyl)piperidin-4-yl]propanamide (other name: ortho-methylfentanyl),** 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. The following compounds expected to have hallucinogenic properties:

a. **[3-[2-(diethylamino)ethyl]-1H-indol-4-yl] acetate (other names: 4-acetoxy-N,N-diethyltryptamine; 4-acetoxy DET; 4-AcO-DET; ethacetin),** 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. **3-[2-(diethylamino)ethyl]-1H-indol-4-ol (other names: 4-hydroxy-N,N-diethyltryptamine; 4-hydroxy DET; ethocin),** 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. **3-methylmethcathinone (other names: 3-MMC; metaphedrone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one),** 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. The following compounds classified as cannabimimetic agents:

a. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-INACA)**, 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-cyclohexyl-2-(1-pentylindol-3-yl)acetamide (other names: cyclohexyl-PIATA, CH-PIACA, CH-PIATA)**, 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 17, 2026], unless enacted into law in the Drug Control Act.

Project 7342 - Proposed

Board of Pharmacy

Pharmacy working conditions

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist may, however, volunteer to work longer than 12 continuous hours. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided consistent with 18VAC110-20-113 B 5.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

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

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date ~~he~~ the pharmacist ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

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

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-113. Pharmacy working conditions.

A. A pharmacy permit holder shall protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. A permit holder's decisions shall not override the control of the PIC or other pharmacist on duty regarding appropriate working environments for all pharmacy personnel necessary to protect the health, safety, and welfare of patients.

B. To provide a safe working environment in a pharmacy, a permit holder shall, at a minimum:

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume, but shall consider any other requirements of pharmacy staff during working hours;

2. Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner;

3. Avoid the introduction of external factors, such as productivity or production quotas or other programs, to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

4. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensure staff demonstrate competency, and ensure that pharmacy technician trainees work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the PIC;

5. Provide appropriate opportunities for uninterrupted rest periods and meal breaks consistent with 18VAC110-20-110 and the following:

a. A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty provided that the pharmacy has complied with the 14-day notice to the public pursuant to § 54.1-3434 of the Code of Virginia and 18VAC110-20-135;

b. If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking a break within the prescription department or on the premises. The pharmacist on duty must determine whether pharmacy technicians or pharmacy interns may continue to perform duties and whether the pharmacist is able to provide adequate supervision; and

c. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel any person filling a new prescription must be offered pursuant to § 54.1-3319 of the Code of Virginia. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling and document when such counseling is provided;

6. Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

a. Drug utilization review;

b. Immunization;

c. Counseling;

d. Verification of prescriptions;

e. Patient testing; and

f. All other duties required by Chapter 33 (§ 54.1-3300 et seq.) and Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and this chapter; and

7. Ensure that pharmacy technicians shall never perform duties otherwise restricted to a pharmacist.

C. A pharmacy permit holder shall not override the control of the pharmacist on duty regarding any aspects of the practice of pharmacy, including a pharmacist's decision not to administer vaccines when one pharmacist is on duty and, in the pharmacist's professional judgment, vaccines cannot be administered safely.

D. Staffing requests or concerns as described in this section shall be communicated by the PIC or pharmacist on duty to the permit holder using the Staffing Requests or Concerns Form developed by the board or a form containing information identical to the form developed by the board, which may be electronic.

1. Such forms, once completed, shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board within 48 hours of request.

2. The PIC or pharmacist on duty may report any staffing issues directly to the board if the PIC or pharmacist on duty believes the situation warrants immediate board review.

3. Under no circumstances shall a good faith report of staffing concerns by the PIC, pharmacist on duty, or notification of such issues by pharmacy personnel to the PIC, pharmacist on duty, or board result in workplace discipline against the reporting staff member.

E. Permit holders shall review completed staffing reports and shall:

1. Respond to reporting staff member to acknowledge receipt of the staffing request or concern;

2. Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;

3. Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on site or produced for inspection by the board within 48 hours of request; and

4. Communicate corrective action taken or justification for inaction to the PIC or reporting pharmacist on duty.

FORMS (18VAC110-20)

Application for a Pharmacy Permit (rev. 1/2024)

Application for a Nonresident Pharmacy Registration (rev. 1/2024)

Application for a Nonresident Wholesale Distributor Registration (rev. 4/2024)

Application for Registration as Nonresident Manufacturer (rev. 10/2020)

Application for a Nonresident Third-Party Logistics Provider Registration (rev. 4/2024)

Application for Registration as a Nonresident Warehouser (rev. 10/2020)

Application for a Nonresident Outsourcing Facility Registration (rev. 10/2020)

Application for an Outsourcing Facility Permit (rev. 10/2020)

Application for a Medical Equipment Supplier Permit (rev. 10/2020)

Application for a Permit as a Restricted Manufacturer (rev. 10/2020)

Application for a Permit as a Nonrestricted Manufacturer (rev. 10/2020)

Application for a Wholesale Distributor Permit (rev. 4/2024)

Application for a Permit as a Warehouser (rev. 10/2020)

Application for a Permit as a Third-Party Logistics Provider (rev. 4/2024)

Application for Registration as a Nonresident Medical Equipment Supplier (rev. 10/2020)

Application for a Controlled Substances Registration Certificate (rev. 8/2024)

Closing of a Pharmacy (rev. 5/2018)

Application for Approval of an Innovative (Pilot) Program (rev. 8/2023)

Registration for a Pharmacy to be a Collection Site for Donated Drugs (rev. 5/2018)

Application for Approval of a Repackaging Training Program (rev. 10/2020)

Registration for a Facility to be an Authorized Collector for Drug Disposal (rev. 5/2018)

Application for Reinspection of a Facility (rev. 3/2023)

Notification of Distribution Cessation due to Suspicious Orders (rev. 5/2018)

Staffing Requests or Concerns Form (eff. 9/2023)

Project 7695 - Proposed

Board of Pharmacy

Increase in fees

Chapter 20

Regulations Governing the Practice of Pharmacy

18VAC110-20-20. Fees.

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

B. Initial application fees.

1. Pharmacy permit	~~$500~~ $700
2. Permitted physician licensed to dispense drugs	~~$500~~ $700
3. Medical equipment supplier permit	~~$235~~ $350
4. Outsourcing facility permit	~~$350~~ $900
5. Nonresident pharmacy registration	~~$350~~ $700
6. Nonresident outsourcing facility registration	~~$350~~ $900
7. Controlled substances registrations	~~$120~~ $180
8. Innovative program approval.	~~$325~~ $415
If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	
9. Approval of a repackaging training program	~~$65~~

	$85
10. Sterile compounding initial fee	$200

Applicants for a pharmacy permit or nonresident pharmacy registration that intend to perform sterile compounding shall submit a sterile compounding fee in addition to the pharmacy permit or nonresident pharmacy initial application fee.

C. Annual renewal fees.

1. Pharmacy permit – due no later than April 30	~~$350~~ $490
2. Physician permit to practice pharmacy – due no later than February 28	~~$350~~ $490
3. Medical equipment supplier permit – due no later than February 28	~~$235~~ $350
4. Outsourcing facility permit – due no later than April 30	~~$350~~ $1,100
5. Nonresident pharmacy registration – due no later than the date of initial registration	~~$350~~ $490
6. Nonresident outsourcing facility registration – due no later than the date of initial registration	~~$350~~ $1,100
7. Controlled substances registrations – due no later than February 28	~~$120~~ $180
8. Innovative program continued approval based on board order not to exceed ~~$260~~ $375 per approval period.	
9. Repackaging training program	~~$40~~ $50 every two years
10. Sterile compounding renewal fee	$400

Permitted pharmacies and registered nonresident pharmacies performing sterile compounding shall submit a sterile compounding renewal fee in addition to the pharmacy permit or nonresident pharmacy renewal fee.

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired permit or registration within one year of the expiration date. In addition, engaging in activities requiring a permit or registration after the expiration date of such permit or registration shall be grounds for disciplinary action by the board.

1. Pharmacy permit	$120
2. Physician permit to practice pharmacy	$120
3. Medical equipment supplier permit	$80
4. Outsourcing facility permit	$120
5. Nonresident pharmacy registration	$120
6. Nonresident outsourcing facility registration	$120
7. Controlled substances registrations	$40
8. Repackaging training program	$15

E. Reinstatement fees.

1. Any person or entity attempting to renew a permit or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

	a. Pharmacy permit	~~$315~~ $440
	b. Physician permit to practice pharmacy	~~$315~~ $440

	c. Medical equipment supplier permit	~~$275~~ $385
	d. Outsourcing facility permit	~~$315~~ $500
	e. Nonresident pharmacy registration	~~$150~~ $440
	f. Nonresident outsourcing facility registration	~~$315~~ $500
	g. Controlled substances registration	~~$235~~ $350
	h. Repackaging training program	~~$65~~ $85

F. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	~~$65~~ $125
2. Change of ownership for any facility	~~$65~~ $125
3. Inspection for remodeling or change of location for any facility	~~$300~~ $435
4. Reinspection of any facility	~~$300~~ $435
~~5. Board-required inspection for a robotic pharmacy system~~	~~$300~~
~~6.~~ 5. Board-required inspection of an innovative program location	~~$300~~ $435
~~7.~~ 6. Change of pharmacist responsible for an approved innovative program	~~$35~~ $150

G. Miscellaneous fees.

1. Handling fee for returned check or a dishonored credit card or debit card	$50
2. Duplicate permit or registration	~~$15~~ $20
3. Verification of permit or registration	$35

Chapter 21

Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians

18VAC110-21-20. Fees.

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

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	~~$235~~ $300
2. Pharmacy intern registration	~~$20~~ $30
3. Pharmacy technician trainee registration	~~$20~~ $30
4. Pharmacy technician registration	~~$35~~ $40
~~5. Approval of a pharmacy technician training program~~	~~$200~~
~~6.~~ 5. Approval of a continuing education program	~~$130~~ $190

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	~~$120~~ $175
2. Pharmacist inactive license – due no later than December 31	~~$60~~ $95
3. Pharmacy technician registration – due no later than December 31	~~$35~~ $45
~~4. Pharmacy technician training program~~	~~$100 every two years~~

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license or registration within one year of the expiration date ~~or within two~~

~~years in the case of a pharmacy technician training program~~. In addition, engaging in activities requiring a license or registration after the expiration date of such license or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$40
2. Pharmacist inactive license	$20
3. Pharmacy technician registration	$15
~~4. Pharmacy technician training program~~	~~$20~~

F. Reinstatement fees. Any person or entity attempting to renew a license or registration more than one year after the expiration date~~, or more than two years after the expiration date in the case of a pharmacy technician training program,~~ shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	~~$275~~ $300
2. Pharmacist license after revocation or suspension	~~$650~~ $750
3. Pharmacy technician registration	~~$45~~ $50
4. Pharmacy technician or pharmacy technician trainee registration after revocation or suspension	~~$165~~ $200
~~5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.~~	
5. Pharmacy technician trainee	$25

G. Miscellaneous fees.

1. Duplicate wall certificate	$50
2. Handling fee for returned check or a dishonored credit card or debit card	$50

3. Duplicate license or registration	~~$15~~ $20
4. Verification of licensure or registration	$35

Chapter 30

Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

18VAC110-30-15. Fees.

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

B. Initial application fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$235~~ $300.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$315~~ $700.

C. Annual renewal fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$120~~ $175.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$315~~ $490.

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substances: $40.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$50~~ $120.

E. Reinstatement fees. Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances: ~~$195~~ $300.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: ~~$315~~ $415.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: ~~$650~~ $750.

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit. Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.

G. The fee for reinspection of any facility shall be ~~300~~ $435.

H. The handling fee for returned check or a dishonored credit card or debit card shall be $50.

Chapter 50

Regulations Governing Wholesale Distributors, Manufacturers and Warehousers

18VAC110-50-20. Fees.

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

B. Initial application fees.

1. Nonrestricted manufacturer permit	~~$350~~ $1,000
2. Restricted manufacturer permit	~~$235~~ $850
3. Wholesale distributor license	~~$350~~ $750
4. Warehouser permit	~~$350~~ $510

5. Nonresident wholesale distributor registration	~~$350~~ $750
6. Controlled substances registration	~~$120~~ $180
7. Third-party logistics provider permit	~~$350~~ $750
8. Nonresident manufacturer registration	~~$350~~ $1,000
9. Nonresident warehouser registration	~~$350~~ $510
10. Nonresident third-party logistics provider registration	~~$350~~ $750

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	~~$350~~ $1,000
2. Restricted manufacturer permit	~~$235~~ $850
3. Wholesale distributor license	~~$350~~ $750
4. Warehouser permit	~~$350~~ $510
5. Nonresident wholesale distributor registration	~~$350~~ $750
6. Controlled substances registration	~~$120~~ $180
7. Third-party logistics provider permit	~~$350~~ $750
8. Nonresident manufacturer registration	~~$350~~ $1,000
9. Nonresident warehouser registration	~~$350~~ $510
10. Nonresident third-party logistics provider registration	~~$350~~ $750

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Nonrestricted manufacturer permit	$120
2. Restricted manufacturer permit	$80
3. Wholesale distributor license	$120
4. Warehouser permit	$120
5. Nonresident wholesale distributor registration	$120
6. Controlled substances registration	$40
7. Third-party logistics provider permit	$120
8. Nonresident manufacturer registration	$120
9. Nonresident warehouser registration	$120
10. Nonresident third-party logistics provider registration	$120

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Nonrestricted manufacturer permit	~~$315~~ $440
b. Restricted manufacturer permit	~~$275~~ $385
c. Wholesale distributor license	~~$315~~ $440
d. Warehouser permit	~~$315~~ $440
e. Nonresident wholesale distributor registration	~~$315~~ $440
f. Controlled substances registration	~~$235~~ $350
g. Third-party logistics provider permit	~~$315~~ $440
h. Nonresident manufacturer registration	~~$315~~ $440
i. Nonresident warehouser registration	~~$315~~ $440
j. Nonresident third-party logistics provider registration	~~$315~~ $440

F. Application for change or inspection fees.

1. Reinspection fee	~~$300~~ $435
2. Inspection fee for change of location, structural changes, or security system changes	~~$300~~ $435
3. Change of ownership fee	~~$65~~ $125
4. Change of responsible party	~~$65~~ $125

G. The handling fee for a returned check or a dishonored credit card or debit card shall be $50.

H. The fee for verification of license, permit, or registration shall be $35.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Tuesday, June 25, 2024

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

CALL TO ORDER: A full board meeting was called to order at 9:11AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Cheri Garvin, RPh, Vice Chair
Michelle Hoffer, JD
Larry Kocot, JD
Sarah Melton, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Ling Yuan, PharmD

MEMBERS ABSENT: Wendy Nash, PharmD

STAFF PRESENT:
Caroline Juran, RPh, Executive Director
Brent Saunders, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Jenkins, RN, Deputy Director, DHP
Arne Owens, Director, DHP
Sorayah Haden, Executive Assistant
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:

QUORUM: With 9 members present, a quorum was established.

APPROVAL OF AGENDA: The Chairman stated a tentative agenda was previously provided to board

members and the public, and that several handouts were provided that morning at their seat and on the table for the public. The first handout was from Jodi Roth on behalf of the Virginia Association of Chain Drug Stores offering comment on central fill pharmacy regulations. The second was from Jay Gill offering comment on pharmacy technician training requirements. The third was a revised handout related to licensure fees that replaces page 64 of the agenda. The fourth was an illustrative table of changes, current costs, and comparisons related to licensure fees. The sixth was an NABP gap analysis of training requirements for pharmacy technicians, and the seventh was a printout from Regulatory Town Hall regarding a public comment period for the 2022 pharmacists initiating treatment action. Hearing no additional items, the Chairman approved the agenda as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES:

Hearing no corrections to the minutes, the Chairman stated that the minutes for the meetings held between May 2nd and June 5th were approved as presented.

PUBLIC COMMENT:

- Jeenu Philip, Director of Pharmacy Affairs, Walgreens, provided public comment of behalf of Walgreens Central Fill #21420 regarding the emergency regulations for central fill pharmacies. Walgreens Central Fill #21420 is currently operating as an approved pilot program utilizing a 12:1 pharmacist to pharmacy technician ratio to fill prescriptions. Mr. Philip informed the board the central fill pharmacy in Virginia services 175 Walgreens locations in Virginia and 113 out-of-state locations. It has filled a little under 6 million prescriptions thus far. Mr. Philip requests consistency amongst the emergency regulations and the approved pilot program by removing unlicensed persons to be included in the 12:1 pharmacist to pharmacy Technician ratio.
- Lauren Paul, Executive Director of Pharmacy Affairs, CVS Health provided public comment on behalf of CVS Health regarding the emergency regulations for central fill pharmacies and remote processing by pharmacy technicians. She encouraged the board to keep regulations broad and open to improve workforce conditions.
- Jamie Fisher, Executive Director, VPhA, provided public comment on behalf of the Virginia Pharmacists Association. Ms. Fisher provided updates on active workgroups in place to improve the working conditions of pharmacies throughout the Commonwealth. VPhA requests further analysis of the central fill pharmacy pilot and caution when expanding ratios. It favors enforcing licensing requirements as currently found in 18VAC110-20-276. VPhA requests striking "or possesses credentials similar to Virginia" and stated that "substantially equivalent" is unclear.
- Natalie Nguyen, PharmD, Immediate Past-President, VSHP, provided

public comment on behalf of the Virginia Society of Health-System Pharmacists. VSHP requested clarification regarding if Guidance Document 110-19 *Use of Automated Dispensing Devices in Certain Facilities* excludes facilities currently utilizing automated dispensing devices or if they would now need a CSR. She questioned what information is available across the states regarding ratios and the outcome of the central fill pharmacy pilot. Dr. Nguyen expressed VSHP's concern of increase in possible diversion of highly valuable Schedule VI drugs as the result of allowing unlicensed persons to perform duties within a pharmacy.

- Patrick Baker, PharmD, Senior Vice President and General Manager, Mosaic Pharmacy provided public comment on behalf of Mosaic Pharmacy regarding pharmacy technician educational requirements. Mr. Baker expressed concerns for the decrease in pharmacy technician applicants due to the cost of the ASHP/ACPE-accredited training programs. He shared concerns ASHP/ACPE-accredited training programs appear to favor chain pharmacies over independent pharmacies for serving as clinical sites. Mr. Baker requests the approval of additional training programs such as PTCB-approved programs to provide more affordable educational opportunities. A handout of his public comments was also provided to the Board.

DHP DIRECTOR'S REPORT: Arne Owens provided general updates on behalf of the Department of Health Professions and indicated that Janet Kelly will soon become Virginia's Secretary of Health and Human Resources.

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF REGULATORY ACTIONS: Erin Barrett briefly reviewed the regulatory actions chart in the agenda packet and provided updated information. The chart provided an update regarding proposed regulations in the Governor's office, Secretary's office, the Attorney General's office, and those recently effective or awaiting publication.

CONSIDERATION OF PETITION FOR RULEMAKING TO ADD KRATOM TO SCHEDULE I: The Board reviewed and discussed the petition for rulemaking received requesting the amendment of 18VAC110-20-322 to add Mitragynine and 7-Hydroxymytragynine (Kratom) to Schedule I. Approximately 3,000 public comments were received on the petition. Approximately 500 comments were in support and over 2,000 were in opposition. Kocot expressed concern for placing it into Schedule I when the elected members of the General Assembly had recently passed legislation regarding the sale of Kratom to persons 21 and older. Ratliff indicated he supported the NOIRA and that it needs to be studied. Garvin stated she was not convinced it should be placed into Schedule I based on the conflicting public comments.

MOTION

The Board voted unanimously to deny the petition for rulemaking to amend 18VAC110-20-322 to place Mitragynine and 7-Hydroxymytragynine (Kratom) into Schedule I as it did not feel it possessed sufficient evidence at the meeting to determine that Kratom has no medicinal value, but that the Board may research and review this matter at a future meeting. (motion by Kocot, seconded by Garvin)

ADOPTION OF EMERGENCY REGULATIONS FOR CENTRAL FILL PHARMACIES AND REMOTE PROCESSING BY PHARMACY TECHNICIANS

The Board reviewed and discussed the emergency regulations for central fill pharmacies and remote processing by pharmacy technicians. The agenda package included HB1068, the draft regulatory changes which comply with legislation, suggested amendments offered by Publix Pharmacy, and relative Boards orders for active pilot programs utilizing central filling and remote pharmacies.

MOTION:

The Board voted unanimously to adopt emergency regulations amending 18VAC110-20-112, 18VAC110-20-276, and adopting 18VAC110-20-277 as presented and amended as indicated below, and to issue a Notice of Intended Regulatory Action for permanent regulations.

- **18VAC110-20-112: at the end of subsection A, insert "except as provided in 18VAC110-20-276 and 18VAC110-20-277."**
- **18VAC110-20-276: insert new subsection G to read:**

G. A pharmacist may only supervise a maximum of six pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians accessing the employer pharmacy's database from a remote location as provided in subsection F, with a maximum of four of the six on site at the employer pharmacy. The supervising pharmacist shall be readily available to the pharmacy technicians and pharmacy interns and technology shall be available for adequate supervision of pharmacy technicians and pharmacy interns performing the duties of pharmacy technicians.

- **18VAC110-20-277: amend subsection D to read:**

D. A pharmacist practicing at a central fill pharmacy may supervise up to 12 licensed or registered persons, to include pharmacy technicians, pharmacy technician trainees, and pharmacy interns, and may supervise up to 12 unregistered or unlicensed persons performing non-dispensing functions authorized in this subsection. Each pharmacist shall determine the number of persons he can safely and competently supervise at one time.

(motion by Garvin, seconded by Yuan)

ADOPTION OF FINAL ACTION ON ALLOWANCES FOR CENTRALIZED WAREHOUSER/

The Board reviewed and discussed the final regulations regarding allowance for centralized warehouser or wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals.

WHOLESALE DISTRIBUTOR TO VERIFY SCHEDULE VI DRUGS FOR ADDs IN HOSPITALS

MOTION:

The Board voted unanimously to adopt the final regulations regarding allowances for centralized warehouser and wholesale distributor to verify Schedule VI drugs for automated dispensing devices in hospitals as presented and amended to state the following:

- **18VAC110-20-490 (D)(5) – strike "each unit" and replace with "in accordance with the hospital's policies and procedures"**
- **18VAC110-20-490 (D)(6) – after "automated dispensing device" insert "or associated drug database".**

(motion by Garvin, seconded by Richards-Spruill)

ADOPTION OF PROPOSED REGULATORY AMENDMENTS FOR LICENSURE FEE INCREASE

The Board reviewed and discussed the proposed regulatory amendments for licensure fee increases. The agenda packet included information regarding factors impacting the needs for fee increases, comparison of neighboring states licensure fees, and proposed fee amendments to Chapter 20, 21, 30, and 50.

MOTION

The Board voted unanimously to adopt the proposed regulatory amendments for licensure fee increases as presented. (motion Dowdy, seconded by Hoffer)

ADOPTION OF EXEMPT ACTION CONFORMING SCHEDULING REGULATION(S) TO GENERAL ASSEMBLY ACTIONS

The Board reviewed and discussed the exempt regulatory action pursuant to SB111/HB1333. The agenda packet included draft changes to 18VAC110-20-322 and 18VAC110-20-323 to conform to scheduling changes enacted by the legislature in the 2024 General Assembly Session.

MOTION

The Board voted unanimously to adopt the exempt regulatory amendments of 18VAC110-20-322 and 18VAC110-20-323 as presented. (motion by Kocot, seconded by Garvin)

ADOPTION OF FINAL REGULATORY ACION – IMPLEMENTATION OF 2022 LEGISLATION FOR PHARMACISTS INITIATING TREATMENT

The Board reviewed and discussed the adoption of final regulatory action pertaining to the implementation of 2022 legislation for pharmacists initiating treatment.

MOTION

The Board voted unanimously to adopt the final regulatory action of 18VAC110-21-46 as presented and pertaining to the implementation of 2022 legislation for pharmacists initiating treatment. (motion by Yuan,

seconded by Melton)

ADOPTION OF EXEMPT REGULATORY ACTION – ADDITION OF CHEMICALS TO SCHEDULE I

The Board reviewed and discussed the adoption of exempt regulatory action pertaining to the addition of chemicals to Schedule I. The agenda packet included recommendations from the Department of Forensic Science to place certain chemicals in Schedule I.

MOTION

The Board voted unanimously to adopt the exempt regulatory changes as presented to 18VAC110-20-322 to add the following chemicals to Schedule I:

F. 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. The following compounds expected to have hallucinogenic properties:

a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine), 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. 4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP), 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.

c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), 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.

2. The following cannabimimetic agent: Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 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.

(motion by Richards-Spruill, seconded by Hoffer)

AMENDMENT OF GUIDANCE DOCUMENT 110-9

The Board reviewed and discussed the draft amendment of Guidance Document 110-9 to repeal deficiency 125 due to elimination of this language by USP.

MOTION	**The Board voted unanimously to amend Guidance Document 110-9 as presented to repeal deficiency 125. (motion by Garvin, seconded by Dowdy)**
DISCUSSION REGARDING PHARMACY TECHNICIAN EDUCATIONAL STANDARD AND WORKFORCE CHALLENGES	The Board reviewed the background information on this subject in the agenda packet and discussed the difficulties some pharmacies are facing in hiring and training pharmacy technicians, along with the cost associated with completing an ASHP/ACPE-accredited training program.
MOTION	**The Board voted unanimously to adopt a legislative proposal that would amend 54.1-3321 (B)(2) by inserting a new section "iii" to allow for successfully completing a pharmacy technician training program that is recognized by PTCB or NHA. (motion by Kocot, seconded by Garvin)**
AMEND 2024 PHARMACY TECHNICIAN WORKFORCE SURVEY REPORT	Following the adoption of the 2023 Virginia Pharmacy Technician Workforce Survey Report at an earlier meeting, staff identified that the 8,063 pharmacy technician trainees are not included in the report because they do not renew their trainee registration. Thus, the report did not appear to comprehensively represent the total workforce of persons that may be performing the duties of a pharmacy technician. Staff recommended minor amendments to the 2023 report and stated they are working with the Healthcare Workforce Center to capture additional data elements of pharmacy technician trainees in subsequent pharmacy technician workforce reports.
MOTION:	**The Board voted unanimously to amend the 2023 Virginia Pharmacy Technician Workforce report as presented. (motion by Kocot, seconded by Garvin)**

NEW BUSINESS:

DISCUSSION REGARDING 2024 MAP OF PHARMACY PERMIT LOCATIONS	The Board reviewed and discussed the 2024 map of pharmacy permit locations. The agenda packet included maps with data from May 2024, maps previously provided to Board using data from June 2023, and an excerpt of current count of licenses as of Q3 2024. Total number of pharmacies as of May 2024 was 1,735 compared to 1,746 in June 2023. There are four counties that do not appear to have a pharmacy.
ELECTION OF CHAIRMAN	Mr. Kocot nominated Ms. Cheri Garvin to serve as the 2024-2025 Chairman of the Virginia Board of Pharmacy.
MOTION	**The Board voted unanimously to close nominations for Chairman. (motion by Richards-Spruill, seconded by Dowdy)** **The Board voted unanimously to elect Ms. Cheri Garvin to serve as Chairman of the Virginia Board of Pharmacy for the term of July 1, 2024 through June 30, 2025.**

ELECTION OF VICE-CHAIRMAN	Mrs. Richards-Spruill nominated Dr. Ling Yuan to serve as the 2024-2025 Vice-Chairman of the Virginia Board of Pharmacy. Dr. Ratliff nominated Dr. Shannon Dowdy to serve as the 2024-2025 Vice-Chairman of the Virginia Board of Pharmacy.
MOTION	**The Board voted (5-4) to elect Dr. Ling Yuan to serve as Vice-Chairman of the Virginia Board of Pharmacy for the term of July 1, 2024 through June 30, 2025.**
SCHEDULE 2025 MEETING DATES	The Board chose the following dates for the 2025 Full Board Meetings: March 25th, June 17th, September 30th, and December 10th.
CONSIDERATION OF AGENCY SUBORDINATE RECOMMENDATIONS	The Board reviewed the confidential attachments consisting of the agency subordinate recommendations regarding ten informal conference hearings previously held.
MOTION	**The Board voted unanimously to accept the agency subordinate recommendations regarding ten informal conference hearings as presented. (Motion by Ms. Garvin, seconded by Dr. Yuan)**
REPORTS:	
CHAIRMAN'S REPORT	Dr. Dale St. Clair thanked the board for their service and support of him as the Chairman of the Virginia Board of Virginia. A recap of the year including meetings attended and regulations passed was provided. He emphasized the importance of mental health resources which was the presidential initiative of NABP President Lenora Newsome, and action Virginia has taken to improve questions on licensing applications related to this subject.
BOARD OF HEALTH PROFESSIONS	Dr. Melton reported the Board of Health Professions has not met since the last update provided.
LICENSURE PROGRAM	Mr. Logan presented the Licensing Report of individuals and facilities licenses within Virginia which included data from November 2022 through June 2024. As of June 5, 2024, the Virginia Board of Pharmacy has a total of 44,816 licenses consisting of individual and pharmacy permits currently issued.
INSPECTION PROGRAM	Melody Morton, Inspections Manager with the Enforcement Division, presented the Inspections Report including data from January 2024 through March 2024. A total of 442 pharmacy inspections have been completed from January 2024 through March 2024.

DISCIPLINARY PROGRAM	Dr. Shinaberry presented the Disciplinary Program Report. As of June 5, 2024, the Virginia Board of Pharmacy has a total of 308 open cases consisting of 185 patient care related cases and 123 non-patient care related cases. She also announced that Compliance Case Manager Rose DeMatteo will be retiring on July 24, 2024. The Board expressed sincere appreciation for Ms. DeMatteo's service to the Board and the Commonwealth and wished her all the best in her retirement.
EXECUTIVE DIRECTOR'S REPORT	Ms. Juran provided a report including staff updates such as the addition of Disciplinary Administrative Specialist Nicole Copeland, the transition of Deputy Executive Director Annette Kelley to another health regulatory board at DHP, the upcoming retirement of the Compliance Case Manager Rose DeMatteo, and the ongoing recruitment for this position. The Board is currently working with Impact Makers to review and identify efficiencies in the licensure process. A recap of meetings previously attended and upcoming meetings was also provided.
CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS	
SUMMARY SUSPENSION PRESENTATION	Sean Murphy with the OAG presented a possible summary suspension for Board consideration regarding Tyler Coffey (Pharmacist License 0202-219563).
MOTION	**Upon a motion by Hoffer, and duly seconded by Ratliff, the Board unanimously voted to summarily suspend the pharmacist license of Tyler Coffey (0202-219563).**
CONSENT ORDER	Sean Murphy presented consent orders for Board consideration regarding CVS Pharmacy #7561 (0201-002726) and CVS Pharmacy #1985 (0201-002743)
MOTION	**Upon a motion by Garvin, and duly seconded by Richards-Spruill, the Board unanimously voted to accept the consent orders for CVS Pharmacy #7561 (0201-002726) and CVS Pharmacy #1985 (0201-002743).**

MEETING ADJOURNED: 3:15 PM

_____
Caroline Juran, RPh
Executive Director

_____
DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CHEMICALS INTO SCHEDULE I
AND
PROPOSED REGULATIONS FOR EXEMPTION OF AUTOMATED DISPENSING DEVICES STOCKED SOLELY WITH EMERGENCY OR STAT-USE MEDICATIONS FROM CERTAIN REQUIREMENTS OF 18VAC110-20-555.

Tuesday, June 25, 2024

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

CALL TO ORDER: A public hearing on two subjects was called to order at 9:07 AM.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Cheri Garvin, RPh
Michelle Hoffer, JD
Larry Kocot, JD
Sarah Melton, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Ling Yuan, PharmD

MEMBERS ABSENT: Wendy Nash, PharmD

STAFF PRESENT:
Caroline Juran, RPh, Executive Director
Brent Saunders, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Jenkins, RN, Deputy Director, DHP
Arne Owens, Director, DHP
Sorayah Haden, Executive Assistant
Ellen Shinaberry, PharmD, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director

QUORUM: With 9 members present, a quorum was established.

The Chairman indicated the first subject for which public comment may be

received is consideration for the placement of the following chemicals into Schedule I as recommended by the Department of Forensic Science (DFS):

Based on their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. **1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine)**, 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.

2. **4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP),** 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.

3. **8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam),** 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.

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

4. **Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 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.

PUBLIC COMMENT: Robyn Weimer provided public comment on behalf of the Department of Forensic Science indicating the proposed chemicals have been found in recent cases and are a risk to public safety. Ms. Weimer stated the proposed chemicals have no medicinal use and three of the chemicals have hallucinogenic effects.

The Chairman indicated the second subject for which public comment may be received is regarding the proposed regulations for exemption of automated dispensing devices stocked solely with emergency or stat-use medication from certain requirements of 18VAC110-20-555.

PUBLIC COMMENT: No public comments were offered on this subject.

MEETING ADJOURNED: 9:12 AM

_____ _____

Caroline Juran, RPh DATE:
Executive Director

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
FORMAL HEARING

Tuesday, June 25, 2024
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 3:31 PM for the purpose of a formal hearing in the matter of Caremark PCS PA Mail Pharmacy to act on the application for reinstatement of the non-resident pharmacy permit as provided in the notice dated May 3, 2024.
PRESIDING:	Cheri Garvin, Chairman
MEMBERS PRESENT:	Ms. Michelle Hoffer Mrs. Patricia Richards-Spruill Dr. Ling Yuan Dr. Kris Ratliff Dr. Shannon Dowdy Mr. Larry Kocot Dr. Sarah Melton
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen B. Shinaberry, Deputy Executive Director Bren Saunders, Assistant Attorney General Jess Weber, Adjudication Specialist Sorayah Haden, Executive Assistant
PANEL:	With eight (8) members of the Board present, a panel of the board was established.
CAREMARK PCS PA MAIL PHARMACY REGISTRATION NO.: 0214-000732	Jess Weber, Adjudication Specialist, presented the case on behalf of the Commonwealth. Caremark PCS PA Mail Pharmacy was represented by counsel Mike Hurst, Esq and Anna Cathcart, Esq.

WITNESSES:	Kimberly Hyler, DHP Investigator, testified in person on behalf of the Commonwealth.
CLOSED MEETING:	Upon a motion by Dr. Dowdy, and duly seconded by Mr. Kocot, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Caremark PCS PA Mail Pharmacy. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Brent Saunders, and Sorayah Haden attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (Dowdy/Ratliff)
DECISION:	Upon a motion by Ms. Hoffer, and duly seconded by Mrs. Richards-Spruill, the Board voted 8-0 to reinstate the non-resident pharmacy permit of Caremark PCS PA Mail Pharmacy.
CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") convened for the purpose of a formal hearing in the matter of Ted Nasol act on his application for reinstatement of his pharmacy technician registration as provided in the notice dated June 5, 2024.
TED NASOL PHARMACY TECHNICIAN REGISTRATION NO. 0230-029081	Jess Weber, Adjudication Specialist, presented the case on behalf of the Commonwealth.
WITNESSES:	Katie Land, DHP Investigator, testified in person on behalf of the Commonwealth. Mr. Nasol was not present at the formal hearing and was not represented by counsel.

CLOSED MEETING:	Upon a motion by Dr. Dowdy, and duly seconded by Mr. Kocot, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Ted Nasol. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Brent Saunders, and Sorayah Haden attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (Dowdy/Ratliff)
DECISION:	Upon a motion by Ms. Hoffer, and duly seconded by Dr. Yuan, the Board voted 8-0 to deny the reinstatement application of Ted Nasol and revoke the pharmacy technician registration.
ADJOURNED:	6:40 PM

Caroline D. Juran, Executive Director

Date:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Tuesday, September 24, 2024

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

CALL TO ORDER: A full board meeting was called to order at 9:32 AM.

PRESIDING: **Ling Yuan**, PharmD, Vice Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Kelly Hasty Kale, RPh
Larry Kocot, JD
Wendy Nash, PharmD
Derek Webb, PharmD

MEMBERS ABSENT:
Cheri Garvin, RPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowksi, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Tim Reilly, RPh, Pharmacy Compliance and Pilot Program Manager

PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:
Michael Elkin
Amanda Richardson
Katrina Trelease

QUORUM: With 7 members present, a quorum was established.

APPROVAL OF AGENDA:

An amended agenda was previously posted online with hard copies available at the meeting. Hearing no additional amendments, Dr. Yuan stated that the amended agenda was approved as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The following amendments were offered to the draft minutes for the meetings held between July 11, 2024, and August 29, 2024:

- Spelling corrections of the name "Kelly" Hasty Kale within the final minutes of the Formal Hearing held on August 29, 2024.
- Grammatical correction within the final minutes of the Formal Hearing held on August 29, 2024.

Hearing no other amendments, Dr. Yuan stated that the minutes were approved as presented and amended.

PUBLIC COMMENT:

Dr. Natalie Nguyen, Immediate Past-President, Virginia Society of Health-System Pharmacists (VSHP), thanked the board for its continued efforts with the emergency medical services drug kit transition. She indicated further education on accessible prescription labels will be provided during the VSHP fall seminar.

Jamie Fisher, Executive Director, Virginia Pharmacy Association (VPhA), provided comment regarding VPhA's continued support and encouragement of the Board to progress with the implementation and expansion of statewide protocols that increases patient access to care. VPhA encourages the Board to review the study and documentation of the "pharmacy deserts" increasing throughout the Commonwealth and the concerns with minimal Medicaid reimbursement rates. A handout of her comments was provided to Ms. Haden.

DHP DIRECTOR'S REPORT:

Arne Owens provided a DHP Director's Report consisting of the following updates:

- The Perimeter Center is continuing to undergo updated security measures to mirror the safety measures required within downtown state offices. Metal detectors have been installed. The next implementation phase will consist of updated security badges and verification systems for employees.
- The General Assembly will resume in approximately three months.
- The agency will undergo a Salary Study soon.
- The agency held a Wholesale Drug Importation Work Group meeting on behalf of the Secretary of Health and Human Resources. A legislative report will be drafted to detail the work group's discussion of wholesale drug importation.

<u>LEGISLATIVE/ REGULATORY/GUIDANCE</u>

CHART OF REGULATORY ACTIONS

Erin Barret briefly reviewed the chart in the agenda packet and provided the following regulatory updates:

- 18VAC110-21 *2022 Pharmacists Initiating Treatment* has been approved. It will become effective on November 20, 2024.
- 18VAC110-20 *Requirements for Use of Central Fill Pharmacy and Remote Databases* is currently under review in the Secretary's Office.
- 18VAC110-20 *Crisis Stabilization Services and Use of Automated Dispensing Systems and Remote Dispensing Systems* will be presented for proposed final language before the Board at the December Full Board Meeting.
- 18VAC110-20 *Allowances for Emergency Drugs by EMS Agencies* will be presented for proposed final language before the Board at the December Full Board Meeting.

ADOPTION OF EXEMPT REGULATORY ACTION – ADDITION OF CHEMICALS TO SCHEDULE I

The Board reviewed and discussed the recommendation from the Department of Forensic Science to place certain chemicals into Schedule I and the draft proposed amendments to 18VAC110-20-322.

MOTION

The Board voted unanimously to adopt the exempt changes to 18VAC110-20-322 to add the following chemicals to Schedule I:

Compounds expected to have depressant properties.

1. **7-Bromo-5-(2-chlorophenyll_-1,3-dihydro-2H-1,4-benzodiazepin-2-one (other name: phenazepam), its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**

Compounds classified as a cannabimimetic agent:

1. **Methyl N-[{5-methyl-1H-indazol-3-yl)carbonyl]-3-mythl-valinate (other name: MDMB-5Me-INACA), its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemicals designation. (motion by Hoffer, seconded by Webb)**

ADOPTION OF FINAL REGULATORY ACTION REGARDING EXEMPTIONS OF AUTOMATED DEVICES STOCKED SOLELY WITH EMERGENCY OR STAT-USE MEDICATIONS FROM CERTAIN REQUIREMENTS

The Board reviewed and discussed the public comment received and the draft final version of changes to 18VAC110-20-555 regarding the exemption of automated dispensing devices stocked solely with emergency or stat-use medication from certain requirements.

OF 18VAC110-20-555

MOTION: **The Board voted unanimously to adopt final regulatory amendments of 18VAC110-20-555 as presented and amended by inserting "after the pharmacist has reviewed the prescription order but" into subsection 4c after the word "accessed". (motion by Kocot, seconded by Dowdy)**

ADOPTION OF NOTICE OF INTENDED REGULATORY ACTION REGARDING PROHIBITION OF CONTROLLED SUBSTANCE REGISTRATION ISSUANCE TO A PRIVATE DWELLING OR RESIDENCE

The Board reviewed and discussed the notice of intended regulatory action regarding prohibition of controlled substance registration issuance to a private dwelling or residence. The Board reviewed 18VAC110-50-30 and 18VAC110-20-110 which already contains such prohibition for other licensing types.

MOTION: **The Board voted unanimously to adopt the notice of intended regulatory action to amend 18VAC110-20-690 to prohibit controlled substance registration issuance to a private dwelling or residence. (motion by Dowdy, seconded by Hoffer)**

ADOPTION OF FAST-TRACK REGULATORY ACTION TO ALLOW AGENCY SUBORDINATES TO HEAR CREDENTIALS CASES

The Board reviewed and discussed the adoption of the fast-track regulatory action to allow agency subordinates to hear credentials cases, e.g., cases wherein reasons may exist to deny issuance of a license. The review consisted of the draft regulatory amendments to allow agency subordinates to hear credential cases which mirror the statutory amendments passed in HB 1622 of the 2023 General Assembly.

MOTION: **The Board voted unanimously to adopt the fast-track regulatory action to amend 18VAC110-15-10 to allow agency subordinates to hear credentials cases. (motion by Webb, seconded by Kocot)**

ADOPTION OF EXEMPT REGULATIONS FOR ACCESSIBLE PRESCRIPTION LABELS

The Board reviewed and discussed the adoption of exempt regulations for accessible prescription labels. The review consisted of HB516 and a draft of 18VAC110-20-351 as recommended by the Visually Impaired Work Group which recently met.

MOTION: **The Board voted unanimously to adopt the exempt regulation 18VAC110-20-351 regarding accessible prescription labels as presented and amended by changing "a person authorized to perform the duties of a pharmacist" to "pharmacy intern" and inserting "pharmacy technician trainee" after "technician" in subsection B. (motion by Hoffer, seconded by Kocot)**

ADOPTION OF GUIDANCE DOCUMENT FOR ACCESSIBLE PRESCRIPTION LABELS	The Board reviewed and discussed the adoption of Guidance Document 110-14 regarding accessible prescription labels and recommended by the Visually Impaired Work Group which recently met.
MOTION:	**Based on public comment received at the beginning of the meeting to offer additional guidance to pharmacists on options available to assist visually impaired patients, the Board voted unanimously to refer the matter to the Regulation Committee which is scheduled to meet in November. (motion by Nash, seconded by Dowdy)**
CONSIDER RECOMMENDATIONS TO AMEND THE FOLLOWING STATEWIDE PROTOCOLS:	
HIV PRE-EXPOSURE PROPHYLAXIS (PrEP) STATEWIDE PROTOCOL	The Board reviewed and discussed the draft amendments to the HIV Pre-Exposure Prophylaxis (PrEP) statewide protocol as recommended by the statewide protocol work group, consisting of representatives of the Board of Medicine, Board of Pharmacy, and Department of Health, which recently met.
MOTION:	**The Board voted unanimously to amend the HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol as presented and recommended by the statewide protocol work group. (motion by Dowdy, seconded by Webb)**
PHARMACIST PROTOCOL FOR TESTING AND INITIATING TREATMENT FOR COVID-19 VIRUS INFECTION	The Bord reviewed and discussed the recommendations to amend the Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection. There was discussion regarding whether references to the emergency use authorization should be amended. The Board concluded that the EUA remains currently in place for pediatric patients 12 and over.
MOTION:	**The Board voted unanimously to amend the Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection as presented and amended by inserting into the first paragraph on the first page of the protocol after "(FDA)" the phrase "approval and". (motion by Hoffer, seconded Kocot)**
ADOPTION OF EXEMPT REGULATORY ACTION – ADDITION OF CHEMICALS TO SCHEDULE I PURSUANT	The Board reviewed and discussed the adoption of exempt regulatory action regarding the addition of chemicals to Schedule I pursuant to Virginia Code

TO VIRGINIA CODE §54.1-3443(E)

§54.1-3443 (E). The Board reviewed excerpts of recent DEA scheduling action from December 2023 through September 12, 2024.

MOTION:

The Board voted unanimously to adopt exempt changes to 18VAC110-20-322 to place the following chemicals into Schedule I in conformity with recent federal scheduling actions and pursuant to Virginia Code §54.1-3443(E):

1. *meta*-fluorofentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide);

2. *meta*-fluoroisobutyryl fentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide);

3. *para*-methoxyfuranyl fentanyl (other name: *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

4. 3-furanyl fentanyl (other name: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide);

5. 2′,5′-dimethoxyfentanyl (other name: *N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide);

6. isovaleryl fentanyl (other name: 3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide);

7. *ortho*-fluorofuranyl fentanyl (other name: *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

8. *para*-methylcyclopropyl fentanyl (other name: *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

9. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA);

(motion by Webb, seconded by Hoffer)

NEW BUSINESS:

REQUEST FROM GATES HEALTHCARE ASSOCIATED, INC. TO

Ernest P. Gates Jr., President and Michelle Woosley, Vice President of Gates Healthcare Associates presented a request for Gates Healthcare Associates' pharmacy inspection reports to be recognized as an alternative inspection report if the jurisdiction cannot perform an inspection in a timely manner.

RECOGNIZE ITS INSPECTION REPORT AS AN ACCEPTABLE ALTERNATIVE TO AN INSPECTION BY THE LICENSING OR REGULATORY AGENCY OF JURISDICTION OR AN INSPECTION BY THE BOARD OF PHARMACY'S OWN AGENT

They provided an over of their inspection report template which was included in Attachment 2 of the amended agenda packet. Mr. Grates and Dr. Woosley verbally walked the board through Gates Healthcare Associates' inspection process and explained the color-coded rubric used for easier comprehension of the inspection's findings. Gates Healthcare Associates expressed their current primary focus are nonresident compounding pharmacies seeking licensure or renewal in Virginia. They indicated that their inspection reports are currently recognized in 12 states. The Board was curious how their inspection report compares to the NABP VPP inspection report which is currently recognized by the Board. Gates indicates they can provide the Board with their USP <795> and <800> inspection reports as well.

MOTION:

The Board voted unanimously to refer the matter to the Regulation Committee for further review and discussion. (motion by Nash, seconded by Kale)

PRESCRIPTION MONITORING PROGRAM UPDATES

Ashley Carter, MPH, Director, Prescription Monitoring Program, presented a PowerPoint Presentation explaining the mission and statistics of the Prescription Monitoring Program (PMP). As of September 2024, the PMP consisted of 80,000 registered users. Pharmacists represent 16% of the reported 80,000 users which totals 13,047 registered users. Trending topics for the PMP are the rise in states collecting federally non-controlled substances, regulatory changes to require date sold on all prescription recordkeeping, and emergency dispensing from emergency departments. The program has a compliance reporting of 95%-98%. Reasons for non-compliance consist of changes in DEA numbers, changes in software vendors, and staffing/personnel-related issues. At the current spending rate, the forecasted PMP Trust Account is expected to be depleted in 2032.

<u>REPORTS:</u>

CHAIRMAN'S REPORT

Dr. Yuan thanked the participants on the HB 516 Visually Impaired work group and Statewide Protocol work group for their dedication and hard work. Dr. Yuan informed the Board that Ms. Juran and Mrs. Richards-Spruill will be representing the Virginia Board of Pharmacy at the upcoming NABP/AACP Districts 1 & 2 Meeting in Boston, MA in October.

LICENSURE PROGRAM

Ryan Logan, Deputy Executive Director presented the Licensing Program Report which included data from February 2023 through September 6, 2024. As of September 6, 2024, the Virginia Board of Pharmacy reported a total of 46,113 registered licenses consisting of, but no limited to, the following licenses:

- 16,579 registered pharmacists
- 13,300 registered pharmacy technicians
- 7,951 registered pharmacy technician trainees
- 1,728 registered pharmacies

- 964 registered non-resident pharmacies

INSPECTION PROGRAM

Beth O'Halloran, Deputy Executive Director, presented the Inspections Report including data from April 1, 2024, through June 30, 2024. As of June 30, 2024, the Enforcement Division has conducted 381 inspections during the reported period. A total of 222 deficiencies were documented during routine inspections within the reported period. The Enforcement Division completed a total of 3,636 inspections during the time period of June 30, 2022 through June 30, 2024.

DISCIPLINARY PROGRAM

Dr. Shinaberry presented the Disciplinary Program Report. As of August 21, 2024, the Board of Pharmacy has a current active caseload of 300 cases consisting of 184 patient care cases and 116 non-patient care Cases. The Board is utilizing the Agency Subordinate to perform probable cause review for certain cases. Tim Reilly joined Board staff as the new Pharmacy Compliance and Pilot Program Manager in August 2024.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided the Executive Director's Report consisting of in-person and virtual meetings previously attended and future meetings to attend on behalf of the Board. Updates from the upcoming meetings will be provided upon return. Ms. Juran informed the Board that Virginia's turn to serve as the host state for a future NABP/AACP District 1 & 2 meeting will be approaching sooner than expected. Additional information regarding the date is expected to be received at the upcoming NABP District 1 & 2 meeting in October 2024.

MEETING ADJOURNED: 1:11 PM

_____
Caroline Juran, RPh
Executive Director

_____
DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CHEMICALS INTO SCHEDULE I

Tuesday, September 24, 2024

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

CALL TO ORDER: A public hearing was called to order at 9:05 AM.

PRESIDING: **Ling Yuan**, PharmD, Vice Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Kelly Hasty Kale, RPh
Larry Kocot, JD
Wendy Nash, PharmD
Derek Webb, PharmD

MEMBERS ABSENT:
Cheri Garvin, RPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowksi, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Tim Reilly, RPh, Pharmacy Compliance and Pilot Program Manager

QUORUM: With 7 members present, a quorum was established.

Dr. Yuan indicated the public hearing is being held to consider the placement of two chemical compounds into Schedule I in consultation with the Department of Forensic Science (DFS) and in accordance with subsection D of 54.1-3443(D). The following compounds were proposed:

Compounds expected to have depressant properties.

1. **7-Bromo-5-(2-chlorophenyll_-1,3-dihydro-2H-1,4-benzodiazepin-2-one (other name: phenazepam),** its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Compounds classified as a cannabimimetic agent:

1. **Methyl N-[{5-methyl-1H-indazol-3-yl)carbonyl]-3-mythl-valinate (other name: MDMB-5Me-INACA),** its alt, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemicals designation.

PUBLIC COMMENT: Robyn Weimer provided public comment on behalf of the Department of Forensic Science indicating the proposed chemicals are a risk to public safety and serve no medical use.

MEETING ADJOURNED: 9:07 AM

_____ _____

Caroline Juran, RPh
Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING REGARDING THE ADDITION OF CHEMICALS INTO SCHEDULE I PURSUANT TO VIRGINIA CODE §54.1-3443 (E)

Tuesday, September 24, 2024

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

CALL TO ORDER: A public hearing was called to order at 9:28 AM.

PRESIDING: **Ling Yuan**, PharmD, Vice Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Kelly Hasty Kale, RPh
Larry Kocot, JD
Wendy Nash, PharmD
Derek Webb, PharmD

MEMBERS ABSENT:
Cheri Garvin, RPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowksi, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Tim Reilly, RPh, Pharmacy Compliance and Pilot Program Manager

QUORUM: With 7 members present, a quorum was established.

Dr. Yuan indicated the public hearing is being held to receive public comment regarding the adoption of exempt regulatory action for the placement of the following chemicals into Schedule I to conform to recent federal scheduling action and pursuant to Virginia Code §54.1-3443(E):

1. *meta*-fluorofentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)propionamide);

2. *meta*-fluoroisobutyryl fentanyl (other name: *N*-(3-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)isobutyramide);

3. *para*-methoxyfuranyl fentanyl (other name: *N*-(4-methoxyphenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

4. 3-furanyl fentanyl (other name: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylfuran-3-carboxamide);

5. 2′,5′-dimethoxyfentanyl (other name: *N*-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-*N*-phenylpropionamide);

6. isovaleryl fentanyl (other name: 3-methyl-*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylbutanamide);

7. *ortho*-fluorofuranyl fentanyl (other name: *N*-(2-fluorophenyl)-*N*-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

8. *para*-methylcyclopropyl fentanyl (other name: *N*-(4-methylphenyl)-*N*-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);

9. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA);

PUBLIC COMMENT: No public comment was provided.

MEETING ADJOURNED: 9:31 AM

_____ _____

Caroline Juran, RPh
Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING FOR PROPOSED REGULATIONS REGARDING PRESCRIPTION ACCOMMODATIONS PURSUANT TO HB 516

Tuesday, September 24, 2024

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

CALL TO ORDER: A public hearing was called to order at 9:07 AM.

PRESIDING: **Ling Yuan**, PharmD, Vice Chairman

MEMBERS PRESENT:
Shannon Dowdy, PharmD
Michelle Hoffer, JD
Kelly Hasty Kale, RPh
Larry Kocot, JD
Wendy Nash, PharmD
Derek Webb, PharmD

MEMBERS ABSENT:
Cheri Garvin, RPh
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowksi, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Tim Reilly, RPh, Pharmacy Compliance and Pilot Program Manager

QUORUM: With 7 members present, a quorum was established.

Dr. Yuan indicated the public hearing is being held to receive public comment regarding the proposed exempt regulations for accessible prescription labels.

PUBLIC COMMENT:

Lauren Paul, PharmD provided comment on behalf of CVS Health submitting a request for an amendment to 18VAC110-20-351 B to state "…. a pharmacist, a person authorized to perform the duties of a pharmacist, a pharmacy technician, or a pharmacy technician trainee shall affix the label prior to dispensing to the patient as required in 18VAC110-20-270".

Stewart Prost provided comment on behalf of the National Federation of the Blind of Virginia requesting the Board provide additional guidance on its website and in communications with pharmacists regarding the available options for assisting patients with vision impairments. Mr. Prost's public comment consisted of a handout and demonstration of the Mini-Me device which records up to 60 seconds of information by the touch of a button.

MEETING ADJOURNED: 9:28 AM

_____ _____

Caroline Juran, RPh
Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, October 31, 2024

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on October 31, 2024, at 9:06 AM, to consider summary suspensions in case number 239658.

PRESIDING: Cheri Garvin, Chairman

MEMBERS PRESENT:
Ling Yuan
Kristopher Ratliff
Kelly Kale
Derek Webb
Michelle Hoffer
Patricia Richards-Spruill
Larry Kocot
Shannon Dowdy

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Amanda Padula-Wilson, Asst Attorney General
Christine Andreoli, DHP Adjudication Specialist

POLLING OF BOARD MEMBERS

The Board members were polled prior to scheduling the telephone conference call as to whether they could attend the meeting in Richmond.

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

BILAL ABBOUD
License No. 0202-216500

Amanda Padula-Wilson, Assistant Attorney General, presented a summary of the evidence in case no. 239658 regarding the pharmacist license of Bilal

	Abboud. Ms. Padula-Wilson was assisted by Christine Andreoli, Adjudication Specialist.
CLOSED MEETING:	Upon a motion by Dr. Yuan, and duly seconded by Mr. Kocot, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Bilal Abboud. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, and Mykl Egan attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision. (Yuan/Hoffer)
DECISION:	Upon a motion by Dr. Ratliff and duly seconded by Ms. Richards-Spruill, the Board unanimously voted (9-0) that, with the evidence presented, the continued practice of Bilal Abboud poses a substantial danger to the public; and therefore, his license shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Bilal Abboud in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 0942 AM.

Ellen B. Shinaberry, BS,PharmD.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SUMMARY SUSPENSION PRESENTATION

Tuesday, November 12, 2024

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

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

TIME & PURPOSE: A meeting of the Virginia Board of Pharmacy was held on November 12, 2024, at 9:06 AM, to consider summary suspensions in case number 239790.

PRESIDING: Ling Yuan, Chairman

MEMBERS PRESENT:
Kristopher Ratliff
Kelly Kale
Larry Kocot
Shannon Dowdy
Cheri Garvin – participated by telephone

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
James Rutkowski, Sr Assistant Attorney General – participated by telephone
David Robinson, Asst Attorney General
Rebecca Ribley, DHP Adjudication Specialist

QUORUM: With six (6) members participating, a quorum was established.

BRANDI FRETWELL
Registration No. 0245-

David Robinson, Assistant Attorney General, presented a summary of the evidence in case no. 239790 regarding the pharmacy technician trainee registration of Brandi Fretwell. Mr. Robinson was assisted by Rebecca Ribley, Adjudication Specialist.

DECISION: Upon a motion by Mr. Kocot and duly seconded by Dr. Dowdy, the Board unanimously voted (6-0) that, with the evidence presented, the continued practice of Brandi Fretwell poses a substantial danger to the public; and therefore, her registration shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Brandi

	Fretwell in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 0915 AM.

Ellen B. Shinaberry, BS,PharmD.
Deputy Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

Tuesday, November 12, 2024
Commonwealth Conference Center
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: A meeting of the Regulation Committee of the Board of Pharmacy ("Board") was called to order at 9:15AM.

PRESIDING: **Ling Yuan**, PharmD, Committee Chairperson, Board Vice Chairperson

MEMBERS PRESENT:
Kristopher Ratliff, DPh
Kelly Hasty Kale, RPh
Larry Kocot, JD
Shannon Dowdy, PharmD

STAFF PRESENT:
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP (left at 11:25AM)
Beth O'Halloran, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Ryan Logan, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy

QUORUM: With all members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: An amended agenda cover page, and an amended page 77 of the original agenda packet mailed to the board was provided by staff at the meeting. A link to the Board's routine inspection report was listed on the amended page 77, instead of including all pages of the inspection report.

MOTION: The Committee voted unanimously to accept the amended agenda as presented. (motioned by Ratliff, seconded by Kale)

PUBLIC COMMENT: No public comment was offered during the public comment period of the meeting.

CHART OF CURRENT REGULATORY ACTIONS: Erin Barret briefly reviewed the chart of regulatory actions provided in the agenda packet and provided the following updates on the Administrative Review process since the chart was posted:

- Proposed regulatory amendments of 18VAC110-20, 18VAC110-21, 18VAC110-30, and 18VAC110-50 for an *Increase in Fees* have moved from the Secretary's office to the Governor's Office for review and consideration.
- Notice of Intended Regulatory Action to amend 18VAC110-20 for the *Exclusion of private dwellings or residences from operating locations of CSRs* has moved from the Department of Planning and Budget to the Secretary's office for review and consideration.
- Proposed regulatory amendments of 18VAC110-21 for *2023 Pharmacists Initiating Treatment* have moved from the Office of the Attorney General to the Department of Planning and Budget for review and consideration.

The Committee questioned why several actions do not appear to be moving through the Administrative Review process timely such as the *Prohibition against incentives to transfer prescriptions* and the NOIRA for the *2021 Periodic Review*. Ms. Juran commented that the Board may have success in addressing critical subjects included in the NOIRA in separate regulatory actions such was recently done to address the prohibition of a private dwelling or residence to obtain a CSR. Additionally, she is aware that a petition for rulemaking may soon be received to address another subject included in the 2021 periodic review NOIRA.

ACTION ITEM: **There was general consensus that the Committee should review the *Prohibition against incentives to transfer prescriptions* regulatory action during the May 2025 Regulation Committee meeting to determine if a patient safety risk still exists or if the action should be withdrawn.**

ADOPT RECOMMENDATIONS FOR GUIDANCE DOCUMENT FOR ACCESSIBLE PRESCRIPTION LABELS The Committee reviewed enactment clause 3 of HB 516 requiring the Board to adopt guidance identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients. The Committee also considered the public comment provided in the agenda packet from the National Federation of the Blind, Virginia chapter. Ms. Barrett commented that reiterating information captured in the U.S. Access Board's Best Practices document within a Board guidance document is generally

frowned upon and that it's more appropriate to simply provide a link to the Best Practices document. Additionally, it was acknowledged that listing specific technologies in the guidance document may give the appearance of a bias for one over another. Ms. Juran commented that the Virginia Pharmacy Association (VPhA) and/or the Virginia Society of Health-System Pharmacists (VSHP) may be willing to assist in educating pharmacists on technologies offered to aid patients, particularly if the National Association of the Blind was willing to develop and revise the document as needed over time. During the discussion, some members expressed concern for the financial survivability of pharmacies and the increased access challenges that will result from additional pharmacies closing.

MOTION:

MOTION: **The Committee voted unanimously to recommend that the Board adopt the guidance document, *Dispensing Medications to Blind or Low-Vision Patients,* as presented and for staff to contact VPhA and VSHP to request assistance in further educating pharmacists on best practices and technology options available for accommodating these patients. (motion by Kocot, seconded by Ratliff).**

CONSIDERATION OF POTENTIAL CHANGES TO CRISIS STABILIZATION UNIT EMERGENCY REGULATIONS PRIOR TO BOARD ADOPTION OF PROPOSED STAGE

The Committee reviewed and discussed the draft proposed regulations for crisis stabilization units (CSU) and use of automated drug dispensing systems (ADS) and remote dispensing systems (RDS). It was noted that no comments were received during the public comment period which closed 9/25/24. Staff commented that they recently identified that 18VAC110-20-700(C) should probably be amended as well to conform with the allowance for pharmacy technicians to have access to the dispensing systems in a CSU. Additionally, staff stated that the Department of Planning and Budget questioned during the administrative review process if the language in 18VAC110-20-490(B)(3) regarding maintenance of a key to access an ADD or RDS should be added to 18VAC110-20-555 for consistency. The Committee had a lengthy discussion regarding whether any facility should have access to the key for an ADS or RDS since it can be used to bypass normal operations and may impose a safety risk with no record of identifying who used the key to access the device. Ms. Juran stated that certain innovative pilot program board orders for use of these devices had allowed a key to be maintained in the possession of the director of nursing (DON) or designee licensed to administer drugs when the provider pharmacy was not located within the facility. It was noted that should the board remove the allowance when adopting the proposed regulations, information may be gleaned during the next public comment period to help inform the adoption of the final regulations.

ACTION ITEM: **Board staff will research the need for a key to have been used by a DON or designee to access such devices under the previous innovative pilot programs or if routinely provided in other facilities, e.g., long term care, community service boards.**

MOTION: **The Committee voted unanimously to recommend to the full Board that it strike the proposed amendment in 18VAC110-20-490 (B)(3) which reads "If a key may be used to access the automated drug dispensing system or remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the director of nursing or an individual designated by the director of nursing who is licensed to administer medications." when adopting the proposed regulations for CSUs and use of ADSs and RDSs. (motion by Kocot, seconded by Kale)**

MOTION: **The Committee voted unanimously to recommend to the full Board that it amend 18VAC110-20-700 (C) as presented which:**

- **inserts "drug" after "automated",**
- **strikes "devices",**
- **inserts "systems or remote dispensing systems" after "dispensing", and**
- **strikes "Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists."**

and to include it in the proposed regulations for CSUs and use of ADSs and RDSs. (motion by Ratliff, seconded by Dowdy)

CONSIDERATION OF PUBLIC COMMENTS TO EMERGENCY MEDICAL SERVICES EMERGENCY REGULATIONS PRIOR TO BOARD ADOPTION OF PROPOSED STAGE

The Committee reviewed and discussed the draft proposed regulations for emergency medical services (EMS) and the public comment received following the publication of the emergency/NOIRA stage of the regulatory process. Several written comments described the need for emergency drug kits to be maintained on quick response vehicles (QRV) which may be parked at a location other than an EMS agency. Ms. Juran stated that the Office of Emergency Medical Services (OEMS) confirmed to her that a QRV is a permitted EMS vehicle regulated by OEMS that are often used by rural EMS agencies and are equipped and staffed by a certified EMS provider. The vehicles respond to the scene of an emergency to render care until an ambulance arrives that is transport capable. The QRV is locked at all times and equipped with auxiliary power connections (shore power) to maintain temperature of the drug boxes. OEMS agreed that it would be appropriate for a QRV to maintain an emergency drug kit. In response to a written comment to provide more clarity regarding drug storage requirements, the Committee believed the regulatory requirements were sufficient and feared being more specific may decrease an EMS agency's

flexibility in determining optimal storage mechanisms for that location. In response to a written comment to allow for use of automated dispensing machines, the Committee acknowledged that such allowance already exists in 18VAC110-20-710(E).

MOTION:

The Committee voted unanimously to recommend to the full Board that it adopt the proposed EMS regulations as presented and amended as follows:

- **18VAC110-20-710(G)(3), at the end, insert ", or location where an EMS agency or EMS council approves an EMS vehicle to be stored";**
- **18VAC110-20-710(G)(4), after "council", insert "or location where an EMS agency or EMS council approves an EMS vehicle to be stored". (motion by Ratliff, seconded by Dowdy)**

REQUEST FROM GATES HEALTHCARE ASSOCIATES, INC. TO RECOGNIZE ITS INSPECTION REPORT AS AN ACCEPTABLE ALTERNATIVE TO AN INSPECTION BY THE LICENSING OR REGULATORY AGENCY OF JURISDICTION OR AN INSECTION BY THE BOARD OF PHARMACY'S OWN AGENT

The Committee discussed and reviewed the inspection report provided by Gates Healthcare Associates, Inc. to the full board at the September full Board Meeting. The Virginia Board of Pharmacy's Inspection Report was provided as additional documentation to compare to Gates Healthcare Associates, Inc. inspection report.

MOTION/ACTION ITEM:

The Committee voted unanimously to recommend to the full Board to approve Gates Healthcare Associates, Inc.'s request to recognize its inspection report of an out of state pharmacy as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board's own agent pending responses to the following questions:

- **Which states currently recognize a pharmacy inspection performed by Gates?**
- **Will the report include a list of deficiencies observed by the inspector at the time of the inspection, along with the pharmacy's corrective action to address the deficiencies? (motion by Kocot, seconded by Ratliff)**

The Committee Chairman asked if there was any other business to

discuss. Ms. Kale questioned if the Board had considered convening a retreat to discuss various pharmacy-related topics to assist the Board, particularly new board members. It was shared with Ms. Kale that Dr. Nash had raised such a request last year and that the members had responded to a survey of topics it may wish to discuss at a retreat. The Board ultimately decided at that time that it would not convene a retreat, but that the Chairman would work with Ms. Juran to address individual topics from the survey during already scheduled meetings. During the discussion the following topics were mentioned by some of the Committee members as subjects they may be interested in discussing: learning what's going on in the other board members' practice settings, workplace challenges, if lesser expensive alternatives for licensees exist compared to the HPMP, the future of pharmacy, length of the routine pharmacy inspection report, barriers to using statewide protocols, report on innovative pilot programs, and major challenges facing the profession or agency.

ACTION ITEM: **Ms. Juran will consult with the Chairman regarding a possible December full board meeting agenda item to re-discuss if the Board would like to convene a Retreat, and if so, the development of the agenda. Ms. Juran will gather information from previous Board retreats and the topics suggested by the Board members during last year's survey.**

ADJOURN: With all business concluded, the meeting adjourned at 12:25PM.

_____
Caroline Juran, RPh
Executive Director

_____
DATE

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, December 3, 2024
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233

CALL TO ORDER:	A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 9:05 am.
PRESIDING:	Cheri Garvin, Committee Chairman
MEMBER PRESENT:	Ling Yuan, Committee Member
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Jess Weber, DHP Adjudication Specialist Tim Reilly, Compliance & Innovative Pilot Program Manager
SENTARA RMH MEDICAL CENTER PHARMACY	Julia Bynaker, Pharmacy Team Coordinator, Pharm D, BCPS, Laura Adkins, Pharmacy Manager, Pharm D, BCPS, and Brenton Campbell, Pharmacy Resident, Pharm D, appeared in person to discuss the proposed innovative pilot program "Emergency Department Starter Pack Dispensing" as stated in the Notice dated November 18, 2024**.**
DISCUSSION:	Representatives of Sentara RMH Medical Center Pharmacy presented information related to the application for use of a Starter Pack Dispensing.
DECISION:	Upon a motion by Cheri Garvin, and duly seconded by Ling Yuan, the Committee decision was unanimous to deny the innovative pilot program for "Emergency Department Starter Pack Dispensing".
	With all business concluded, the meeting adjourned at 10:50 am.

Caroline D. Juran
Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of December 2, 2024

In the Governor's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	3/29/2017	2385 days; 7.9 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-21	Proposed	2023 pharmacists initiating treatment	4/4/2024	7 days	Implements legislation from 2023 Session regarding pharmacists initiating treatment

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	974 days 2.7 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	974 days 2.7 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and

					registration of pharmacy technicians
18VAC110-21	Fast-Track	Repeal of outdated sections	4/18/2023	474 days	Repeals outdated regulations regarding pharmacy technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	465 days	Implements changes identified during the periodic review process
18VAC110-20	Fast-Track	Amendment to clarify application of 18VAC110-20-735	6/21/2023	461 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	238 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation
18VAC110-20	Final	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	7/8/2024	126 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-20	Emergency/ NOIRA	Requirements for use of central fill pharmacy and remote database	7/8/2024	83 days	Implements requirements of Chapter 407 of the 2024 Acts of Assembly.

18VAC110-20	Final	Exemption of ADDs stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555	10/1/2024	54 days	Response to a petition for rulemaking to allow certain ADDs exemption from requirements under regulations
18VAC110-20	NOIRA	Exclusion of private dwellings or residences from operating locations of CSRs	10/1/2024	53 days	Excludes private residences from operating locations of CSRs, similar to pharmacy permit exclusions.

In the Department of Planning and Budget

None.

In the Office of the Attorney General

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Fast-track	Replacement of analytic lab regulation for pharmaceutical processors	5/15/2024	201 days	Replaces the former 18VAC110-60-300(A) into Board of Pharmacy regulations as required by Virginia Code § 4.1-1602
18VAC110-15	Fast-track	Amendment to allow agency subordinates to hear credentials cases	10/1/2024	62 days	Conforms regulatory language to changes in the Virginia Code.
18VAC110-20	Exempt/ Final	September 2024 scheduling of chemicals in Schedule I	10/1/2024	62 days	Implements scheduling as recommended by DFS.

18VAC110-20	Exempt/ Final	Accessible prescription labels	10/1/2024	62 days	Implements legislation from the 2024 General Assembly Session.
18VAC110-20	Exempt/ Final	September 2024 action to conform state schedules to federal schedule changes	10/1/2024	62 days	Coordinates state regulatory schedules with federal regulatory changes.

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC110-20	Emergency/ NOIRA	Crisis stabilization services and use of automated dispensing systems and remote dispensing systems	8/26/2024	Emergency regulations effective 8/12/2024 – 2/11/2026. Proposed stage before the Board for action.
18VAC110-20	Emergency/ NOIRA	Allowances for emergency drugs by EMS agencies	9/9/2024	Emergency regulations effective 8/20/2024 – 2/19/2026. Proposed stage before the Board for action.
18VAC110-21	Final	2022 pharmacists initiating treatment	10/21/2024	Effective 11/20/2024 (replaces emergency regulations)
18VAC110-20	Proposed	Pharmacy working conditions	11/18/2024	Public comment period 11/18/2024 – 1/17/2024. Board will vote on final regulations at March 2025 meeting.
18VAC110-20	Proposed	Increase in fees	12/30/2024	Public hearing on proposed changes today; comment

18VAC110-21 18VAC110-30 18VAC110-50				period until 2/28/2025. Board will vote on final action in March.

Agenda Item: Adoption of proposed stage regulatory amendments regarding allowances for emergency drugs by EMS agencies

Included in your agenda package:

- Draft proposed stage regulations as recommended by the Regulatory Committee following review of public comment;

- Public comments received following the publication of the emergency/NOIRA stage of the regulatory process.

Action needed:

- Motion to either:
    - Accept the recommendation of the Regulatory Committee (changes highlighted in yellow); or
    - Adopt proposed regulatory amendments regarding allowances for emergency drugs by EMS agencies as further amended by the Board.

Project 7873 - Proposed

Board of Pharmacy

Allowances for emergency drugs by EMS agencies

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"Acquisition" of an existing entity permitted, registered, or licensed by the board means (i) the purchase or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor or change in partnership composition; (iii) the acquiring of 50% or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; or (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity with another business or corporation.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any

recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be ~~assured~~ ensured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or the prescriber's designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Designated location" means a station, EMS agency substation or satellite location, or other location approved by the DEA, if applicable, and designated by an EMS agency or regional EMS council.

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

1. Variation from the prescriber's prescription drug order, including:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

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

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

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

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

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

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedules II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300.

"Emergency medical services provider" or "EMS provider" means the same as defined in 12VAC5-31-10.

"Emergency medical services vehicle" or "EMS vehicle" has the same meaning prescribed in § 32.1-111.1 of the Code of Virginia.

"EMS agency" ~~means emergency medical services~~ has the same meaning as prescribed in § 32.1-111.1 of the Code of Virginia.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"Faxed prescription" means a written prescription or order that is transmitted by an electronic device that sends over telephone lines the exact image to the receiver (pharmacy) in a hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Hospital-owned" means, with respect to an EMS agency, owned by a hospital.

"Initials" means the first letters of a person's name or other unique personal identifier.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Other EMS vehicle" means a vehicle used by the EMS agency or regional EMS council for the purpose of providing or facilitating emergency medical care or transporting controlled substances to and from the registered and designated locations. Such vehicles must be either owned by or registered to an EMS agency, regional EMS council, or jurisdiction and operated by an EMS agency or regional EMS council.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing, and storage of all Schedules II through VI drugs and devices and any Schedule I investigational drug.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts

that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Regional EMS council" means an organization designated by the State Board of Health pursuant to § 32.1-111.4:2 of the Code of Virginia.

"Registered EMS agency headquarters" means the principal office and primary business location of an EMS agency that maintains a controlled substances registration issued by the board or a hospital-owned EMS agency that is covered by the registration of a hospital.

"Registered location" means, for the purposes of emergency medical services, a location that appears on a DEA certificate of registration or controlled substances registration issued to an EMS agency or regional EMS council, which shall be the location at which the agency or council receives Schedules II through VI controlled substances from those entities authorized to distribute controlled substances.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, compounding, labeling, dispensing, or distribution of medications and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration

of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Station" means an enclosed structure that houses one or more EMS vehicles or other EMS vehicles in the state in which the EMS agency is registered that is actively and primarily being used for emergency response by the EMS agency.

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

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is controlled between -25° and -10°C (-13° and 14°F). In those instances in which articles may have a recommended storage condition below -20°C (-4°F), the temperature of the storage location should be controlled to plus or minus 10 degrees.

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

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

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

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

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

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

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for ~~his~~ that person's own use or for the use of a member of ~~his~~ that person's household or for an animal owned by ~~him~~ that person or a member of ~~his~~ that person's household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

"USP-NF" means the United States Pharmacopeia-National Formulary.

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

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

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

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

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

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

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

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

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

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

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

a. The record of filling and verifying the kit to include the drug contents of the kit, the initials of the pharmacist verifying the contents, the date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit, which shall be

no later than the expiration date associated with the first drug or device scheduled to expire.

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-20-505. Use of radio-frequency identification.

A. A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for ~~licensed~~ emergency medical services pursuant to ~~18VAC110-20-500~~ 18VAC110-20-591 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of ~~a~~ an RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs, and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist, verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in subsection C of 18VAC110-20-490, subsection A of 18VAC110-20-460, and subsection A of 18VAC110-20-355.

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

B. A registered EMS agency headquarters, regional EMS council, or designated location of the EMS agency or regional EMS council may use RFID to verify the accuracy of drugs placed into a kit for emergency medical services under the following conditions:

1. An EMS supervising practitioner or responsible party shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of an RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A person authorized to administer drugs or a pharmacy technician may place the RFID tag on the drugs, and the EMS responsible party or designee authorized to administer drugs shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A person authorized to administer drugs or a pharmacy technician may remove RFID-tagged drugs from the EMS inventory whose RFID tags have been previously verified for accuracy by the EMS responsible party or designee authorized to administer drugs and place the drugs into the kit's container. A person authorized to administer drugs may then place the container into the device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. An EMS responsible party or designee authorized to administer drugs shall perform a weekly random check for verification of the accuracy of 5.0% of all kits prepared that week utilizing RFID technology. A manual or electronic record from which information can be readily retrieved shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of the EMS responsible party or designee authorized to administer drugs verifying the accuracy of the process.

5. All records required by this subsection shall be maintained for a period of one year from the date of verification by the EMS responsible party or designee authorized to administer drugs.

18VAC110-20-591. Allowances for emergency medical services agencies to obtain drugs.

A. This section contains specific provisions by which an EMS agency may obtain drugs for administration.

B. Unless prohibited by federal law, a pharmacy may prepare a kit for an EMS agency, provided:

1. The PIC of the pharmacy shall be responsible for all prescription drugs contained in this kit. Except as authorized in 18VAC110-20-505, a pharmacist shall (i) check each kit after filling and (ii) initial the filling record certifying the accuracy and integrity of the contents of the kit.

2. The kit containing drugs in Schedules II through V is sealed, secured, and stored in such a manner that will deter theft or loss of drugs and aid in detection of theft or loss. Kits containing only drugs in Schedule VI are not required to be sealed but must be secured in a manner to deter theft or loss.

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

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

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

3. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The EMS provider shall make a record of all drugs administered to a patient.

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the drug kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV, or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV, or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

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

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

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

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

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

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

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

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

11. Drug kits shall be secured on the EMS vehicle or other EMS vehicle at all times, unless the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service. The EMS agency is not required to obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia to participate in a pharmacy kit exchange in accordance with this section unless the EMS agency needs to temporarily store a secured drug kit within the EMS building when a vehicle is incapable of maintaining appropriate drug storage temperature or is out of service and the EMS agency does not otherwise serve as a designated location of a current, active controlled substances registration. An alarm system consistent with requirements in 18VAC110-20-710 is not required under these conditions.

C. An EMS agency or regional EMS council that has been issued a controlled substances registration pursuant to 18VAC110-20-690 G and a registration from DEA in accordance with federal law may receive drugs in Schedules II through VI and deliver or transfer the drugs to any designated location of the registered EMS agency headquarters or regional EMS council. Delivery of the drugs shall not constitute wholesale distribution.

D. For sites that are not designated locations of the entity providing the drug, nothing shall preclude a hospital, EMS agency, or regional EMS council from transferring or distributing drugs in Schedule VI to another EMS agency, regional EMS council, or a designated location of either entity during a shortage of drugs or in an emergency.

E. A hospital, EMS agency, regional EMS council, and designated locations may deliver drugs in Schedules II through V to each other consistent with federal law in the event of shortages of such drugs, a public health emergency, or a mass casualty event. All entities transferring, delivering, and receiving drugs shall comply with recordkeeping requirements listed in 18VAC110-20-721.

F. In compliance with federal law, a hospital pharmacy may provide drugs to a hospital-owned EMS agency operating as an extension of the hospital pharmacy's DEA registration.

G. If an EMS agency that is not hospital owned has obtained a controlled substances registration and a DEA registration in accordance with federal law, a pharmacy may provide that EMS agency drugs for restocking an EMS vehicle or other EMS vehicle, provided all of the following criteria are met:

1. The registered or designated location of the agency operating the EMS vehicle or other EMS vehicle maintains the record of receipt of drugs in accordance with state and federal law.

2. The pharmacy maintains a record of the delivery to the EMS agency in accordance with state and federal law.

3. If the EMS vehicle or other EMS vehicle is primarily situated at a designated location of an EMS agency, the designated location notifies the registered location of the agency within 72 hours of the EMS vehicle or other EMS vehicle receiving drugs in Schedules II through V.

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

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

6. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs, such Schedule VI drugs shall remain in a separate container.

H. Schedule VI drugs stored on an EMS vehicle or other EMS vehicle are not required to be stored in a sealed kit, but must be stored in a manner to deter theft or loss. Drugs in Schedules II through V stored on a ground EMS vehicle, other EMS vehicle, or EMS vehicle that is a licensed fixed-wing aircraft shall be stored in a sealed, secured kit or device within a locked cabinet that is accessible from the patient compartment of the vehicle. Drugs in Schedules II through V stored on an EMS vehicle that is a licensed rotary aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.

1. The method of sealing the kits shall ensure that once the seal is broken, it cannot be reasonably resealed without the breach being detected.

2. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The EMS registered agency headquarters, regional EMS council, or designated location sealing and resealing the kit shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

3. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by EMS personnel may be used.

I. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall implement a process to review expiration dates no less often than every three months to ensure drugs are not administered beyond the expiration date.

J. Registered EMS agency headquarters, regional EMS councils, and designated locations of the registered EMS agency headquarters or regional EMS councils shall perform drug inventories and report drug theft or unusual loss to the board in accordance with § 54.1-3404 of the Code of Virginia.

K. Registered EMS agency headquarters and regional EMS councils shall audit the security of the drug storage location and perform a random audit of Schedules II through V drugs and required recordkeeping for accuracy at least every six months at each designated location under the controlled substances registration. Documentation verifying the completion of the audit for each designated location shall be maintained at the registered EMS agency headquarters or regional EMS council for two years from the date performed.

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'~~ manufacturer 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, and regional EMS councils, 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.

G. The board may issue a controlled substances registration to an EMS agency or regional EMS council to receive controlled substances in Schedules II through VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The EMS agency or regional EMS council shall identify to the board any designated location to which the EMS agency or regional EMS council may deliver controlled substances. The EMS agency or

regional EMS council shall also obtain a registration from DEA in accordance with federal law prior to delivery of Schedules II through V drugs. The EMS agency or regional EMS council shall identify on the controlled substances registration application the name and physical address of the designated locations and attest that each designated location of the EMS agency or regional EMS council complies with the storage and security requirements of 18VAC110-20-710. Any changes to the designated locations shall be submitted to the board in advance of delivering or ceasing to deliver controlled substances to that location and the designated locations must be approved sites under federal law.

H. An EMS agency receiving only Schedule VI drugs from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy or temporarily storing a secured drug kit within the EMS building when the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service shall obtain a controlled substance registration or operate as a designated location of a registered EMS agency headquarters.

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'~~ manufacturer's 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~~ the controlled substances registrant 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. A registered EMS agency headquarters or regional EMS council may store controlled substances in an automated dispensing device that is located at a secured site at the registered location or designated location of the EMS agency or regional EMS council that is (i) installed and operated by the EMS agency or regional EMS council, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law.

F. 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~~; registered EMS agencies or regional EMS councils, or designated locations of registered EMS agency headquarters or regional EMS councils stocking only ~~intravenous fluids with no added drug,~~ Schedule VI drugs or temporarily securing a secured drug kit that may contain Schedules II through VI drugs when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; 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.

G. A registered EMS agency headquarters or regional EMS council may store controlled substances at any of the following secured locations:

1. A registered location of the EMS agency or regional EMS council;

2. A designated location of the EMS agency or regional EMS council of which the board has been notified and DEA has granted approval if stocking drugs in Schedules II through V;

3. In an EMS vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional EMS council [or other location where an EMS agency approves an EMS vehicle to be stored] ; or

4. In an EMS vehicle or other EMS vehicle used by the EMS agency that is traveling from or returning to a registered location or designated location of the EMS agency or EMS council [or other location where an EMS agency approves an EMS vehicle to be stored] in the course of responding to an emergency or otherwise actively in use by the EMS agency.

H. Drugs secured in an EMS agency, regional EMS council, EMS vehicle, or other EMS vehicle shall be stored at an appropriate temperature pursuant to manufacturer's directions at all times. If the EMS vehicle or other EMS vehicle cannot maintain appropriate temperature or is out of service, the drug kit may be temporarily maintained within the building of the EMS agency. The drug kit shall be stored in compliance with this section.

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~~ Schedules II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia to include the reporting of any drug theft or unusual loss 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~~ Except as provided in subdivision 9 of this section, 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~~ that 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~~ that 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.

6. Documents that describe the conditions and extent of the responsible party's authorization to dispense controlled substances for each EMS provider employed by or practicing at an EMS agency holding a controlled substances registration. Such documents shall be maintained in a readily retrievable manner and be available for inspection and copying by authorized agents of the board. Examples of such documentation include protocols, practice guidelines, or practice agreements.

7. Records of all controlled substances that are received, administered, or otherwise disposed of, records of deliveries of controlled substances between all locations of an EMS agency or regional EMS council pursuant to the controlled substance registration, and record of the standing or verbal orders issued or adopted.

8. Documentation verifying the completion of audit for each designated location pursuant to 18VAC110-20-591 K.

9. Records required to be maintained by an EMS agency or regional EMS council shall be maintained, whether electronically or otherwise, pursuant to subdivision 2 of this section or at each registered location, designated location of the EMS agency, or regional EMS council where the controlled substances involved are received, administered, or otherwise disposed of for two years from the date of execution of the record.

18VAC110-20-721. Additional recordkeeping requirements for EMS agencies.

A. Each EMS agency holding a controlled substances registration or serving as a designated location of an EMS agency or regional EMS council, including a hospital-owned EMS agency operating under a hospital registration, responsible for administering a drug must maintain written standing protocols signed by the operational medical director for the EMS agency that authorize the administration. Oral orders authorizing the administration shall be reduced to writing by the EMS provider and shall be signed by a medical practitioner and maintained by the EMS entity responsible for administering the drug.

B. A record for each dose of drug in Schedules II through VI administered and destruction of partially administered drug in the course of providing emergency medical services must also be maintained. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Except as indicated in 18VAC110-20-591 for emergency drug kits provided by a pharmacy, documentation shall be maintained in the EMS agency or the designated location of an EMS agency or regional EMS council for a period of two years from the date of destruction.

C. The following records shall be maintained for each acquisition of a drug in Schedules II through VI from another registrant of the board or each distribution of a drug in Schedules II through VI to another registrant of the board:

1. For each acquisition of a drug from another registrant:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of commercial containers acquired;

e. Date of the acquisition;

f. Name, address, and registration number of the person from whom the substance was acquired; and

g. Name and title of the person acquiring the drug.

2. For each distribution of drug in Schedules II through VI to another registrant:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of commercial containers distributed;

e. Date of the distribution;

f. Name, address, and registration number of the person to whom the substance was distributed; and

g. Name and title of the person in receipt of the distributed drugs.

3. For each delivery of drug in Schedules II through VI between a designated location and a registered location:

a. Name of the drug;

b. Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

d. Number of units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial);

e. Date of the delivery;

f. Name and address of the designated location to which the substance was delivered; and

g. Name and title of the person in receipt of the controlled substances.

4. For destruction of a drug in Schedules II through VI, unless otherwise authorized under federal law, expired or unwanted drugs shall be transferred to another person or entity authorized to possess or provide for proper disposal of such drugs.

D. A designated location of an EMS agency that receives drugs in Schedules II through V must notify the EMS agency's registered location within 72 hours of receipt of the drugs in the following circumstances:

1. An EMS vehicle or other EMS vehicle primarily situated at a designated location of the EMS agency acquires drug from a hospital while restocking following a response; or

2. The designated location of the EMS agency receives drugs from another designated location of the same agency.

E. To the extent permitted by federal law, registered EMS agency headquarters, regional EMS councils, or designated locations of the EMS agency or regional EMS council in which the repackaging or prepackaging of over-the-counter drugs is performed shall maintain adequate control records for a period of one year or until the expiration of the drugs, whichever is greater.

1. The records shall show the name of the drugs used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist, EMS responsible party, or designee authorized to administer drugs verifying the process; the assigned lot or control number; the manufacturer or distributor name and lot or control number; and an expiration date.

2. Any subsequently repackaged units shall show the name of the drug; strength, if any; the assigned lot or control number or the manufacturer or distributor name and lot or control number; and an appropriate expiration date determined by the pharmacist, EMS responsible party, or designee authorized to administer drugs in accordance with USP guidelines.

3. Repackaging of drugs shall be performed in compliance with USP-NF standards.

Action: Allowances for emergency drugs by EMS agencies [6452 / 10312]			
Commenter	**Title**	**Comment**	**Date/ID**
Bolar Volunteer Rescue Squad	Drugbox on Rapid Response Unit	Iam writing this comment because Iam Rescue Captain of Bolar Volunteer Rescue Squad in Bolar Virginia. We cover Southeren Highland and Northern Bath Counties. I live 14 minutes from on Station. I keep a VAOEMS Certified First Responder Unit at my house locked up and shore line plugged in. Where we live we have no cellular service and our radios are limited on the power that our repeaters can transmit on because of the NARO over in Greenbank, WVA. We are trying to get the board to realize the importance of saving lives, if our First Responder Unit could be equipped with a BLS Schedule 6 box. We have the temperature controlled unit, on Responder 9. When it is 45 minutes to 60 minutes before an epipen can be administered to a patient, and yes I have been in this situation before this ruling could save countless lives. Please help us help our community Matthew Ratcliffe Bolar Volunteer Rescue Squad Chief	10/3/24 6:06 pm CommentID:228049
Ryland Kendrick, Stafford County Fire & Rescue	Medication storage	The transition away from hospital-supplied sealed drug kits (and especially sealed narcotics kits) is a great challenge but also may have some benefits going forward. My own experience has been that sealing all the controlled medications in one catch-all bag has had some unintended negative consequences due to the inevitable out of sight/out of mind effect. Clinicians were not able to handle and inspect the vials, and there were measurable decreases in pain medication use based on the less accessible nature (and increased restocking time) of the multiple-medicine kits. 18VAC110-20-591 section 6H refers to keeping Schedules II-V drugs in "sealed, secured kit or device" but does not provide further detail and the terms are not in the Definitions section. Our goal is to track at the individual vial level, and also make sure the medications are easy to account for (to identify any problems as soon as possible). Under the old system when we carried all our controlled meds in a single sealed bag provided by the hospital, it prevented us from tracking except at the bag level, and also made close examination of each vial difficult if not impossible. We consulted a DEA Diversion Investigator and a pharmacist and proposed storing all medications in a single box, with each Sched II-V drug vial separately sealed in its own individual bar-coded tamper-evident bag (clear so we can monitor each vial), with the entire drug box locked in our access-controlled compartment in the EMS vehicle? We were trying to set up functional controlled medication kits, i.e. seizure kit, sedation kit, pain kit, to help our clinicians and increase medication accountability, and for regulatory purposes each kit would be both sealed and secured. Both the DEA Investigator and the pharmacist agreed these were compliant and secure solutions	10/8/24 5:45 pm CommentID:228077

		(although not the same as the traditional all-in-one solution). Our goal was to keep the controlled medications secure but easier to visually access, inspect, and verify/account for by sealing and storing them individually, which would also coincidentally reduce barriers to use to benefit patients, and reduce medication error potential by separating the often very similar vials. Could the language in the regulations be revised to provide more clarity on this aspect of storage?	
John M. Montgomery, President, Highland County Volunteer Rescue Squad	Drug Boxes on Quick Response Vehicles in Rural Areas	The Highland County Volunteer Rescue Squad ("HCVRS") has been operating two Quick Response Vehicles ("QRV's") in Highland County for a number of years to try to speed response times in our rural and very mountainous county. The County is one of the largest counties in Virginia by land mass, but is the least populated county, with a population of around 2000 residents. Additionally, the County has several mountain ranges with valleys in between, making cross-county transport time-consuming and difficult. Accordingly, it poses a great challenge to HCVRS and the Highland Emergency Medical Service ("HEMS") to reach remote citizens with challenging medical needs. Each of our QRV's is equipped with full drug boxes to address the most critical patients. Each QRV has the full capability of our ambulance units, with the single exception of the ability to transport patients. The QRV's are located in Blue Grass and in McDowell, and the main transport units are located in Monterey, the county seat. It has come to our attention that the Board of Pharmacy has expressed concern about the storage of drug boxes on the QRV units. With respect, if the Board of Pharmacy disallows the drug boxes on our QRV units, it will significantly increase response times and puts patients' lives in danger. The QRV units are locked at all times, and are equipped with auxiliary power connections to maintain the temperature of the drug boxes on the QRV units. The drug boxes within the QRV units are also locked. Accordingly, the units are double-locked and secured with power connections, as they would be in any of our EMS bays. HCVRS is prepared to register the locations of the QRV units as contemplated by the proposed regulations, but wishes to convey how critical these QRV units are to the response times in our rural area, and for our ability to meet the emergency medical needs of our community.	10/8/24 9:16 pm CommentID:228080
Anonymous	Reduction of Fire Station Security Requirements	I recommend reducing the stringent security requirements for the storage of Schedule II-V controlled substances by updating regulations to explicitly allow DEA-compliant storage systems, such as Automated Dispensing Machines (ADM). Including ADM and other DEA-compliant technologies in the approved methods for storage and exchange would streamline operations,	10/9/24 12:31 pm CommentID:228085

		enhance efficiency, and maintain the necessary safeguards to prevent diversion and unauthorized access. The current security requirements for SII-V are cost prohibitive for agencies and reduce EMS access for medication exchange in both urban and rural communities.	
Debbie Trible, Highland County Vol Rescue Squad	QRV	Highland County is 416 square miles of rugged mountainous terrain with a ridge and valley topography. A location five miles away can easily be a thirty-minute drive. Our volunteer rescue squad has developed a fleet of Quick Response Vehicles parked at a volunteer home. Each unit has the same equipment as an ambulance, with the exception of a stretcher. These units, all equipped with a drug box, respond locally while an ambulance responds from a more distant central location. A trained volunteer arriving quickly on scene can provide lifesaving/stabilizing medications...IF THEY HAVE A DRUG BOX IN THE UNIT. Removing the drug box from our QRV units will completely undo years of hard work creating a best result Emergency Services System and ***will result in a significantly elevated risk of death, serious injury, or complications for our local residents and visitors***. This is unacceptable. One size does not fit all. We are well over an hour to the nearest suitable hospital. Our QRV fleet allows our providers to stabilize a patient earlier in the process while the ambulance is on the way. Our county has a small population and cannot afford to fund and staff Emergency Services stations throughout the county. Instead, we utilize volunteers and FULLY EQUIPPED QRV's to produce good outcomes for our residents.	10/9/24 4:59 pm CommentID:228089

Agenda Item: Consideration of resubmission of final action for exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555

Included in your agenda package:

- Draft revised final regulatory language regarding exemption of ADDs stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555.

Staff note: The Board voted on final regulations for this action at its September meeting. The action has been proceeding through executive branch review.

Stakeholders approached staff and indicated issues with the adopted final amended language. The revisions provided in this agenda packet address the stakeholders' issues.

Because the action is under executive branch review, the Board's option is to withdraw the final stage action and adopt revised final regulatory amendments. The action will be resubmitted for executive branch review with revisions.

Action needed (2):

- Motion to withdraw the final action regarding exemption of ADDs stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555.

- Motion to adopt revised final regulatory amendments as presented.

Project 7251 – Potential Revised Final

Board of Pharmacy

Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555

18VAC110-20-555. Use of automated dispensing devices.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber~~,~~ or a registered pharmacy technician for the purpose of stocking or reloading.

4. 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 under the following conditions:

a. ~~A~~ No drug~~, including a drug that would be stocked in a stat drug box pursuant to subsection B of 18VAC110-20-550,~~ may ~~not~~ be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order [except as provided in subsection 4 c] .

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 or a stat drug box pursuant to subsection B of 18VAC110-20-550 may be accessed [~~after the pharmacist has reviewed the prescription order but~~] [pursuant to a valid prescription or lawful order of a prescriber and] prior to receiving electronic authorization from the pharmacist, provided that the absence of the [~~drugs~~ emergency drug] would threaten the survival of the ~~patients~~ patient or that a delay in administration of the [stat] drug could result in harm to the patient.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

7. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

8. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

9. 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 PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

10. The PIC of the provider pharmacy or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution and administration 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 drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or ~~his~~ the PIC's 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.

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

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. 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.

11. 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.

12. Personnel allowed access to an automated dispensing device shall have a specific access code ~~which~~ that records the identity of the person accessing the device.

13. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and ~~assure~~ ensure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing

system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and ~~assuring~~ ensuring compliance with the requirements of this chapter. The manual shall be ~~capable of being accessed~~ accessible at both the pharmacy and the nursing home.

14. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home, except:

a. Manual Schedule VI distribution records 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 storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically, provided:

(1) 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.

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

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

c. Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 14 a and 14 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained offsite or electronically, provided that (i) they can be readily retrieved upon request; ~~provided~~ (ii) they are maintained in a read-only format that does not allow alteration of the records; and ~~provided~~ (iii) 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.

Agenda Item: Adoption of proposed stage regulatory changes for crisis stabilization units

Included in your agenda package:

- Draft proposed stage regulations with changes adopted by the Regulatory Committee; and

- Town Hall summary page showing no comments on the emergency/NOIRA stage.

Staff note: The Department of Planning and Budget questioned during the administrative review process if the language in 18VAC110-20-490(B)(3) regarding maintenance of a key to access an ADD or RDS should be added to 18VAC110-20-555 for consistency. Refer to the draft minutes of the Regulatory Committee meeting included in this agenda packet for background. The Committee ultimately recommended that the draft language in 18VAC110-20-490(B)(3) should be removed. The Regulatory Committee also recommended incorporating amendments to 18VAC110-20-700 in this regulatory action to ensure pharmacy technicians may access these devices in a CSU.

Changes made by the Regulatory Committee are indicated by brackets.

Action needed:

- Motion to accept recommendation of the Regulatory Committee and adopt proposed regulatory changes as presented; or

- Motion to adopt proposed regulatory changes as amended by the Board.

Project 7883 - Proposed

Board of Pharmacy

Crisis Stabilization Services and Use of Automated Drug Dispensing Systems and Remote Dispensing Systems

18VAC110-20-200. Storage of drugs, devices, and controlled paraphernalia; expired drugs.

A. Prescriptions awaiting delivery. Prescriptions prepared for delivery to the patient may be placed in a secured area outside of the prescription department, not accessible to the public, where access to the prescriptions is restricted to individuals designated by the pharmacist. With the permission of the pharmacist, the prepared prescriptions may be transferred to the patient at a time when the pharmacist is not on duty. If a prescription is delivered at a time when the pharmacist is not on duty, written procedures shall be established and followed by the pharmacy that detail security of the dispensed prescriptions and a method of compliance with counseling requirements of § 54.1-3319 of the Code of Virginia. Additionally, a log shall be made and maintained of all prescriptions delivered to a patient when a pharmacist is not present to include the patient's name, prescription number, date of delivery, and signature of the person receiving the prescription. Such log shall be maintained for a period of one year. Notwithstanding the provisions of this subsection, prescriptions prepared for delivery to the patient may also be secured in an area outside of the prescription department in a remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490.

B. Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe or maintained in a manner that combines the two methods for storage. The cabinet, drawer, or safe

may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.

C. Safeguards for controlled paraphernalia and Schedule VI medical devices. Controlled paraphernalia and Schedule VI medical devices shall not be placed in an area completely removed from the prescription department whereby patrons will have free access to such items or where the pharmacist cannot exercise reasonable supervision and control.

D. Expired, or otherwise adulterated or misbranded drugs; security. Any drug that has exceeded the expiration date or is otherwise adulterated or misbranded shall not be dispensed or sold; it shall be separated from the stock used for dispensing. Expired prescription drugs shall be maintained in a designated area within the prescription department until proper disposal.

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

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

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner~~,~~ or have a written contract or agreement specifying the services to be

provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

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

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

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

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

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

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

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

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

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

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200 and subsection A of 18VAC110-20-490, if applicable.

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

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

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

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

b. Procedure for providing counseling;

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

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

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

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

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

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

F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

1. To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to

where the drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, remote dispensing system as defined in § 54.1-3401 of the Code of Virginia and pursuant to subsection A of 18VAC110-20-490, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with inherited bleeding disorders who may require therapy to prevent or treat bleeding episodes.

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

A. A hospital, state facility as defined in § 37.2-100 of the Code of Virginia that is established pursuant to Title 37.2 of the Code of Virginia, facility as defined in § 37.2-100 of the Code of Virginia that is licensed by the Department of Behavioral Health and Developmental Services and provides site-based crisis stabilization services, or other facility authorized by the board may use automated ~~devices~~ drug dispensing systems and remote dispensing systems 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. Unless prohibited under federal law, a remote dispensing system that solely stores drugs labeled and verified by the provider pharmacist for patients to obtain medication may be placed within close proximity of a permitted pharmacy or at a location issued a controlled substance registration pursuant to § 54.1-3420.2 of the Code of Virginia in a secure area under constant surveillance to ensure security of drugs, confidentiality of protected health information, and appropriate recordkeeping.

B. Policy and procedure manual; access codes.

1. Proper use of the automated drug dispensing ~~devices~~ system and remote dispensing system 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 drug dispensing ~~device~~ system and remote dispensing system shall have a specific access code ~~that records~~ or other means to record 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.

[~~3. If a key may be used to access the automated drug dispensing system or remote dispensing system and the provider pharmacy is not located within the facility, a key may be maintained in the possession of the director of nursing or an individual designated by the director of nursing who is licensed to administer medications.~~]

C. Distribution of drugs from the pharmacy.

1. Except when the automated drug dispensing system or remote dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside

of the hospital or facility it services shall first obtain a controlled substance registration issued in the name of the pharmacy at the address of the hospital or facility and a registration from the Drug Enforcement Administration, if required, prior to stocking controlled substances in Schedules II through VI.

2. Drugs authorized pursuant to § 54.1-3434.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Pharmacies using a remote dispensing device that only stores patient-specific dispensed drugs for patients to obtain medication may place pharmacist-verified dispensed drug into the device.

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

~~2.~~ 4. 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 drug dispensing ~~device~~ system or remote dispensing system 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 and dispensing of drugs from the device.

1. Automated drug dispensing ~~devices in hospitals~~ and remote dispensing systems 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 drug dispensing ~~device~~ system or remote dispensing system 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.

3. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope.

4. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 B on the label, medication envelope, or the medication run report.

5. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology to ensure accuracy of the dispensed drug.

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~~ the PIC's 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~~ the PIC's 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~~ system and remote dispensing system, to include procedures for timely termination of access codes when applicable, accuracy of distribution and dispensing from the device, and proper recordkeeping.

2. The PIC or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution and dispensing of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system 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~~ the PIC's designee shall conduct at least a monthly audit to review the dispensing and administration records of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system as follows:

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

b. The hard-copy distribution, dispensing, 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~~ the PIC's 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~~ the PIC's designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections. Automated drug dispensing ~~devices~~ systems and remote dispensing systems 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~~ the PIC's 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~~ the 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 or facility 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, dispensing, and administration records that are printed and reviewed in conducting required audits may be maintained at an ~~off-site~~ offsite 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 drug dispensing ~~device~~ system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-555. Use of automated dispensing devices and remote dispensing devices in nursing homes.

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems and remote dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system or remote dispensing system in a nursing home shall be under the control of the pharmacy providing services to the

nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A pharmacy that is not located within the nursing home ~~without an in-house pharmacy~~ it services shall obtain a controlled substances registration issued in the name of the pharmacy at the address of the nursing home and a registration from the Drug Enforcement Administration, if required, prior to ~~using an automated dispensing system~~ stocking drugs in Schedules II through VI, unless the automated drug dispensing system or remote dispensing system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. ~~For facilities not required to obtain a controlled substance registration, access~~ Access to the automated drug dispensing ~~device~~ system or remote dispensing system shall be restricted to a licensed nurse, pharmacist, or prescriber~~,~~ or a registered pharmacy technician ~~for the purpose of stocking or reloading~~ pursuant to designation by the PIC or pharmacist on duty.

4. Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated drug dispensing ~~device~~ system or remote dispensing system until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated drug dispensing ~~devices~~ systems and remote dispensing systems shall be capable of producing a hard-copy record of distribution and dispensing, if applicable, that shall show patient name, drug name and strength, dose or quantity withdrawn, dose to be administered, if applicable, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated drug dispensing ~~devices~~ systems shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

6. Drugs authorized pursuant to § 54.1-3434.02 of the Code of Virginia may be placed into and removed from automated drug dispensing systems or remote dispensing systems. Pharmacies servicing remote dispensing systems that package and label drugs for a specific patient may repackage drugs into bulk bins that are verified for accuracy by a pharmacist pursuant to 18VAC110-20-355. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with the labeling requirements in §§ 54.1-3410 and 54.1-3463 of the Code of Virginia and board regulations. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

7. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated drug dispensing ~~device~~ system and remote dispensing system, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

~~7.~~ 8. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

~~8.~~ 9. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

~~9.~~ 10. 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 drug dispensing ~~device~~ system or remote dispensing system is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

~~10.~~ 11. Remote dispensing systems that dispense patient-specific drugs into an envelope shall satisfy compliance with 18VAC110-20-340 if the medication is assigned an expiration date of no more than 48 hours from the date of the packaging in an envelope and is not self-administered.

12. Remote dispensing systems that dispense multiple medications into a single container for a specific patient shall include a medication description as set forth in 18VAC110-20-340 on the label, medication envelope, or the medication run report.

13. Pharmacist verification of a patient-specific dispensed drug as required in 18VAC110-20-270 from a remote dispensing system is waived if a pharmacist verified the drug placed in the bulk bin that is placed in the device and the device incorporates sufficient technology assistance to ensure accuracy of the dispensed drug.

14. The PIC of the provider pharmacy or ~~his~~ the PIC's designee shall conduct at least a monthly audit to review distribution ~~and~~, administration, and dispensing, if applicable, of Schedules II through V drugs from each automated drug dispensing ~~device~~ system and remote dispensing system 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 drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or ~~his~~ the PIC's 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.

c. The audit shall include a review of a sample of administration and dispensing records, if applicable, from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered and dispensed for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered or dispensed.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution, dispensing, 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.

~~11.~~ 15. Automated drug dispensing ~~devices~~ systems and remote dispensing systems 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.

~~12.~~ 16. Personnel allowed access to an automated drug dispensing ~~device~~ system or remote dispensing system shall have a specific access code ~~which~~ that records the identity of the person accessing the device.

~~13.~~ 17. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and ~~assure~~ ensure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system and remote dispensing system, accountability for and security of all drugs maintained in the ~~automated drug dispensing~~ system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and ~~assuring~~ ensuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

~~14.~~ 18. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records 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 storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) 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.

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

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

c. Schedules II through V distribution and delivery records may only be stored ~~offsite~~ off site or electronically as described in subdivisions ~~14~~ 18 a and ~~14~~ 18 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution ~~and,~~ administration, and dispensing records that are printed and reviewed in conducting required audits may be maintained ~~offsite~~ off site 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 drug dispensing ~~device~~ system or remote dispensing system being audited, the time period covered by the audit and review, and the initials of all reviewers.

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 drug dispensing [~~devices~~ systems or remote dispensing systems] , 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.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply for and obtain a controlled substances registration in order to maintain a stock of ~~Schedule~~ Schedules II through VI controlled substances for immediate treatment of patients in crisis. ~~Schedule II through V controlled substances shall not be stocked.~~ The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to ~~Schedule VI controlled substances and only~~ those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an ~~off-site~~ offsite database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. 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~~ that the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

Agency Department of Health Professions

Board Board of Pharmacy

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

Action: Crisis Stabilization Services and Use of Automated Drug Dispensing Systems and ...

Emergency/NOIRA Stage

Action 6460 / Stage 10323

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	6/27/2024 1:03 pm	Sync Text with RIS
Agency Background Document	5/15/2024	Upload / Replace
Attorney General Certification	6/27/2024	
Governor's Review Memo	8/6/2024	
Registrar Transmittal	8/11/2024	

Status	
Public Hearing	Will be held at the **proposed** stage
Governor's Review Needed By	12/10/2024
Emergency Authority	2.2-4011(B)
Attorney General Review	Submitted to OAG: 5/15/2024 Review Completed: 6/27/2024 Result: Certified
DPB Review	Submitted on 6/27/2024 Policy Analyst: Cari Corr Review Completed: 7/18/2024
Secretary Review	Secretary of Health and Human Resources Review Completed: 7/24/2024
Governor's Review	ORM Review: ORM Approved 8/6/2024 Governor Review Completed: 8/6/2024 Result: Approved
Virginia Registrar	Submitted on 8/11/2024 The Virginia Register of Regulations Publication Date: 8/26/2024 Volume: 41 Issue: 1
Comment Period	Ended 9/25/2024 0 comments

Effective Date	8/12/2024
Expiration Date	2/11/2026

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This person is the primary contact for this chapter.

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RIS System last updated this stage on 08/12/2024 at 9:36am

Agenda Item: Adoption of exempt regulatory action to place drugs and chemicals in Schedule I

Included in your agenda package:

- Recommendation from the Department of Forensic Science to add eight drugs and chemicals to Schedule I; and

- Draft regulatory language adding those chemicals to 18VAC110-20-322.

Action needed:

- Motion to adopted changes to 18VAC110-20-322 by exempt action.

COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

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To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: October 15, 2024
RE: **Recommendation for Expedited Scheduling of Controlled Substances**

Ms. Juran,

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified eight (8) compounds for recommended inclusion into the Code of Virginia.

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

1. **2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)benzimidazole (other names: metonitazepyne, N-pyrrolidino 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.

2. **2-[2-[(4-ethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N-ethylethanamine (other name: N-desethyl etonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

3. **N-(2-methylphenyl)-N-[1-(2-phenethyl)piperidin-4-yl]propanamide (other name: ortho-methylfentanyl),** 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.

Based on their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

4. **[3-[2-(diethylamino)ethyl]-1H-indol-4-yl] acetate (other names: 4-acetoxy-N,N-diethyltryptamine; 4-acetoxy DET; 4-AcO-DET; ethacetin),** 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.

5. **3-[2-(diethylamino)ethyl]-1H-indol-4-ol (other names: 4-hydroxy-N,N-diethyltryptamine; 4-hydroxy DET; ethocin),** 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.

6. **3-methylmethcathinone (other names: 3-MMC; metaphedrone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one),** 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 following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

7. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-INACA)**, 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.

8. **N-cyclohexyl-2-(1-pentylindol-3-yl)acetamide (other names: cyclohexyl-PIATA, CH-PIACA, CH-PIATA)**, 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.

Robyn Weimer
Chemistry Program Manager

Project 8124 - Final

Board of Pharmacy

December 2024 scheduling of chemicals in Schedule I

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 opioid.

a. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other name: N-desethyl 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.

b. 7-[(3-chloro-6-methyl-5,5-dioxo-11H-benzo[c][2,1]benzothiazepin-11-yl)amino]heptanoic acid (other name: Tianeptine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Cannabimimetic agent. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-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.

The placement of drugs listed in this subsection shall remain in effect until July 31, 2025, 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 compounds expected to have hallucinogenic properties in Schedule I of the Drug Control Act:

1. 1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA, 3C-P, 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), 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.

2. 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), 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.

The placement of drugs listed in this subsection shall remain in effect until August 28, 2025, 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. Compounds expected to have hallucinogenic properties:

a. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), 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. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), 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.

c. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), 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.

2. Compound classified as a cannabimimetic agent. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), 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 April 8, 2026, 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. The following compounds expected to have hallucinogenic properties:

a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine), 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. 4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP), 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.

c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), 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.

2. The following cannabimimetic agent: Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 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 April 8, 2026, unless enacted into law in the Drug Control Act.

E. 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. The following compounds classified as synthetic opioids:

a. **2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)benzimidazole (other names: metonitazepyne, N-pyrrolidino 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.

b. **2-[2-[(4-ethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N-ethylethanamine (other name: N-desethyl etonitazene),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

c. **N-(2-methylphenyl)-N-[1-(2-phenethyl)piperidin-4-yl]propanamide (other name: ortho-methylfentanyl),** 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. The following compounds expected to have hallucinogenic properties:

a. **[3-[2-(diethylamino)ethyl]-1H-indol-4-yl] acetate (other names: 4-acetoxy-N,N-diethyltryptamine; 4-acetoxy DET; 4-AcO-DET; ethacetin),** 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. **3-[2-(diethylamino)ethyl]-1H-indol-4-ol (other names: 4-hydroxy-N,N-diethyltryptamine; 4-hydroxy DET; ethocin),** 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. **3-methylmethcathinone (other names: 3-MMC; metaphedrone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one),** 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. The following compounds classified as cannabimimetic agents:

a. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-INACA)**, 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-cyclohexyl-2-(1-pentylindol-3-yl)acetamide (other names: cyclohexyl-PIATA, CH-PIACA, CH-PIATA)**, 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 17, 2026], unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of fast-track regulatory action to update scheduling regulation consistent with statutory changes

Included in your agenda package:

- Draft fast-track regulatory changes to 18VAC110-20-323.

Staff note: The drugs and chemicals removed from 18VAC110-20-323 have been added to the respective schedules in Code by the General Assembly over the last several years. These drugs and chemicals no longer need to be included in the regulatory schedules.

Action needed:

- Motion to adopt fast-track regulatory language to amend 18VAC110-20-323 as presented.

Project 8169 - Fast-Track

Board of Pharmacy

Removal of chemicals and drugs currently listed in both regulation and the Code of Virginia

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

1. ~~Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;~~

~~2. Adds Dronabinol ((-) delta-9-trans-tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;~~

~~3. Deletes naldemedine from Schedule II;~~

~~4. Deletes naloxegol and 6β-naltrexol from Schedule II;~~

~~5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);~~

~~6. Adds 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR) to Schedule I;~~

~~7. Adds 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA) to Schedule I;~~

~~8. Adds ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate) to Schedule I;~~

~~9. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl) to Schedule I;~~

~~10. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl) to Schedule I;~~

~~11. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;~~

~~12. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;~~

~~13. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;~~

~~14. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;~~

~~15. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl) to Schedule I;~~

~~16. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl) to Schedule I;~~

~~17. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl) to Schedule I;~~

~~18. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;~~

~~19. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl) to Schedule I;~~

~~20. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;~~

~~21. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl) to Schedule I;~~

~~22. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;~~

~~23. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl]- ethanamine (Flunitazene) to Schedule I;~~

~~24.~~ Deletes Samidorphan from Schedule II; and

~~25. Adds N-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine) to Schedule I;~~

~~26. Adds N-phenyl-N′-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate (other name: mesocarb) to Schedule I;~~

~~27. Adds 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol) to Schedule I;~~

~~28. Adds 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine) to Schedule I; and~~

~~29.~~ Adds zuranolone to Schedule IV.

Agenda Item: Adoption of guidance document regarding accessible labels

Included in your agenda package:

- Draft Guidance Document 110-14; and
- HB516 from the 2024 General Assembly Session.

Staff note: Guidance Document 110-14 was before the Board in September. The Board had received public comment regarding the draft document and sent the document to the Regulatory Committee to review for potential changes in response to public comments. The Regulatory Committee met on November 12 (refer to draft minutes included in this agenda packet) and considered the draft document, the purpose of a guidance document, and the public comment received. The Regulatory Committee recommended no changes to the draft document, that it be adopted by the Board as presented, and requested that staff contact VPhA and VSHP to request assistance in further educating pharmacists on best practices and technology options available for accommodating blind or low-vision patients.

Action needed:

- Motion to accept recommendation of the Regulatory Committee and adopt Guidance Document 110-14 as presented.

Virginia Board of Pharmacy

Dispensing Medications to Blind or Low-Vision Patients

In addition to complying with Virginia Code § 54.1-3410.3 and 18VAC110-20-351, pharmacists should refer to the United States Access Board at **https://www.access-board.gov/rx.html** for information regarding various delivery methods for providing accessible prescription drug container labels, best practices to use for all formats, and format-specific best practices such as for audible, braille, and large print labels. Pharmacists should ensure patients are counseled in compliance with Virginia Code § 54.1-3319 and in a manner that identifies and aids their understanding of how to properly use the accessible label or other accommodation provided. To assist the pharmacist and patient in determining the appropriate accommodation, a collaborative communication should occur. Additionally, the Board recommends that the pharmacy record the accommodation provided to each patient to ensure that all pharmacy personnel are aware of how to consistently provide patient care to each accommodated patient.

References

Va. Code § 54.1-3319
Va. Code § 54.1-3410.3
18VAC110-20-351

United States Access Board: **https://www.access-board.gov/rx.html**

CHAPTER 725

An Act to amend the Code of Virginia by adding a section numbered 54.1-3410.3, relating to prescription drugs; labels; blind and disabled users.

[H 516]

Approved April 8, 2024

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3410.3 as follows:

§ 54.1-3410.3. Accessible prescription labels.

A. For the purposes of this section, "prescription reader" means a device that is designed to audibly identify the prescription drug contained on the label of a prescription drug.

B. A pharmacy shall notify each person who identifies themselves or a patient as blind, visually impaired, or otherwise print disabled to whom a prescription drug is dispensed that an accessible prescription label or alternate accommodation is available to the person upon request at no additional cost.

C. If a person informs the pharmacy that he is blind, visually impaired, or otherwise print disabled, and the person requests an accessible prescription label or accommodation, as determined between the pharmacist and the patient, the pharmacy shall:

1. Upon request of a person for an accessible prescription label, provide the person, either at the pharmacy or through mail order, an accessible prescription label fixable to the bottle or container that:

a. Is available to the person in a timely manner comparable to other patient wait times and will remain available for at least the duration of the prescription;

b. Utilizes audible or large print labels or enclosures that are appropriate to the disability and preference of the person making the request;

c. Seeks to attain best practice standards established by the U.S. Access Board; and

d. Is compatible with a prescription reader; or

2. As determined between the pharmacist and patient, provide appropriate counseling and accommodation to the patient and dispense the medication in suitable packaging with sufficient labeling and other information.

2. That the Board of Pharmacy shall adopt initial regulations to implement the provisions of this act no later than December 31, 2024. The Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the provisions of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall consult with organizations of blind or low-vision consumers and other individuals who are blind, community pharmacists, and other pharmacy stakeholders to assist in the development of necessary regulations and shall provide an opportunity for public comment on the regulations prior to adoption.

3. That the Board of Pharmacy shall issue a guidance document identifying appropriate technologies, packaging, labeling, and counseling for dispensing medications to blind or low-vision patients. In developing guidance documents, the Board of Pharmacy shall consider best practices and formatting suggestions as published and revised by the U.S. Access Board.

Agenda Topic: Request from Gates Healthcare Associates, Inc. to recognize its inspection report as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Background: Currently inspection reports from the National Association of Boards of Pharmacy that satisfy the inspection report requirements of §54.1-3434.1 are the only deemed acceptable alternative. Refer to Guidance Document 110-38. This agenda topic was referred by the full board in September to the Regulation Committee for further consideration. The Regulation Committee voted unanimously to recommend to the full Board to approve Gates Healthcare Associates, Inc.'s request to recognize its inspection report of an out of state pharmacy as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board's own agent pending responses to the following questions: Which states currently accept a pharmacy inspection performed by Gates? Will the report include a list of deficiencies observed by the inspector at the time of the inspection, along with the pharmacy's corrective action to address the deficiencies?

Actions Needed:

- Discuss any verbal updates from staff regarding responses to questions.

- Vote on the Regulation Committee's recommendation to recognize Gates Healthcare Associates, Inc's inspection report of an out of state pharmacy as an acceptable alternative to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board's own agent.

Agenda Item: Revision of Guidance Document 110-38 to include non-resident outsourcing facilities

Included in your agenda package:

- Draft revised version of Guidance Document 110-38 in redline;
- Draft revised version of Guidance Document 110-38.

Action needed:

- Motion to revise Guidance Document 110-38 as presented, or further amended to include reference to Gates Healthcare Associates, Inc under non-resident pharmacy section.

Guidance Document 110-38 ~~Reaffirmed: March 30, 2021~~Revised: December 17, 2024

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies and Outsourcing Facilities to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy or nonresident outsourcing facility that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. ~~The law (Code of Virginia) provides:~~

~~**§ 54.1-3434.1. Nonresident pharmacies to register with Board.**~~

~~...~~

~~*As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.*~~

~~...~~

~~**§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.**~~

~~*As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.*~~

~~*The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.*~~

~~...~~

~~Revised: June 5, 2006, June 18, 2013, June 4, 2014, December 12, 2016~~

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For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

For a nonresident pharmacy, an application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of Virginia Code § 54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

An "opening" inspection report for a newly opened pharmacy or a new location for an existing pharmacy indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an "operational" inspection report shall be provided during the subsequent renewal of the registration. An "opening" inspection report for a newly opened pharmacy or a new location for an existing pharmacy performing sterile compounding shall not satisfy the requirements for obtaining initial registration or renewal as a nonresident pharmacy. Submission of an "operational" inspection report indicating compliance with USP-NF standards for sterile compounding shall be required for consideration for obtaining initial registration or renewal as a nonresident pharmacy.

For a nonresident outsourcing facility, an application for new registration or renewal must include documentation of an FDA outsourcing facility inspection and any facility related responses to documented observations within the required timeframe as outlined in §54.1-3434.5. If the facility has not been inspected by the FDA within the required time frame, outsourcing facility cGMP inspections from the California Board of Pharmacy, Florida Board of Pharmacy or Bestech GMP are acceptable alternatives.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

References
Va. Code § 54.1-3434.1
Va. Code § 54.1-3434.5

~~Revised: June 5, 2006, June 18, 2013, June 4, 2014, December 12, 2016~~

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies and Outsourcing Facilities to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy or nonresident outsourcing facility that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

For a nonresident pharmacy, an application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of Virginia Code § 54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

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Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

References

Va. Code § 54.1-3434.1
Va. Code § 54.1-3434.5

Agenda Topic: Amend Vaccine and Coronavirus Testing Statewide Protocols

Staff Note: The eleventh amendment to the Declaration under the PREP Act for COVID-19 Medical Countermeasures extends only through December 31, 2024. Also, enactment clause 3 of HB1323 passed by the 2022 General Assembly states "3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors." Therefore, amendments to the Coronavirus Testing and Vaccine Statewide Protocols are needed.

Included in Agenda Packet:

- HB 1323 passed in 2022
- Draft amendments to Pharmacist Statewide Protocol for Coronavirus Testing of Persons Three Years of Age and Older (redlined)
- Draft amendments to Vaccine Statewide Protocol for Persons 3 or Older (redlined; combines the current protocol for ages 3-17 with the adult protocol)
- Current Vaccine Statewide Protocol for 3-17 (for reference)
- Current Vaccine Statewide Protocol for 18+ (for reference)

Action Needed:

- Motion to amend the Coronavirus Testing Statewide Protocol and the Vaccine Statewide Protocol for Persons Ages Three (3) or Older as presented or amended.

CHAPTER 791

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

[H 1323]

Approved May 27, 2022

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and Human Services pursuant to federal law; administration of plan; contracts with health care providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto. The Board shall include in such plan:

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed $5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;

5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such family planning services shall begin with delivery and continue for a period of 24 months, if the woman continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions;

8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a breast for any medical reason. Breast reductions shall be covered, if prior authorization has been obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any supporting verifiable documentation shall be signed, dated, and returned by the physician, physician assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 days from the time the ordered durable medical equipment and supplies are first furnished by the durable medical equipment provider;

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen;

16. A provision for payment of medical assistance for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast;

17. A provision, when in compliance with federal law and regulation and approved by the Centers for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program and may be provided by school divisions, regardless of whether the student receiving care has an individualized education program or whether the health care service is included in a student's individualized education program. Such services shall include those covered under the state plan for medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and

restore a range of physical and social functioning in the activities of daily living;

19. A provision for payment of medical assistance for colorectal cancer screening, specifically screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in accordance with the most recently published recommendations established by the American College of Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and frequencies referenced in such recommendations;

20. A provision for payment of medical assistance for custom ocular prostheses;

21. A provision for payment for medical assistance for infant hearing screenings and all necessary audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the United States Food and Drug Administration, and as recommended by the national Joint Committee on Infant Hearing in its most current position statement addressing early hearing detection and intervention programs. Such provision shall include payment for medical assistance for follow-up audiological examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss;

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer when such women (i) have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise eligible for medical assistance services under any mandatory categorically needy eligibility group; and (v) have not attained age 65. This provision shall include an expedited eligibility determination for such women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and services delivery, of medical assistance services provided to medically indigent children pursuant to this chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for both programs;

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

25. A provision for the payment of medical assistance for otherwise eligible pregnant women during the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. 111-3);

26. A provision for the payment of medical assistance for medically necessary health care services provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or whether the patient is accompanied by a health care provider at the time such services are provided. No health care provider who provides health care services through telemedicine services shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is located, including any medical care facility or office of a health care provider, the home of the patient, the patient's place of employment, or any public or private primary or secondary school or postsecondary institution of higher education at which the person to whom telemedicine services are provided is located;

27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not impose any utilization controls or other forms of medical management limiting the supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time or (ii) exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic health condition who have had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" means the use of digital technologies to collect medical and other forms of health data from patients in one location and electronically transmit that information securely to health care providers in a different location for analysis, interpretation, and recommendations, and management of the patient. "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence monitoring, and interactive videoconferencing with or without digital image upload.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when

such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § 32.1-162.13.

For the purposes of this subsection, "provider" may refer to an individual or an entity.

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

F. When the services provided for by such plan are services which a marriage and family therapist, clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for covered services as provided in the state plan. The Board shall promulgate regulations which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers, licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria, including the professional credentials required for licensure.

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

1. Include in its provider networks and all of its health maintenance organization contracts a provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for medically necessary assessment and treatment services, when such services are delivered by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable expertise, as determined by the Director.

2. Amend the Medallion II waiver and its implementing regulations to develop and implement an exception, with procedural requirements, to mandatory enrollment for certain children between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors and enrolled providers for the provision of health care services under Medicaid and the Family Access to Medical Insurance Security Plan established under § 32.1-351.

4. Require any managed care organization with which the Department enters into an agreement for the provision of medical assistance services to include in any contract between the managed care organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of the pharmacy benefits manager from conducting spread pricing with regards to the managed care organization's managed care plans. For the purposes of this subdivision:

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a managed care plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible recipients with special needs. The Board shall promulgate regulations regarding these special needs patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board.

J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law

and regulation.

K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide reimbursement for such service.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older *with whom the pharmacist has a bona fide pharmacist-patient relationship and* in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ *and vaccines for COVID-19*;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention*;*

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; and

11. Tests for COVID-19 and other coronaviruses.

B. *Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:*

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.).* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

~~C.~~ *D.* A pharmacist who administers a vaccination pursuant to ~~subdivision~~ *subdivisions* A 7 *and B 1* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*

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

B. To be registered as a pharmacy technician, a person shall submit:

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A

when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health, shall establish a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2022, and the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq., as amended.

3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol for Coronavirus Testing of ~~Adults~~Persons Three Years of Age and Older

Consistent with Virginia Code § 54.1-3303.1 and CLIA requirements administered by the U.S. Food and Drug Administration, a pharmacist may initiate treatment with, dispense, or and administer tests for COVID-19 and other coronaviruses to persons ~~18~~ three years of age or older.

PHARMACIST EDUCATION AND TRAINING

Pharmacists collecting specimen samples and performing tests for COVID-19 or other coronaviruses shall receive appropriate training to conduct the activity in a safe and effective manner. This includes adherence to the testing device manufacturer's instructions. Completion of training must be documented. For additional information, refer to the "General Guidelines" section on CDC's website and information from the Virginia Department of Health COVID-19 Viral Testing Information for Pharmacists.

PATIENT INCLUSION CRITERIA

Any patient ~~18~~ three years of age or older may receive or be administered a test for COVID-19 or other coronaviruses.

OBTAINING HISTORY

The pharmacist shall obtain a history from the patient or patient's parent/legal guardian, as applicable, including questioning ~~the patient~~ for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of the test.

RECORDKEEPING

The pharmacist shall maintain records in accordance with 18VAC110-21-46 and of §32.1 46.01. shall report all positives to the local or state health department in accordance with §32.1-36 and 12VAC5-90.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

EXCLUSIONS

Nothing shall preclude a pharmacist, pharmacy technician, or pharmacy intern under the supervision of a pharmacist, meaning that the pharmacist is at the same physical location as the pharmacy technician or pharmacy intern, from performing CLIA-waived tests in accordance with the Food and Drug Administration's CLIA requirements.

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol for Persons Ages Three (3) or Older ~~through Seventeen (17)~~

~~***(Does not include influenza or COVID-19 vaccines)***~~

~~Except for influenza and COVID-19 vaccines, C~~consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) ~~and the third enactment clause of HB1323~~, a pharmacist may issue a prescription to initiate treatment with or administer a vaccine to a person age three (3) ~~through seventeen (17)~~ or older recommended at his or her age, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such vaccine. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine. ~~Please note that this protocol does not authorize the administration of influenza or COVID-19 vaccines to persons ages three through seventeen. COVID-19 vaccines may be administered to this age group pursuant to the PREP Act until such authority expires. Influenza vaccines may be administered to this age group pursuant to the PREP Act until such authority expires or §54.1-3408 (W).~~

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s) (e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual ages 3 ~~through 17~~ or older whose immunization history is incomplete or unknown and for whom a vaccine ~~(other than influenza or COVID-19)~~ is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or Adult Immunization Schedule published by the CDC, and
- An individual ages 3 ~~through 17~~ or older preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine ~~(other than influenza or COVID-19)~~ is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age ~~or older than 17 years of age~~;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. The pharmacist shall also provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol for Persons Ages Three (3) through Seventeen (17)

(Does not include influenza or COVID-19 vaccines)

Except for influenza and COVID-19 vaccines, consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) and the third enactment clause of HB1323, a pharmacist may issue a prescription to initiate treatment with or administer a vaccine to a person age three (3) through seventeen (17) recommended at his or her age, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such vaccine. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine. Please note that this protocol does not authorize the administration of influenza or COVID-19 vaccines to persons ages three through seventeen. COVID-19 vaccines may be administered to this age group pursuant to the PREP Act until such authority expires. Influenza vaccines may be administered to this age group pursuant to the PREP Act until such authority expires or §54.1-3408 (W).

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s)

(e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual ages 3 through 17 whose immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule published by the CDC, and
- An individual ages 3 through 17 preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age or older than 17 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. The pharmacist shall also provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

Adopted: 9/24/2021
Revised: 9/26/2023
Effective: 9/26/2023

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines, including vaccines for COVID-19, to persons 18 years of age or older. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination;

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Consideration of Convening Retreat

Staff Note: A member of the Regulation Committee Meeting questioned if the Board should convene a retreat. Background on recent discussions was provided. Refer to meeting minutes from the 9/26/23 and 12/6/23 full board meetings. There was consensus at the Regulation Committee meeting that Ms. Juran will consult with the Chairman regarding a possible December full board meeting agenda item to re-discuss if the Board would like to convene a Retreat, and if so, the development of the agenda. Ms. Juran will gather information from previous Board retreats and the topics suggested by the Board members during last year's survey.

Included in Agenda Package:

- Laws regarding general and Board-specific powers and duties
- Minutes from 2007 and 2019 Retreats
- Update on Board Member Suggested Topics Included in Meeting Agendas

Action Needed:

- Discuss if Board wants to convene a Retreat in 2025 and how the agenda will be developed, or if the Board wishes to continue to address relevant topics during scheduled meetings.

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

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

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions, and the health regulatory boards.

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

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license, permit, or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Director and the Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.). Each health regulatory board shall appoint one such designee.

9. To take appropriate disciplinary action for violations of applicable law and regulations, and to accept, in their discretion, the surrender of a license, certificate, registration, permit, or multistate licensure privilege in lieu of disciplinary action.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, or, when required for special conference committees of the Board of Nursing, not less than one member of the Board and one member of the relevant advisory board, to act in

accordance with § 2.2-4019 upon receipt of information that a practitioner or permit holder of the appropriate board may be subject to disciplinary action or to consider an application for a license, certification, registration, permit or multistate licensure privilege in nursing. The special conference committee may (i) exonerate; (ii) reinstate; (iii) place the practitioner or permit holder on probation with such terms as it may deem appropriate; (iv) reprimand; (v) modify a previous order; (vi) impose a monetary penalty pursuant to § 54.1-2401, (vii) deny or grant an application for licensure, certification, registration, permit, or multistate licensure privilege; and (viii) issue a restricted license, certification, registration, permit or multistate licensure privilege subject to terms and conditions. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019. The recommendation of such subordinate may be considered by a panel consisting of at least five board members, or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.
11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings pursuant to § 2.2-4020 to consider the same matter.
12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates.

13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.
14. To request and accept from a certified, registered, or licensed practitioner; a facility holding a license, certification, registration, or permit; or a person holding a multistate licensure privilege to practice nursing, in lieu of disciplinary action, a confidential consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner or facility. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the

practitioner or facility. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner or facility has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. A certified, registered, or licensed practitioner, a facility holding a license, certification, registration, or permit, or a person holding a multistate licensure privilege to practice nursing who has entered into two confidential consent agreements involving a standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public.

15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit to a mental or physical examination. Failure to submit to the examination shall constitute grounds for disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice nursing.

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics, and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices, and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding, and disposal of such drugs, cosmetics, and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety, and efficacy of drugs or devices distributed, dispensed, or administered.

2. Compliance with the prescriber's instructions regarding the drug and its quantity, quality, and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity, or quality of drugs or substances distributed or dispensed and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner, or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices, or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

B. The Board may collect and examine specimens of drugs, devices, and cosmetics that are manufactured, distributed, stored, or dispensed in the Commonwealth.

(FINAL/APPROVED 06/12/2007)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD RETREAT

March 28, 2007
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: The meeting was called to order at 10AM

PRESIDING: John O. Beckner, Chairman

MEMBERS PRESENT:
Bobby Ison
Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

MEMBERS ABSENT: Diane Langhorst

STAFF PRESENT:
Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Betty Jolly, Assistant Director for Policy and Education

QUORUM: With 9 members present, a quorum was established.

BOARD RETREAT The Board of Pharmacy held a retreat to conduct strategic planning with respect to new initiatives and meeting new agency performance measures. The Board heard a presentation from Lynn Rubenstein, Executive Director, Northeast Recycling Council, on how to set up collection programs for unwanted medication by consumers. The Board also heard a presentation from Donna Horn, Director, Patient Safety- Community Pharmacy, Institute for Safe Medical Practices related to what boards of pharmacy should be doing to promote patient safety and reduce medication dispensing errors. Sandra Ryals, Director, Department of Health Professions provided the Board with statistical information relating to disciplinary caseload and the new agency performance measures. The Board held discussions related to the presentations, and other current issues, and by consensus developed plans to begin implementation of actions to address some of these issues. The outcomes of the discussions are provided in a summary attached to these minutes as Attachment A. No motions were made during this meeting.

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

Elizabeth Scott Russell
Executive Director

John O. Beckner, Board Chairman

Date

CONVERTING CORE VALUES INTO PERFORMANCE STANDARDS
Outcome: Committee formed to review and make any needed modifications to Sanction Reference tool for consideration at next Board meeting.

Discussion by Board for Committee Use:

- Key performance measure of 90% of patient care cases closed in 250 days is a goal to be addressed immediately and with collaborative, dedicated, goal oriented action between Board and staff;
- Data may need scrubbing regarding what is "patient care" in order to determine baseline;
- One tool that has proven useful to other Boards in decreasing days to closure is sanction reference;
- Sanction Reference Point study was discussed as a system to determine appropriate sanctioning for professional misconduct, with no negative actions resulting from its use and the positive result of increasing the potential of respondents acceptance of sanction;
- Board resolved to address key performance measures.

The Board of Pharmacy recognizes high-quality service efforts expected of the Department through Governor Kaine's "Virginia Performs" and encourages effective performance on all three measures, and will begin that focus by examining systems to achieve the 250 day closure on patient care mandate.

TOPIC 1: BOARD FACILITATED DRUG DISPOSAL COLLECTION
Outcome: exploratory committee appointed

- Board Discussion for Committee Use:

  Beginning exploration will be internal, without the immediate input of DEQ or law enforcement;
  Exploration will research what is applicable in Virginia law and regulations for disposal at the present time;
  Exploration will conclude next step of Board action: advisory issues, guidance document developed or regulations sought immediately.

- Expert available for consultation: Lynn Rubinstein, Executive Director, Northeast Recycling Council

TOPIC 2: MANDATE SPECIFIC CONTINUING EDUCATION TOPICS
Outcome: Legislative proposal to be reviewed by Board at next meeting

- Board Discussion for Committee Use:

  Mandate concept applies to pharmacist as well as technicians;

  Mandated course for professionals could include patient safety curriculum, state laws update, or any current core competency;

Flexibility in mandate would include the choice of no mandate for that year;

Notification could be included with renewals, with compliance audit on completion of mandated course.

TOPIC 3: DISPENSING ERRORS AND PROMOTING PATIENT SAFETY
Outcome: CQI committee appointed

- Board Discussion for Committee Use:
  - The need for the Board is to be proactive in continuous quality care (CQI) for patient safety; and should be presented to pharmacies as risk management;
  - Develop a guidance document for pharmacy sites on patient safety approaches to avoiding dispensing errors;
  - Triage factors most likely to lead to dispensing errors;
  - Triage infractions by importance and limit the number to top 3/top 10 rather a menu of every shortcoming; making inspections more substantive and routinized;
  - Approach quality control as ongoing;
  - Examine legislation in other states, directives from other state Boards; JCHC guidelines'; IOM documents;
  - Involve pharmacist input thorough survey or focus group.
- Partner with national expert organization for national data and trends and methods: ISMP Donna Horn
- Draft language to amend 54.1-2400.6 to expand requirement for reporting to include retail (all) pharmacies will be presented at next Board meeting.
- Draft language for anonymous reporting of medication errors will be presented at next Board meeting.

TOPIC 4: AT THE POINT OF INSPECTION FINES
Outcome: Draft legislation to be reviewed by Board at next meeting

- Legislation needed to allow for immediate fines when on site inspection identifies an infraction
- Ticket issued on site and mailed in later
- Fine goes against the pharmacy permit, not PIC
- Payment responsibility left to the business not the Board

TOPIC 5: LICENSE RENEWAL PROCESS REVIEW
Outcome: Group decision: stagger by license type but retain annual renewal

- Pharmacists' and technicians' licenses in state would continue to be due December 31, annually;
- "Outliers" such as non-residents, due same date, TBD, but not 12/31;
- Facility licenses, due same date, TBD, but not 12/31.

(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD RETREAT

April 16, 2019
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:05 am

PRESIDING: Rafael Saenz, Chairman

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

MEMBER ABSENT:
James L. Jenkins, Jr.
Ryan Logan

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

GUEST SPEAKERS:
Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy
Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education
Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy
Al Domeika, Pharmacist-in-Charge, Prime Wellness of Connecticut

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

APPROVAL OF AGENDA: The agenda was unanimously approved as presented.

PURPOSE OF MEETING:	Learning session for the Board of Pharmacy members to provide education on topics of Standards of Care, Pharmacy Technician Education Standards, Endocannaboid System and Cannaboid Research, and Medical Marijuana Dispensary Operations. Board members asked questions of the presenters following each presentation.
PRESENTATIONS:	
STANDARDS OF CARE REGULATORY APPROACH (ATTACHMENT 1)	Carmen Catizone, MS, RPh, DPh, Executive Director/Secretary, National Association of Boards of Pharmacy provided a presentation on the topic of Standard of Care Regulatory Approach.
PHARMACY TECHNICIAN EDUCATION STANDARDS (ATTACHMENT 2)	Peter Vlasses, PharmD, DSc(Hon), FCCP, Executive Director, Accreditation Council for Pharmacy Education, provided a presentation on the topic of Pharmacy Technician Education Standards.
ENDOCANNABINOID SYSTEM AND CANNABIS RESEARCH (ATTACHMENT 3)	Aron Lichtman, PhD, Professor and Associate Dean of Research and Graduate Studies, VCU School of Pharmacy, provided a presentation discussing the topic Endocannabinoid System and Cannabis Research.
MEDICAL MARIJUANA DISPENSARY OPERATIONS (ATTACHMENT 4)	Al Domeika. Pharmacist-in-Charge provided a presentation on the topic of Medical Marijuana Dispensary Operations.
UPDATE ON IMPLEMENTATION OF PHARMACEUTICAL PROCESSOR PROGRAM	Ms. Juran, Mr. Johnson, and Melody Morton provided a brief presentation to update the board on the status of the pharmaceutical processor program.
ADJOURN:	With all business concluded, the meeting adjourned at 3:15 pm.

_____ _____

Rafael Saenz, Chairman Caroline D. Juran, Executive Director

_____ _____

DATE: DATE:

Update on Board Member Suggested Topics Included in Meeting Agendas

- **Pharmacy Closures and Pharmacy Shortages**
  - Discussed in 2023 and 2024; staff assigned practice settings to each permitted pharmacy and created process for pharmacy to confirm practice setting during annual renewal process
  - Staff created geo-mappings of current pharmacy locations in 2023 and 2024
    - Refer to meeting minutes of 5/23/2023, 9/26/2023, and 6/25/2024 full board meetings
  - Information shared with leadership at DMAS, VDH, Secretary HHR, VCU School of Pharmacy researcher
- **Barriers with Pharmacy Technician Educational Standards**
  - Discussed in 2024; legislative proposal to also allow completion of a pharmacy technician training program recognized by PTCB or NHA was adopted and shared with Administration, will be introduced in 2025 GA session
    - Refer to meeting minutes of 6/25/2024 full board meeting
- **Visually trending workforce/licensee data in a chart or graph**
  - Staff has attempted to offer licensure and disciplinary data differently in the last year at each full board meeting
  - Annual Pharmacist and Pharmacy Technician Workforce Reports Adopted
    - Refer to meeting minutes of 3/28/24 and 6/25/24 full board meetings
- **Effectiveness of Health Practitioner Monitoring Program**
  - Overview presentation of HPMP scheduled for 12/17/24 full board meeting
  - Last formal presentation: refer to minutes from 12/6/2022 full board meeting
  - HPMP website with resources, FAQs, associated laws and regulations: https://www.dhp.virginia.gov/PractitionerResources/HealthPractitionersMonitoringProgram/index.html

Virginia Board of Pharmacy
December 17, 2024
Licenses Issued

	5/1/23 - 7/31/23	8/1/23 - 10/31/23	11/1/23 - 1/31/24	2/1/24 - 4/30/24	5/1/24 - 7/31/24	8/1/24 - 10/31/24	License Count 9/6/2024
Business CSR	38	29	20	47	49	114	1,667
CE Courses	0	0	0	0	0	0	9
EMS Designated Locations						403	403
Limited Use Pharmacy Technician	0	0	0	0	0	0	5
Medical Equipment Supplier	12	2	4	3	8	6	224
Non-restricted Manufacturer	0	0	0	0	2	1	36
Outsourcing Facility	0	0	0	0	0	0	1
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	237	273	131	164	212	262	16,770
Pharmacy	11	11	13	18	7	11	1,728
Pharmacy Intern	71	133	74	79	52	72	1,091
Pharmacy Technician	469	327	327	407	461	527	13,639
Pharmacy Technician Trainee	1,074	1,069	1,085	864	964	1,175	8,040
Physician Selling Controlled Substances	15	37	23	15	18	46	624
Limited Use Practitioner Dispensing	0	1	2	2	1	1	10
Nonresident Manufacturer	2	7	8	5	4	13	247
Nonresident Medical Equipment Supplier	6	10	15	9	16	9	386
Nonresident Outsourcing Facility	0	0	0	3	1	2	35
Nonresident Pharmacy	21	27	23	26	27	33	974
Nonresident Third Party Logistics Provider	11	12	6	6	8	12	251
Nonresident Warehouser	3	10	4	9	15	9	158
Nonresident Wholesale Distributor	12	12	8	9	12	12	637
Physician Selling Drugs Location	5	3	5	1	8	3	136
Pilot Programs	2	1	1	4	0	1	10
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	32
Third Party Logistics Provider	0	0	0	0	0	0	5
Warehouser	1	2	2	1	2	1	130
Limited Use Facility Dispensing	0	0	1	0	1	1	5
Wholesale Distributor	0	2	1	1	2	1	64
Total	**1,990**	**1,968**	**1,753**	**1,673**	**1,870**	**2,715**	**47,319**

Virginia Department of Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2025

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

*** Veterinary Establishments are now grouped together, as the board works on designating existing establishments as "Ambulatory" or "Stationary", instead of "Full Service" or "Restricted Service".

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

BOARD	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	CURRENT Q1 2025
Audiology/Speech Pathology	5,432	5,605	5,756	5,894	5,671	5,809	5,975	6,117	5,963	6,108	6,281	6,481	6,083
Counseling	33,693	35,020	36,141	37,436	36,097	37,512	38,791	40,118	39,278	40,239	40,872	41,965	40,958
Dentistry	15,171	15,290	15,284	15,238	15,421	15,275	15,037	15,186	15,190	15,126	15,137	15,413	15,447
Funeral Directing	3,187	3,247	3,295	3,182	3,254	3,308	3,379	3,287	3,351	3,390	3,097	2,969	3,029
Long-Term Care Administrators	2,226	2,293	2,352	2,146	2,232	2,288	2,345	2,159	2,225	2,278	2,317	2,172	2,229
Medicine	78,312	79,452	80,957	82,857	83,193	83,804	85,497	87,470	88,629	89,957	91,077	93,006	92,584
Nurse Aide	50,322	49,967	49,911	50,189	50,085	50,216	50,278	50,817	51,449	51,594	51,361	51,780	51,300
Nursing	174,791	174,984	176,169	177,138	179,221	179,997	181,279	181,581	183,596	184,003	185,352	186,370	188,196
Optometry	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871	1,903	1,930	1,865	1,888
Pharmacy	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374	46,935	44,451	45,347	46,707
Pharmaceutical Processing[1]	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238	10,362	-	-	-
Physical Therapy	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411	14,571	14,743	15,074	15,373
Psychology	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168	6,282	6,377	6,488	6,075
Social Work	11,868	12,405	12,799	13,138	12,952	13,598	14,241	14,913	15,089	15,535	16,012	16,552	16,380
Veterinary Medicine	8,615	8,723	8,429	8,648	8,826	8,947	8,711	9,016	9,192	9,297	9,009	9,289	9,508
Agency Total	482,398	494,685	505,753	518,191	514,037	512,996	505,591	499,117	495,024	497,580	488,016	494,771	495,757

1. The Pharmaceutical Processors Program has moved from DHP's Board of Pharmacy to Virginia Cannabis Control Authority since Q3 2024. DHP is no longer licensing Pharmaceutical Processors.

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2025

Current licenses by board and occupation as of the last day of the quarter.

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BOARD	Occupation	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	CURRENT Q1 2025
Optometry	Optometrist	77	77	78	65	65	65	65	49	50	51	51	46	46
	Optometrist-Volunteer Registration	-	-	-	-	-	-	-	-	1	-	-	-	-
	Professional Designation	-	-	-	-	-	-	-	-	-	-	-	-	-
	TPA Certified Optometrist	1,716	1,736	1,749	1,708	1,758	1,784	1,808	1,777	1,820	1,852	1,879	1,819	1,842
	Total	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871	1,903	1,930	1,865	1,888
Pharmacy	Business CSR	1,478	1,510	1,399	1,463	1,507	1,529	1,423	1,465	1,508	1,533	1,417	1,498	1,599
	CE Courses	9	9	9	9	9	9	9	9	9	9	9	9	9
	Humane Society	-	-	-	-	-	-	-	-	-	-	-	-	-
	Limited Use Facility Dispensing	-	-	-	-	-	1	2	3	3	3	4	4	5
	Limited Use Pharmacy Technician	8	8	7	7	7	7	7	7	7	7	6	6	5
	Limited Use Practitioner Dispensing	-	-	1	2	2	3	3	3	4	6	8	8	10
	Medical Equipment Supplier	230	229	209	217	223	226	213	220	226	224	205	212	216
	Non-Resident Manufacturer	209	215	206	213	218	224	217	226	231	236	229	232	245
	Non-Resident Medical Equipment Supplier	363	373	331	354	361	369	346	355	367	379	345	367	380
	Non Resident Outsourcing facility	34	33	30	29	32	33	35	33	32	31	31	33	33
	Non Resident Pharmacy	876	885	882	898	910	911	924	923	923	934	943	962	973
	Non-Resident Wholesale Distributor	644	660	624	634	643	641	610	624	635	641	612	624	633
	Non Restricted Manufacturer	29	30	31	32	34	34	35	35	35	35	32	34	36
	Non-Resident Third Party Logistics Prov.	186	191	181	181	194	206	207	219	229	238	234	241	247
	Non Resident Warehouser	96	101	98	99	105	115	109	114	123	130	127	142	154
	Outsourcing Facility	-	-	-	-	-	-	1	1	1	1	1	1	1
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	16,210	16,445	15,858	16,079	16,414	16,619	16,064	16,273	16,606	16,796	16,147	16,357	16,663
	Pharmacist-Volunteer Registration	-	-	-	-	-	-	-	1	-	-	-	-	-
	Pharmacy	1,770	1,767	1,773	1,768	1,765	1,765	1,762	1,755	1,751	1,738	1,744	1,737	1,730
	Pharmacy Intern	1,499	1,457	1,247	1,312	1,267	1,352	1,166	1,235	1,213	1,274	1,074	1,125	1,110
	Pharmacy Technician	13,689	14,042	12,421	12,924	13,522	13,875	12,312	12,871	13,310	13,640	12,275	12,807	13,437
	Pharmacy Technician Trainee	3,309	4,628	5,930	6,258	6,977	8,041	8,581	8,178	8,190	8,063	8,095	8,014	8,234

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2025

Current licenses by board and occupation as of the last day of the quarter.

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Pharmacy	Pharmacy Technician Training Program	138	133	128	126	-	-	-	-	-	-	-	-	-
	Physician Selling Controlled Substances	614	631	537	571	600	645	543	565	596	632	547	559	606
	Physician Selling Drugs Location	168	167	160	160	160	164	125	131	135	139	127	129	133
	Pilot Programs	17	20	18	25	23	20	15	15	13	14	15	18	18
	Registered Physician for CBD/THC-A Oil	-	-	-	-	-	-	-	-	-	-	-	-	-
	Repackaging Training Program	2	2	2	2	2	2	2	2	2	2	2	1	2
	Restricted Manufacturer	41	41	36	36	36	36	33	32	32	32	32	32	32
	Third Party Logistics Provider	7	7	8	7	7	7	6	6	6	6	5	5	5
	Warehouser	121	122	117	121	121	122	123	125	127	129	126	128	128
	Wholesale Distributor	66	66	60	62	64	63	60	60	60	63	59	62	63
	Total	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374	46,935	44,451	45,347	46,707
Pharmaceutical[1] Processing	Pharmaceutical Processor Permit	4	4	4	4	4	4	4	4	4	4	-	-	-
	Registered Agent For Medical Cannabis	141	162	180	179	181	166	158	137	109	79	-	-	-
	Registered Practitioner for CBD/THC-A Oil	920	997	720	873	1,059	1,164	938	1,051	1,051	1,051	-	-	-
	Registered Par/Guard For Medical Cannab	212	235	258	262	210	163	133	74	38	28	-	-	-
	Registered Patient For Medical Cannabis	33,204	39,468	47,466	52,903	45,434	38,071	29,214	16,201	7,547	5,282	-	-	-
	Registered Product	568	842	1,178	1,566	1,949	2,271	2,770	3,158	3,489	3,918	-	-	-
		35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238	10,362			
Physical Therapy	Direct Access Certification	1,376	1,384	1,396	1,406	1,420	1,427	1,437	1,448	1,250	1,257	1,268	1,274	1,284
	Physical Therapist	9,161	9,245	9,382	9,634	9,906	10,022	8,878	9,146	9,403	9,523	9,640	9,896	10,114
	Physical Therapist Assistant	3,816	3,852	3,901	3,969	4,061	4,093	3,615	3,676	3,758	3,791	3,835	3,904	3,975
	Total	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411	14,571	14,743	15,074	15,373
Psychology	Applied Psychologist	26	27	27	28	25	25	25	25	23	24	24	24	24
	Clinical Psychologist	4,082	4,224	4,325	4,418	4,230	4,360	4,461	4,573	4,517	4,607	4,692	4,801	4,721
	Resident in School Psychology	12	13	13	13	21	24	26	27	29	33	35	36	32
	Resident In Training	376	376	380	380	397	395	392	392	404	397	392	377	407
	School Psychologist	97	98	99	100	96	96	100	103	98	99	100	101	99
	School Psychologist-Limited	622	640	658	673	550	569	583	598	577	592	601	608	272
	Sex Offender Treatment Provider	433	437	444	455	421	427	439	450	441	450	452	458	447
	SOTP Trainee	125	110	99	100	95	97	79	78	79	80	81	83	73
	Total	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168	6,282	6,377	6,488	6,075

1. The Pharmaceutical Processors Program has moved from DHP's Board of Pharmacy to Virginia Cannabis Control Authority since Q3 2024. DHP is no longer licensing Pharmaceutical Processors.

December 17, 2024 - Full Board of Pharmacy Meeting

Quarterly Inspection Completed Review by License Type – Date Range: 07/01/2024 – 09/30/2024

Insp Status	License Type	Change of Location	Compliance	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	4		63		4	5	30	106
	Limited Use Facility Dispensing			1				1	2
	Medical Equipment Supplier	1		5			2	8	16
	Non-restricted Manufacturer			2					2
	Pharmacy	2	3	12		6	32	143	198
	Physician Selling Drugs Location	2		10				16	28
	Pilot Programs				3				3
	Warehouser			2				3	5
	Wholesale Distributor			1					1
Completed Total		9	3	96	3	10	39	201	361
Completed Virtual	Business CSR	4		25		2	2	1	34
	Medical Equipment Supplier	1						1	2
	Pharmacy						22		22
Completed Virtual Total		5		25		2	24	2	58
Grand Total		14	3	121	3	12	63	203	419

Routine Inspection Results - 07/01/2024 – 09/30/2024

License Type	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	14		17	31
Limited Use Facility Dispensing	1			1
Medical Equipment Supplier	3		6	9
Pharmacy	57	47	39	143
Physician Selling Drugs Location	9		7	16
Warehouser	2		1	3
Grand Total	86	47	68	203

December 17, 2024 - Full Board of Pharmacy Meeting

Routine Pharmacy Inspections – Date Range: 07/01/2024 – 09/30/2024

Top 5 cited deficiencies

Description	Number of times cited
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1- 3410.2	**37**
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	**15**
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	**14**
15. Perpetual inventory not being maintained as required as it does not: • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.	**13**
123. Engaging in remote processing not in compliance **124.** Labels do not include all required information **130a** Compounded products not properly labeled	**Tied at 12**

December 17, 2024 - Full Board of Pharmacy Meeting

Two Year Inspections Completed Review Date Range: 09/30/2022 – 09/30/2024

Number of Inspections Completed by License Type:

License Type	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Business CSR	46		1	303	1	22	64	735	1172
Cannabis Dispensing Facility				10		2		11	23
Limited Use Facility Dispensing				4		1		1	6
Medical Equipment Supplier	23			40			3	118	184
Non-restricted Manufacturer	1			6		2	2		11
Outsourcing Facility				1		1			2
Pharmaceutical Processor Permit	1						2	4	7
Pharmacy	50	19	3	107	1	114	460	1403	2157
Physician Selling Drugs Location	4	2	1	35		3	3	88	136
Pilot Programs					11				11
Third Party Logistics Provider	1							2	3
Warehouser	4			14	2	3	3	70	96
Wholesale Distributor	5			9		3	3	25	45
Grand Total	135	21	5	529	15	151	540	2457	3853

Vacancy / Recruitment for Pharmacy Inspector in Northern VA underway
Large increase in new CSR inspections (EMS and ADD)
Staff recently provided training to Senior Inspectors on the topic of EMS

Discipline Program Report

Open Cases as of 11/6/24:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	TOTALS
Patient Care Cases	66	35	92	1	7	1	1	1	204
Non-Patient Care Cases	40	26	28	5	7	1	1	2	110
						TOTAL:			**304**

Upcoming Disciplinary Proceedings:

January 8, 2025	Ratliff/Hoffer	Informal Conferences
January 9, 2025	All members	Formal Hearings
January 28, 2025	Agency Sub	Informal Conferences
February 18, 2025	All members	Formal Hearings
February 19, 2025	Dowdy/Nash	Informal Conferences
February 26, 2025	Yuan/Kale	Informal Conferences
March 4, 2025	Ratliff/Hoffer	Informal Conferences
March 25, 2025	All members	Full Board Mtg & Formal Hearings

Virginia Department of Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 1 – Fiscal Year 2025

The "Received, Open, Closed" table below shows the number of received and closed cases during the quarters specified and a "snapshot" of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
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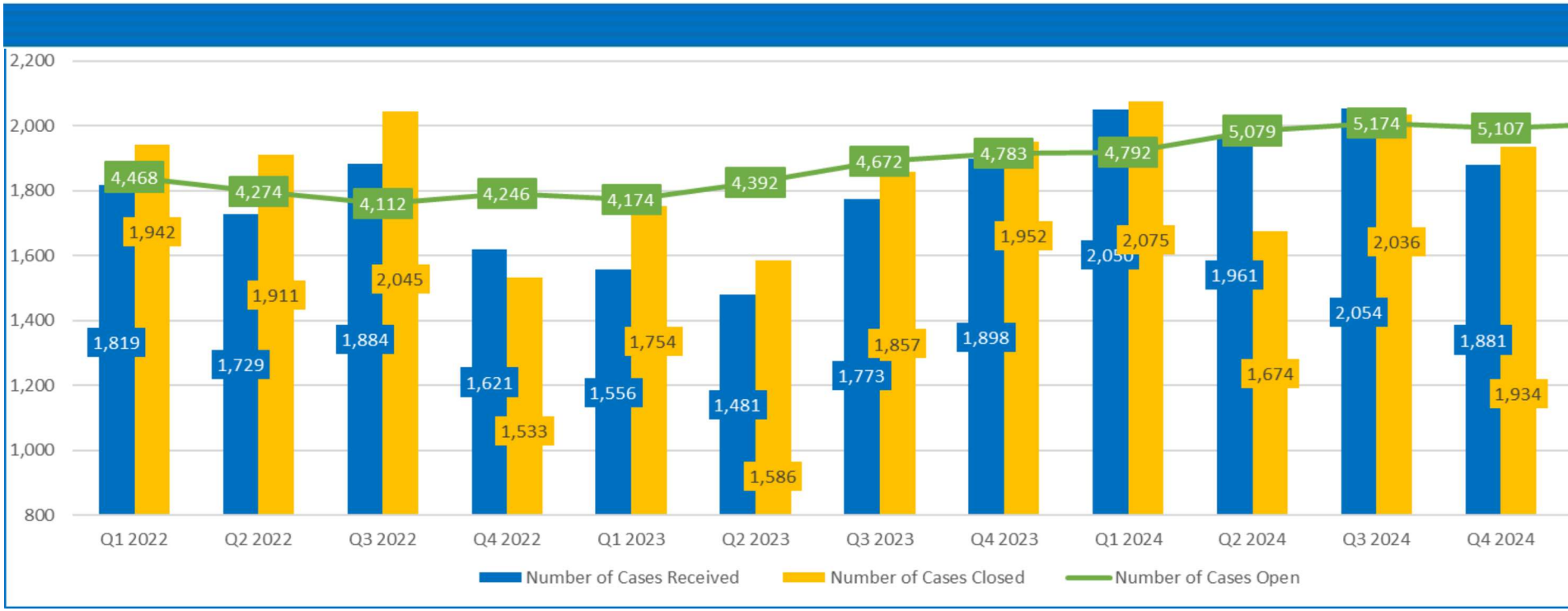

Virginia Department of Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 1 – Fiscal Year 2025

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		Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 202
Pharmacy	Number of Cases Received	212	208	220	185	215	210	204	249	206	179	204
	Number of Cases Open	350	329	399	409	416	437	384	442	390	372	383
	Number of Cases Closed	193	228	154	181	228	214	288	220	257	199	195
Physical Therapy	Number of Cases Received	11	9	15	3	15	13	10	4	10	27	10
	Number of Cases Open	46	47	46	39	35	34	36	35	31	55	52
	Number of Cases Closed	12	8	18	10	21	18	8	5	14	4	15
Psychology	Number of Cases Received	37	32	24	34	20	18	22	31	39	35	32
	Number of Cases Open	140	159	144	162	163	169	174	172	167	157	154
	Number of Cases Closed	29	13	39	22	26	16	24	49	44	43	37

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q1 2021 - Q1 2025

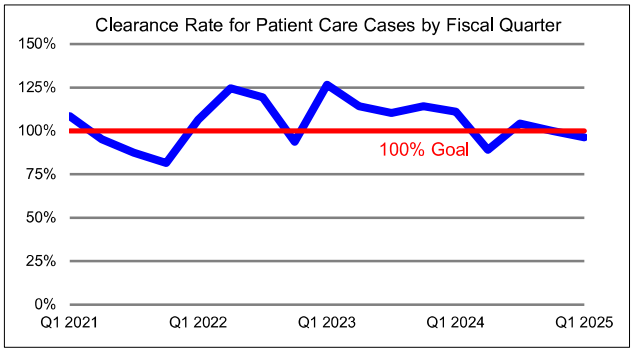
Arne W. Owens
Director

"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."
DHP Mission Statement

In order to uphold its mission relating to discipline, DHP continually assesses and reports on its disciplinary case processing performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement; these three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days that a case was in the continuance activity.

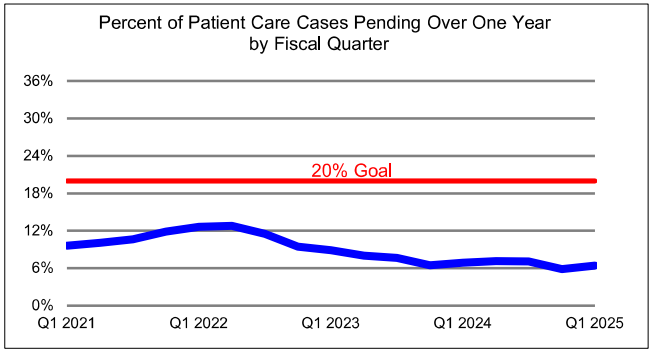
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 96%, with 1,207 patient care cases received and 1,253 closed.



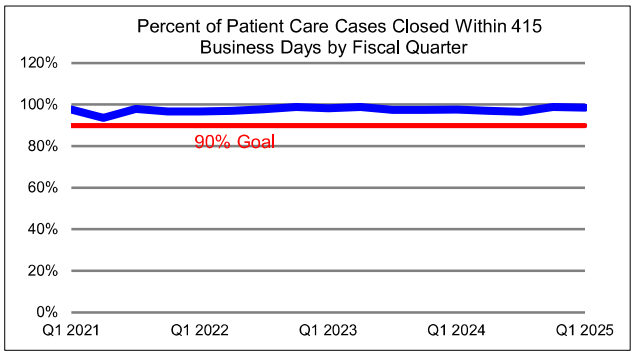
Age of Pending Caseload - the percent of open patient care cases over 415 business days old. This measure tracks the backlog of patient care cases older than 415 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 415 business days at no more than 20%.

The current quarter shows 6% patient care cases pending over 415 business days with 231 of the 3,614 patient care cases pending over 415 business days.



Time to Disposition - the percent of patient care cases closed within 415 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 415 business days.

The current quarter shows 99% of patient care cases being resolved within 415 business days with 1,156 of the 1,173 cases closed within 415 business days.



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days), by Board

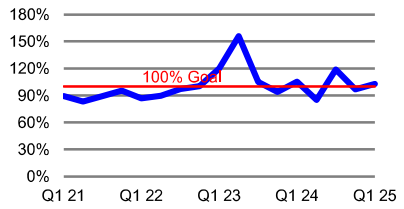
Medicine

Clearance Rate: 103%
413 Cases Received
424 Cases Closed

Pending Caseload Over 415 Days: 4%
31 cases out of 690 are pending over 415 Days

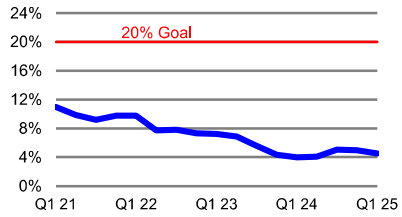
Time to Disposition Within 415 Days: 100%
413 cases out of 415 were closed within 415 Days

Clearance Rate

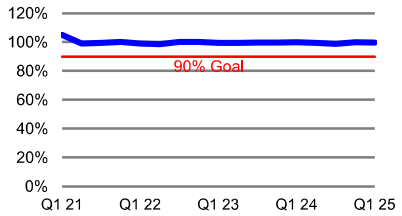


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition

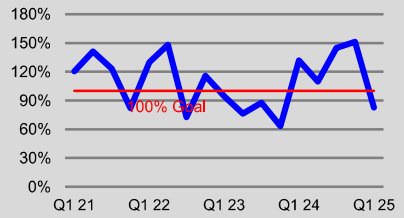


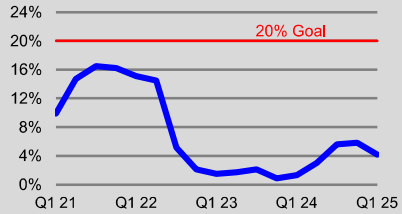
Dentistry

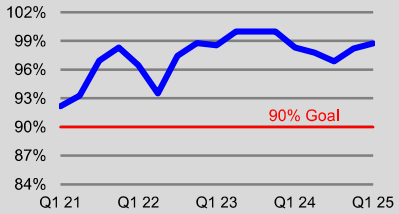
Clearance Rate: 83%
104 Cases Received
86 Cases Closed

Pending Caseload Over 415 Days: 4%
11 cases out of 264 are pending over 415 Days

Time to Disposition Within 415 Days: 99%
78 cases out of 79 were closed within 415 Days





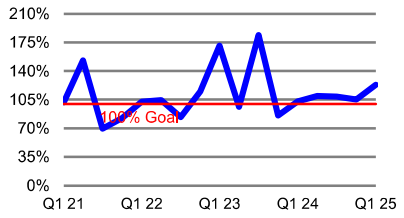


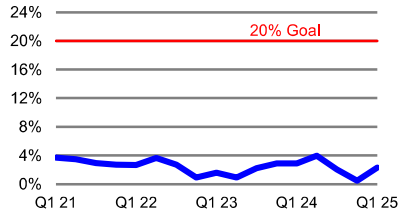
Pharmacy

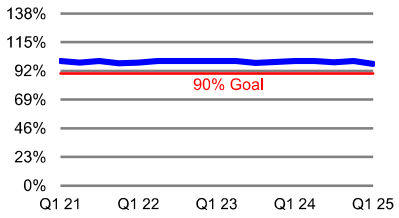
Clearance Rate: 123%
74 Cases Received
91 Cases Closed

Pending Caseload Over 415 Days: 2%
4 case out of 174 are pending over 415 Days

Time to Disposition Within 415 Days: 98%
89 cases out of 91 were closed within 415 Days







Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.
Note: If no cases are received and some cases are closed, we assign 100% as clearance rate

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days Removed): Quarterly Performance Measurement, Q1 2021 - Q1 2025

Arne W. Owens
Director

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Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

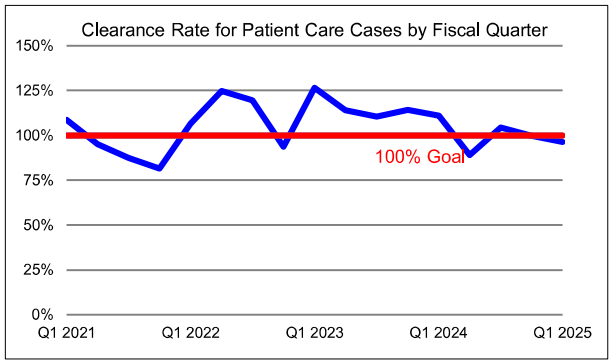
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 250 business days at no more than 20%.

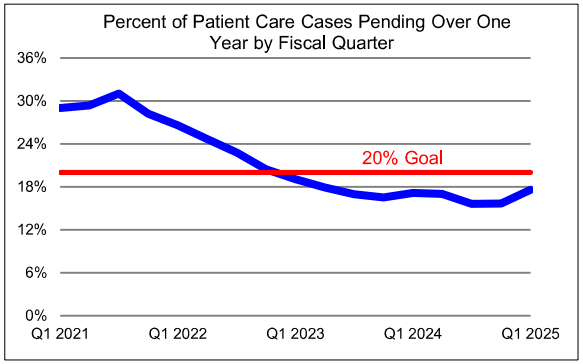
Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 250 business days.

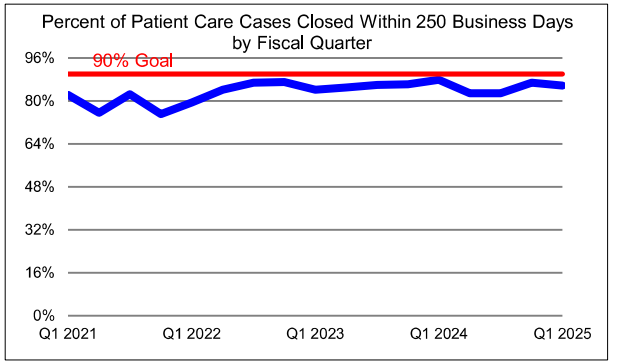
The current quarter's clearance rate is 96%, with 1,253 patient care cases received and 1,207 closed.

The current quarter shows 18% patient care cases pending over 250 business days, with 635 of the 3,614 patient care cases pending over 250 business days.

The current quarter shows 86% patient care cases pending over 250 business days, with 1,005 of the 1,173 cases closed within 250 business days.







Submitted: 11/13/2024

Prepared by: Department of Health Professions

Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

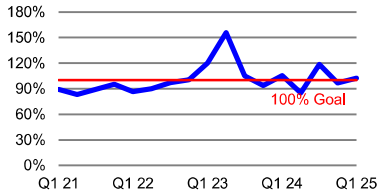
Medicine

Clearance Rate: 103%
413 Cases Received
424 Cases Closed

Pending Caseload: 7%
50 cases out of 690 are pending over 250 Days

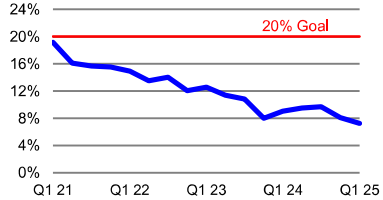
Time to Disposition: 97%
401 cases out of 415 were closed within 250 Days

Clearance Rate

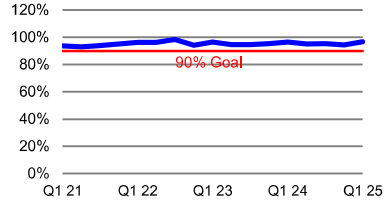


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition

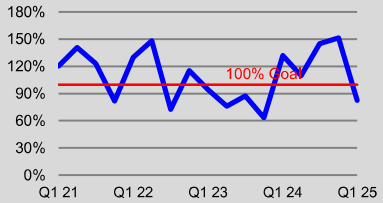


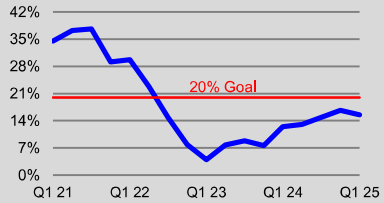
Dentistry

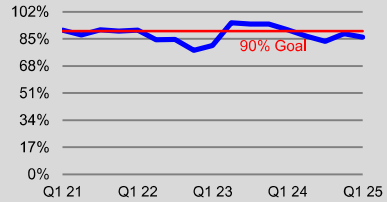
Clearance Rate: 83%
104 Cases Received
86 Cases Closed

Pending Caseload: 16%
41 cases out of 264 are pending over 250 Days

Time to Disposition: 86%
68 cases out of 79 were closed within 250 Days





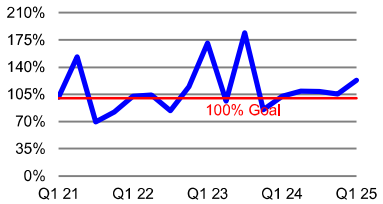


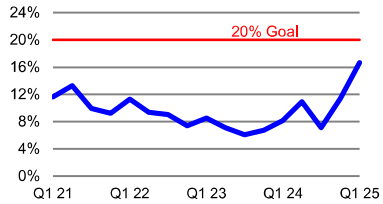
Pharmacy

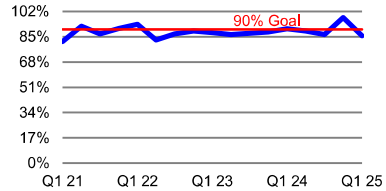
Clearance Rate: 123%
74 Cases Received
91 Cases Closed

Pending Caseload: 17%
29 cases out of 174 are pending over 250 Days

Time to Disposition: 86%
78 cases out of 91 were closed within 250 Days







Note: If no cases are received and some cases are closed, we assign 100% as clearance rate

Executive Director's Report – December 17, 2024

Staff:

- Vacant disciplinary administrative assistant position

In-person or Virtual Meetings Recently Attended:

- Forensic Science Board Meeting
- Monthly Regional EMS Medication Kit Transition Workgroup -Juran/O'Halloran
- VCU SOP CCPR and VSHP Compounding Summit – Juran/O'Halloran presenters
- VSHP Fall Seminar – presenter; Juran/O'Halloran Collaborator Award recipients
- National Federation of the Blind, Virginia Chapter – presenter
- National Association of State Controlled Substances Authorities meeting – O'Halloran
- NABP .Pharmacy Executive Board virtual meeting
- SAMHSA Region 3 Pharmacy Access to Medications for Opioid Use Disorder virtual meeting
- NABP Interactive Member Forum – Yuan
- RxEACH HIV Technical Package virtual meeting
- Virginia Association of Chain Drug Stores annual meeting – presenter
- BOP Staff Volunteering Event at Salvation Army and Holiday Luncheon