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 6, 2022
9AM

TOPIC	PAGES

Call to Order of Public Hearing: Dale St. Clair, PharmD, Chairman
- Welcome & Introductions

Public Hearings:
- Placing Certain Chemicals into Schedule I
- Implementation of 2021 legislation for pharmacists initiating treatment

Adjournment of Public Hearings

Call to Order of Full Board Meeting: Dale St. Clair, PharmD, Chairman
- Approval of Agenda

Approval of Previous Board Meeting Minutes: **1-38**
- September 6, 2022, Full Board Meeting
- September 6, 2022, Public Hearings
- September 6, 2022, Formal Hearings
- September 26, 2022, Telephone Conference Call
- October 12, 2022, Telephone Conference Call
- October 18, 2022, Formal Hearings
- October 19, 2022, Special Conference Committee
- November 2, 2022, Special Conference Committee
- November 17, 2022, Special Conference Committee

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

Updates from the Health Practitioner Monitoring Program: Christina C. Buisset, DHP Health Practitioners' Monitoring Program Manager and Amy Ressler, VCU Health Practitioners' Program Administrative Director **Presentation**

Old Business:
Pharmacy Technician Trainees who are Minors: Jay Withrow, Director, Division of Legal Support, ORA, OPPPI, and OWP, Virginia Department of Labor and Industry **39-40**

New Business:
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh
- Chart of Current Regulatory Actions **41-43**
- Adoption of final regulations – placement of chemicals in Schedule I **44-57**
- Adopt Guidance Document 110-45 *Approved Chemicals for use as Hydrocarbon or Other Flammable Solvents by Pharmaceutical Processors* **58-64**

- Periodic Review of Guidance Documents:
  - Adopt revisions to Guidance Document 110-10 *Mobile Units for Dispensing for the Indigent or Underserved Population* **65-69**
  - Adopt revisions to Guidance Document 110-11 *Proof of Identity when Dispensing Schedule II Drugs* **70-73**
  - Adopt revisions to Guidance Document 110-24 *Competency Examination Required for Licensure as a Pharmacist NAPLEX Passing Score* **74-75**
  - Adopt revisions to Guidance Document 110-28 *Guidance for Free Clinic Pharmacy Applicants* **76-78**
  - Repeal Guidance Document 110-37 *Conduct of an Informal Conference by an Agency Subordinate* **79-85**
  - Adopt revisions to Guidance Document 110-43 *Dispensing with an Authorized Generic* **86-89**
  - Adopt revisions to Guidance Document 110-47 *Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs* **90-94**

Reports:

- Chairman's Report –Dale St. Clair, PharmD
- Report on Board of Health Professions – Sarah Melton, PharmD
- Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh **95**
- Report on Nonresident Facilities – Beth O'Halloran, RPh **96**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **97-107**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **Handout**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **Handout**
- Executive Director's Report – Caroline D. Juran, RPh **108**

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

Adjourn

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

*****A panel of the Board will tentatively convene at 1:00pm or immediately following adjournment of the board meeting, whichever is later.*****

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Monday, September 6, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: A full board meeting was called to order at 9:10AM.

PRESIDING: Dale St.Clair, PharmD, Chairman

MEMBERS PRESENT:
Larry Kocot, J.D.
Bill Lee, DPh
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh
Ling Yuan, PharmD

MEMBERS ABSENT:
Jim Jenkins, RN
Cheri Garvin, RPh
Sarah Melton, PharmD

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director
Erin Barrett, J.D., DHP Senior Policy Analyst
David Brown, D.C., DHP Director
Mykl Egan, J.D., Disciplinary Case Manager
Annette Kelley, MS, CSAC, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Beth O'Halloran, RPh, Deputy Executive Director
Ileita Redd, Disciplinary Specialist
James Rutkowski, J.D., Assistant Attorney General
Ellen Shinaberry, PharmD, Deputy Executive Director

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

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

APPROVAL OF AGENDA: The agenda was adopted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION: **The Board voted unanimously to adopt the minutes for the meetings held between May 23, 2022 and August 17, 2022 as presented. (Motion by Richards-Spruill , seconded by Ratliff; Kocot abstained)**

The Board voted unanimously to adopt the minutes for the meetings held on August 18, 2022 and August 23, 2022 as presented. (Motion by Kocot, seconded by Yuan)

PUBLIC COMMENT: Lauren Paul, Executive Director, Pharmacy Regulatory Affairs, CVS Health offered public comment. She applauded efforts made in Virginia to expand pharmacy clinical services. She requested the Board amend Guidance Document 110-33 to authorize a pharmacist to delegate to a Board-registered pharmacy technician trainee who has completed the practical immunization training approved by ACPE and has obtained a certificate in basic CPR to administer vaccines. She stated the pharmaceutical processor advertising language regarding an "image" was confusing and questioned why advertising allowances needed to be broadened since safeguards should be in place. She offered supportive comments for the draft language in Guidance Document 110-6.

Becky Hobden, Lab Director, Green Analytics Virginia offered verbal comment, in addition to the written comment provided to the Board as a handout. Green Analytics is a cannabis testing lab. She stated that testing residual solvents as proposed may be cost prohibitive, that some of the solvents on the list are not used in cannabis extraction, and that labs may not have an ability to test for all of the solvents on the proposed list. She offered to provide staff with a list of chemicals for which a lab test may not exist if the Board wanted to carve out certain solvents for which there is no ability to test for their presence.

The Board paused for a few minutes to read the written comment provided by gLeaf that was provided to the Board as a handout.

DHP DIRECTOR'S REPORT: Dr. David Brown welcomed the newly appointed board members and congratulated those who were reappointed. He provided an update on the HPMP and suggested the Board invite representatives of the HPMP to offer an overview presentation at a future meeting. He stated that the agency is still experiencing supply chain delays regarding the AV equipment upgrade in the conference center.

LEGISLATIVE/
REGULATORY/GUIDANCE

CHART OF REGULATORY ACTIONS

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information regarding the length of time of each proposed regulation in the various stages of administrative review.

ADOPTION OF EXEMPT FINAL REGULATIONS TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

MOTION:

The Board voted unanimously to adopt the exempt final regulations for 18VAC110-20-322 to place the following chemicals in Schedule I as presented:
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. **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.**

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.

2. **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.**

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. **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.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. **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.**

5. **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. (Motion by Kocot, seconded by Lee)**

ADOPTION OF EXEMPT FINAL REGULATIONS TO CONFORM DRUG SCHEDULES TO FEDERAL SCHEDULING ACTION

MOTION:

The Board voted unanimously to adopt the exempt final regulations for 18VAC110-20-323 to conform drug schedules to federal scheduling action as presented and listed below:

Needs to be Placed into Schedule I to conform to federal scheduling:

1. **4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR);**
2. **1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA);**
3. **ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate);**
4. **N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl);**
5. **N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl);**
6. **N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl);**
7. **N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-**

fluorofentanyl);

8. **N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl);**
9. **N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl);**
10. **N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl);**
11. **N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);**
12. **N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl);**
13. **2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);**
14. **N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl);**
15. **N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl);**
16. **N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl);**
17. **24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene);**
18. **25. N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene)**

Needs to be Placed into Schedule II to conform to federal scheduling:

1. **Oliceridine**

Needs to be Exempted from Schedule II to conform to federal scheduling:

1. **Removal of Samidorphan**

Needs to be Placed into Schedule IV to conform to federal scheduling:

1. **Remimazolam**
2. **Serdexmethylphenidate**
3. **Lemborexant**
4. **Daridorexant**

Needs to be Placed into Schedule V to conform to federal Scheduling:

1. **Ganaxolone**

(Motion by Kocot, seconded by Lee)

ADOPTION OF EXEMPT FINAL REGULATIONS TO REMOVE CHEMICALS RECENTLY SCHEDULED IN CODE

MOTION:

The Board voted unanimously to adopt exempt final regulations for 18VAC110-20-322 and 18VAC110-20-323 as presented to remove Scheduled substances which are now in the Code. (motion by Kocot, seconded by Lee)

ADOPTION OF EMERGENCY REGULATIONS/NOIRA FOR PHARMACISTS INITIATING TREATMENT

During the discussion, Dr. Lee commented that perhaps the Board should consider in a future periodic regulatory review an amendment to 18VAC110-20-150 (G) to require medical-grade refrigeration.

MOTION:

Pursuant to HB 1323, the Board voted unanimously to adopt emergency regulations to amend 18VAC110-21-46 as presented for pharmacist initiating treatment and a NOIRA for replacement regulations. (motion by Yuan, seconded by Kocot)

AMEND CURRENT STATEWIDE PROTOCOLS:

To conform with statutory changes resulting from HB 1323 and recommendations from a recent statewide protocol workgroup hosted by the Board of Medicine regarding vaccine protocols, the Board voted unanimously to amend the following current statewide protocols as presented:

- **Pharmacist Emergency Contraception Statewide Protocol;**
- **Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses;**
- **Tuberculin Skin Testing One-Step Protocol;**
- **Tuberculin Skin Testing Two-Step Protocol;**
- **Pharmacist Epinephrine Statewide Protocol;**
- **Pharmacist Naloxone Statewide Protocol;**
- **Pharmacist Prenatal Vitamin Statewide Protocol;**
- **Pharmacist Hormonal Contraceptive Statewide Protocol;**
- **Pharmacist Vaccine Statewide Protocol**

(motion by Richards-Spruill, seconded by Lee)

ADOPTION OF EXEMPT

REGULATIONS FOR PHARMACEUTICAL PROCESSORS:

MOTION:

In response to HB933/SB671 and public comments received during the 60-day public comment period, the Board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented and amended as outlined below:

- **Strike "a" after "Virginia" in 18VAC110-60-170 (D);**
- **Strike 18VAC110-60-170 (D) (6);**
- **Insert "Virginia" after "any" in 18VAC110-60-280(B)(2)(b) and clarify that the reference to "state" in 18VAC110-60-280 (B)(2)(b) and (c), and 18VAC110-60-281(B)(5) is referring to "Virginia";**
- **Insert new subsection "H" in 18VAC110-60-281 to reference use of an approved list of hydrocarbon-based solvents for cannabis oil products;**
- **Amend 18VAC110-60-300 (G)(6) to acknowledge approved list of hydrocarbon-based solvents in 18VAC110-60-281(H). (motion by Ratliff, seconded by Richards-Spruill)**

ACTION ITEM:

Board to develop guidance document to reference approved list of hydrocarbon-based solvents for which there is a lab test to assess residual solvent.

ADOPTION OF EMERGENCY REGULATIONS/NOIRA FOR PHARMACY WORKING CONDITIONS:

A revised draft of regulatory amendments was provided to the Board for its consideration.

In response to HB1324, the Board voted unanimously to adopt the emergency regulations to amend 18VAC110-20-110 and 18VAC110-20-113 as presented in the handout and amended as outlined below:

- **18VAC110-20-113(B)(1), end sentence after "safety"; strike "recognizing that"; and, replace last sentence with language akin to "Staffing levels cannot solely be determined based on total prescription volume, but shall consider any other requirements of pharmacy staff during working hours.";**
- **18VAC110-20-113(B)(4), replace "and" with "as" after "experience";**
- **18VAC110-20-113(E), insert requirements for permit holder to acknowledge receipt of the staffing report, document steps toward addressing the issue, report action or inaction back to the PIC or reporting pharmacist, and maintain the documentation on-site at the pharmacy or produce the documentation for inspection by the**

Board within 48 hours of request. (motion by Nash, seconded by Yuan)

CONSIDERATION FOR PHARMACY TECHNICIAN TRAINEES TO ADMINISTER VACCINES

MOTION: **The Board voted unanimously to amend Guidance Document 110-33 as presented to not allow pharmacy technician trainees to administer vaccines, consistent with the Board's interpretation of the current allowances in the PREP Act. (motion by Ratliff, Richards-Spruill)**

AMEND GUIDANCE DOCUMENT 110-25 TO ADDRESS LIFE OF WRITTEN CERTIFICATION WHEN PRESCRIBER NO LONGER IN PRACTICE

MOTION: **The Board voted unanimously to amend Guidance Document 110-25 as presented to address the life of a written certification when the prescriber is no longer in practice. (motion by Lee, seconded by Nash)**

ACTION ITEM: **At the Board's request, Ms. Juran will research if there is evidence correlating the number of hours worked by pharmacists to patient harm. She will also discuss with the Workforce Data Center whether a question could be reasonably added to the pharmacist workforce survey to identify the number of pharmacists working longer than 12 consecutive hours.**

AMEND GUIDANCE DOCUMENT 110-6 REGARDING OPIOID TREATMENT PROGRAMS

Ms. Barrett stated that staff recommends that the last two sentences stricken in the second bullet point on the first page of the draft included in the agenda packet that begins "The nurse must ensure…." should remain in the guidance document and not be stricken.

MOTION: **Resulting from SB511 and to address the allowance for a nurse to perform the duties of a pharmacy technician in an opioid treatment program, the Board voted unanimously to amend Guidance Document 110-6 as presented and amended by retaining the last two sentences of the second bullet point on the first page that begins "The nurse must ensure…" (motion by Lee, seconded by Nash)**

AMEND GUIDANCE

DOCUMENT 110-35 REGARDING PRESCRIPTION REQUIREMENTS

MOTION:

To further educate licensees, the Board voted unanimously to amend Guidance Document 110-35 as presented to acknowledge the legal provisions for prescriptions for expedited partner therapy. (motion by Yuan, seconded by Richards-Spruill)

AMEND GUIDANCE DOCUMENT 110-45 REGARDING MINORS WORKING AS PHARMACY TECHNICIAN TRAINEES

In response to concerns raised to staff by the Department of Labor and Industry, a draft guidance document recommending that pharmacy technician trainees under the age of 18 only handle Schedule VI drugs was presented for consideration by the Board.

MOTION/ACTION ITEM:

The Board voted unanimously to table the adoption of a guidance document recommending that pharmacy technician trainees under the age of 18 only handle Schedule VI drugs and to invite a representative from the Department of Labor and Industry to a future meeting to discuss the matter. (motion by Nash, seconded by Lee)

AMEND GUIDANCE DOCUMENT 110-20

MOTION:

To clarify which material owners of a pharmaceutical processor or cannabis dispensing facility must perform a criminal background check when no owner has 5% or greater ownership, the Board voted unanimously to amend Guidance Document 110-20 as presented and amended as outlined below:

- **Strike "such as the chief executive officer and chief financial officer". (motion by Kocot, seconded by Ratliff)**

NEW BUSINESS:

ELECTION OF VICE-CHAIRMAN:

Dr. Ratliff recommended Bill Lee for Vice-Chairman of the Virginia Board of Pharmacy. Term is for September 6, 2022 through June 30, 2023. No other nominations were recommended.

MOTION:

The Board voted unanimously to close nominations for election of the 2022-2023 Vice-Chairman of the Virginia Board of Pharmacy. (motion by Richards-Spruill, seconded by Kocot)

The Board voted unanimously to elect Bill Lee as the 2022-2023 Vice-

VOTE:	**Chairman of the Virginia Board of Pharmacy.**
REPORTS:	
CHAIRMAN'S REPORT	Dr. St.Clair thanked the former board members and welcomed the newly appointed board members. He encouraged attendance at the NABP/AACP Districts 1 and 2 meeting in October and the NABP annual meeting in May.
BOARD OF HEALTH PROFESSIONS	On behalf of Dr. Melton, Dr. St.Clair stated that the last meeting of the Board of Health Professions was cancelled and there was nothing to report.
LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES	Mr. Logan reviewed the Licensing Report of Individuals and In-State Facilities included in the agenda packet.
LICENSURE OF NONRESIDENT FACILITIES	Ms. O'Halloran reviewed the Licensing Report of Nonresident Facilities included in the agenda packet.
INSPECTION PROGRAM	Melody Morton, Inspections Manager with the Enforcement Division presented the Inspections Report which was included in the agenda packet.
PHARMACEUTICAL PROCESSORS	Annette Kelley reviewed the Pharmaceutical Processors Report included in the agenda packet. .
DISCIPLINARY PROGRAM	Dr. Shinaberry reviewed the disciplinary report included in the agenda packet.
EXECUTIVE DIRECTOR'S REPORT	Ms. Juran reviewed her report which was included in the agenda packet. Additionally, she expressed appreciation to staff members Ileita Redd and Mykl Egan who were attendance at the meeting.
MEETING ADJOURNED:	With all business concluded, the meeting adjourned at 3PM.

Dale St.Clair, Chairman	Caroline Juran, Executive Director
DATE:	DATE:

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I AND CONFORM DRUG SCHEDULES TO FEDERAL SCHEDULING ACTION

Monday, September 6, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	The Board of Pharmacy ("Board") convened a public hearing to 1) consider placement of certain chemicals into Schedule I and 2) the conforming of drug schedules to federal scheduling action at 9:05 am.
PRESIDING:	Dale St.Clair, PharmD, Chairman
MEMBERS PRESENT:	Larry Kocot, J.D. Bill Lee, DPh Wendy Nash, PharmD Kristopher Ratliff, DPh Patricia Richards-Spruill, RPh Ling Yuan, PharmD
MEMBERS ABSENT	Jim Jenkins, RN Cheri Garvin, RPh Sarah Melton, PharmD
STAFF PRESENT:	Erin Barrett, J.D., DHP Senior Policy Analyst David Brown, D.C., DHP Director Mykl Egan, J.D., Disciplinary Case Manager Caroline D. Juran, RPh, Executive Director Annette Kelley, MS, CSAC, Deputy Executive Director Ryan Logan, RPh, Deputy Executive Director Beth O'Halloran, RPh, Deputy Executive Director Ileita Redd, Disciplinary Specialist James Rutkowski, J.D., Assistant Attorney General Ellen Shinaberry, PharmD, Deputy Executive Director
QUORUM:	With seven members of the Board present, a quorum of the board was established.
PUBLIC COMMENT	Dr. St.Clair invited members of the public to offer comment on the subjects. Pursuant to article § 54.1-3443(D), the Virginia Department

of Forensic Science (DFS) identified the following five compounds for recommended inclusion into Schedule I of the Drug Control Act.

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. 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.

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.

2. 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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. 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.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. 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.

5. 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.

Additionally, pursuant to subsection E of §54.1-3443, the Board identified the following chemicals that were scheduled or de-scheduled federally during 2021 through July 6, 2022:

Needs to be Placed into Schedule I to conform to federal scheduling:

1. 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR);
2. 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA);
3. ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate);
4. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl);
5. N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl);
6. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl);
7. N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
8. N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl);
9. N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl);
10. N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl);
11. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-

yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl);
12. N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl);
13. 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl);
14. N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl);
15. N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl);
16. N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl);
17. 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene);
18. 25. N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene)

Needs to be Placed into Schedule II to conform to federal scheduling:

1. Oliceridine

Needs to be Exempted from Schedule II to conform to federal scheduling:

1. Removal of Samidorphan

Needs to be Placed into Schedule IV to conform to federal scheduling:

1. Remimazolam
2. Serdexmethylphenidate
3. Lemborexant
4. Daridorexant

Needs to be Placed into Schedule V to conform to federal Scheduling:

1. Ganaxolone

No public comments were offered.

MEETING ADJOURNED

The Public Hearing was adjourned at 9:10am.

Dale St.Clair, Chair

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, September 6, 2022
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 3:18 PM.

PRESIDING: Dale St. Clair, PharmD, Chair

MEMBERS PRESENT: Lee Yuan, PharmD
Patricia Richards-Spruill, RPh
Larry Kocot, Esq.
Bill Lee, PharmD
Wendy Nash, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director, Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Exec. Dir., Board of Pharmacy
James Rutkowski, JD, Assistant Attorney General

QUORUM: With 6 members of the Board present, a quorum of the board was established.

EDWARD BRESLOW
0202-011951

A formal hearing was held in the matter of Edward Breslow to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider whether or not he is safe to practice.

Anne Joseph, DHP Adjudication Specialist, presented the case on behalf of the Commonwealth.

Edward Breslow did not have legal counsel and represented himself.

Todd Troutner, DHP Senior Investigator, and Alicia Barreto-Whitaker, QMPH-A, testified in person on behalf of the Commonwealth.

Edward Breslow testified on his own behalf.

CLOSED MEETING:	Upon a motion by Patricia Richards-Spruill, and duly seconded by Bill Lee, the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Edward Breslow. Additionally, she moved that Caroline Juran, James Rutkowski, and Ellen Shinaberry attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Richards-Spruill, second by Kocot)
DECISION:	Upon a motion by Ling Yuan and duly seconded by Bill Lee, the Board unanimously voted to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth and amended by the Board. Upon a motion by Wendy Nash and duly seconded by Patricia Richards-Spruill, the Board unanimously voted to indefinitely suspend the pharmacist license of Edward Breslow, and to stay the suspension upon entry into and successful completion of HPMP. Mrs. Patricia Richards-Spruill departed at the end of the hearing.
ASHLEY BOWMAN 0245-004089	A formal hearing was held in the matter of Ashley Bowman to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia and to consider whether or not she is safe to practice. Jess Weber, DHP Adjudication Specialist, presented the case on behalf of the Commonwealth. Ashley Bowman did not appear at the formal hearing and was not represented by legal counsel. Amy Branson, DHP Pharmacy Inspector, and Jason Lotts, CVS District Asset Protection Manager, testified by telephone on behalf of the Commonwealth.
CLOSED MEETING:	Upon a motion by Bill Lee, and duly seconded by Larry Kocot, the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Ashley Bowman. Additionally, he moved that Caroline Juran, James Rutkowski, and Ellen Shinaberry attend the closed meeting.

RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Lee, second by Kocot)
DECISION:	Upon a motion by Ling Yuan and duly seconded by Larry Kocot, the Board unanimously voted to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth and amended by the Board. Upon a motion by Wendy Nash and duly seconded by Bill Lee, the Board unanimously voted to revoke the pharmacy technician trainee registration of Ashley Bowman.
ADJOURN:	The meeting was adjourned at 6:17 PM.

Cheryl Nelson, Chair

Caroline Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, September 26, 2022

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 September 26, 2022, at 08:05 AM, to consider the summary suspension in case no. 216177.

PRESIDING: Dale St. Clair, Chair

MEMBERS PRESENT:
Cheri Garvin
James Jenkins
Larry Kocot
Wendy Nash
Sarah Melton
Patricia Richards-Spruill

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Christine Andreoli, DHP Adjudication Specialist

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

With seven (7) members participating, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

JAMES V. ETTARE, II License No. 0245-002763	Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case no. 216177 regarding the pharmacist license of James V. Ettare, II.
DECISION:	Upon a motion by Mr. Jenkins and duly seconded by Dr. Melton, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacist by James V. Ettare, II poses a substantial danger to the public; and therefore, the license of Mr. Ettare shall be summarily suspended and Mr. Ettare provided with a the Notice of formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 08:19 AM.

Dale St. Clair, Chair	Ellen B. Shinaberry, PharmD Deputy Executive Director
Date	

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, October 12, 2022

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 12, 2022, at 09:40 AM, to consider the summary suspensions in case no. 220257 and case no. 221835.

PRESIDING: Dale St. Clair, Chair

BOARD MEMBERS PRESENT:
Larry Kocot
Cheri Garvin
Sarah Melton
Patricia Richards-Spruill
Wendy Nash

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Christine Andreoli, DHP Adjudication Specialist
Anne Joseph, DHP Adjudication Specialist

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

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

MATTHEW EVANS Registration No. 0230-034942	Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case no. 220257 regarding the pharmacy technician registration of Matthew Evans. Mr. Murphy was assisted by Anne Joseph, DHP Adjudication Specialist.
DECISION:	Upon a motion by Ms. Garvin and duly seconded by Ms. Richards-Spruill, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician by Matthew Evans poses a substantial danger to the public; and therefore, the registration of Mr. Evans shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Mr. Malone for the indefinite suspension of his registration for not less than two years in lieu of the formal hearing.
LINDA ASTON Registration No. 0245-003851	Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 220054 regarding the pharmacy technician trainee registration of Linda Aston. Mr. Murphy was assisted by Christine Andreoli, DHP Adjudication Specialist.
DECISION:	Upon a motion by Ms. Garvin and duly seconded by Dr. Melton, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Linda Aston poses a substantial danger to the public; and therefore, the registration of Ms. Aston shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Aston for the revocation of her registration in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 09:55 AM.

Dale St. Clair, Chair	Ellen B. Shinaberry, PharmD Deputy Executive Director
Date	Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, October 18, 2022
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:10 AM.

PRESIDING: Dale St. Clair, PharmD, Chair

MEMBERS PRESENT: Patricia Richards-Spruill, RPh
Cheri Garvin, RPh
Bill Lee, PharmD
Ling Yuan, PharmD
Wendy Nash, PharmD

STAFF PRESENT: Caroline Juran, RPh, Executive Director, Board of Pharmacy
James Rutkowski, JD, Assistant Attorney General

QUORUM: With 6 members of the Board present, a panel of the board was established.

CVS PHARMACY #7558
02001-002605

A formal hearing was held in the matter of CVS Pharmacy #7558 to discuss violations of certain laws and regulations governing the practice of pharmacy in Virginia and to consider the summary restriction of its virtual verification process.

Sean Murphy, Assistant Attorney General, presented the case on behalf of the Commonwealth. He was assisted by David Robinson, DHP Adjudication Specialist.

CVS Pharmacy #7558 was represented by Joe Levino, Sr. Legal Counsel for CVS. CVS Pharmacy #7558 was legally represented by Roger Morris, Esq., who was assisted by Alex Cooper, Esq.

Tim Reilly, DHP Senior Investigator, testified in person on behalf of the Commonwealth. Nancy Frye, pharmacist and PIC of CVS Pharmacy #7558, testified in person for the Commonwealth along with Shawnita Robinson, pharmacy technician at CVS Pharmacy #7558, and John Sofay, staff pharmacist at CVS Pharmacy #7558.

Joe Levino testified in person for CVS Pharmacy #7558, along with Jacob Sicinski, CVS pharmacist in northern Virginia, and Sarah Sanders, pharmacist and PIC at CVS Pharmacy in Glen Allen, VA. Todd Carter, Assistant Professor, Appalachian College of Pharmacy, appeared in person and served as an

expert witness for CVS Pharmacy #7558.

CLOSED MEETING:	Upon a motion by Cheri Garvin, and duly seconded by Patricia Richards-Spruill, the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of CVS Pharmacy #7558. Additionally, she moved that Caroline Juran and James Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Garvin, second by Nash).
DECISION:	Upon a motion by Bill Lee and duly seconded by Ling Yuan, the Board unanimously voted to issue a monetary penalty and to rescind the summary restriction of the virtual verification process with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 7:56 PM.

Dale St. Clair, Chair

Caroline Juran, Executive Director

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, October 19, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:06 am.
PRESIDING:	Cheryl Garvin, Committee Chair
MEMBERS PRESENT:	Wendy Nash, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Claire Foley, DHP Adjudication Specialist Jess Weber, DHP Adjudication Specialist David Robinson, DHP Adjudication Specialist
John Seymour, Pharmacist License No. 0202-006917	John Seymour, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the August 22, 2022, Notice. He was represented by John E. Peterson, Jr., Esq.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of John Seymour. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to order that Mr. Seymour complete additional hours in continuing education.
Michele Turner, Pharmacy Technician Registration No. 0230-012716	Michele Turner, pharmacy technician appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the August 22, 2022, Notice. She was not represented counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Michele Turner. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to place Ms. Turner's permit on probation under certain terms and conditions.
April Arafa, Applicant Registration No.	April Arafa, did not appear to discuss her application for registration as a pharmacy technician and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy that could lead to the denial of her application as stated in the August 9, 2022 Notice. Ms. Arafa was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to

	convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of April Arafa. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to deny Ms. Arafa's application.
Darrelle M. Moses, Pharmacy Technician Trainee Registration No. 0245-000331	Darrelle Moses, Pharmacy Technician Trainee, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician trainee as stated in the August 2, 2022, Notice. She was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Darrelle Moses. Additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to refer the matter to a formal hearing and offer Ms. Moses a consent order
ADJOURNED:	1:15 p.m.

Cheryl Garvin, Chair	Mykl D. Egan Discipline Case Manager
Date	Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, November 2, 2022
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:12 am.
PRESIDING:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	William Lee, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist David Robinson, Adjudication Specialist Jessica Weber, DHP Adjudication Specialist Christine Andreoli, DHP Adjudication Specialist
SALLY DAAMASH License No. 0202-216413	Sally Daamash appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 23, 2022, Notice. Ms. Daamash was not represented by Counsel.
Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Sally Daamash. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.

Decision:	Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee voted unanimously to Committee unanimously voted to issue Ms. Daamash a REPRIMAND and order her to complete additional hours in continuing education.
GIHAN W. SERAKA License No. 0202-204419	Gihan W. Seraka appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 23, 2022, Notice. Ms. Seraka was not represented by Counsel.
Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Gihan W. Seraka. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee voted unanimously to Committee unanimously voted to issue Ms. Seraka a REPRIMAND, assess a monetary penalty, and order her to complete additional hours in continuing education.
KC PHARMACY Permit No. 0201-004087	Gihan W. Seraka, Owner of KC Pharmacy appeared as a representative of the pharmacy, to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the September 23, 2022, Notice. They were not represented by counsel. The pharmacy was not represented by counsel.

Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of KC Pharmacy Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee unanimously voted to assess a monetary penalty against KC Pharmacy and order additional terms and conditions placed on the Pharmacy.
STERRX LLC, Reinstatement Applicant Registration No. :0236-000017	James Horger, VP of Quality and Regulatory Compliance, Sagent Pharmaceuticals, Inc., Sarah J. McCoy, Director, Plant Operations, SterRx LLC, and Tracy Roth, Director, Quality Assurance, SterRx, LLC, appeared as representatives of SterRx LLC to discuss the pharmacies application for renewal of its registration to act as a non-resident outsourcing facility and that allegations exist to deny that application as stated in the September 23, 2022, Notice. The pharmacy was represented by Karla Palmer, Esq.
Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of SterRx LLC. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was

deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee unanimously voted to DENY the application of SterRx LLC for renewal of its registration to act as a non-resident outsourcing facility.

GREEN LEAF MEDICAL OF VA
Permit No. 0247-000003

Donald Moore, Compliance Case Manager and Adam Blankinship, Pharmacist-in-Charge of Green Leaf in Manchester, appeared as representatives of Green Leaf Medical of VA ("Green Leaf Dispensing") to discuss allegations that it may have violated certain laws and regulations governing its conduct as a cannabis dispensing facility as stated in the August 30, 2022, Notice. It was represented by Hunter Jamerson, Esquire.

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

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

Decision: Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee voted unanimously to

take no further action against Green Leaf Dispensing.

GREEN LEAF MEDICAL OF VIRGINIA, LLC
Permit No. 0240-000003

Donald Moore, Compliance Case Manager and Adam Blankinship, Pharmacist-in-Charge, appeared as representatives of Green Leaf Medical of Virginia, LLC ("Green Leaf Processing") to discuss allegations that it may have violated certain laws and regulations governing its conduct as a pharmaceutical processor as stated in the August 30, 2022, Notice. They were represented by Hunter Jamerson, Esquire.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee voted unanimously to issue Green Leaf Processing a REPRIMAND and to assess a monetary penalty.

KRISTIN WILKERSON, Reinstatement Applicant
License No. 0202-205439

Kristin Wilkerson did not appear to discuss her application for reinstatement of her license as a pharmacist as stated in the September 23, 2022, Notice. Ms. Wilkerson was not represented by counsel.

Closed Meeting:

Upon a motion by Dr. Lee, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia

Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Kristin Wilkerson. Additionally, he moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Dr. Lee and duly seconded by Mr. Ratliff, the Committee voted unanimously to DENY her application for reinstatement of her pharmacy license.

ADJOURNED: 5:00 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, November 17, 2022
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:06 am.
PRESIDING:	Cheryl Garvin, Committee Chair
MEMBERS PRESENT:	Wendy Nash, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist
CVS PHARMACY #3508 Permit No. 0201-000707	Joseph Levino, Senior Legal Counsel for Regulatory Affairs and Danielle Conklin-Gregory, District Manager, appeared as representatives of CVS/Pharmacy #3508 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the August 22, 2022, Notice. They were represented by Nathaniel Brand, III, Esquire and Margaret Hardy, Esquire.
Closed Meeting:	Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #3508, additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of Virginia Code § 2.2-3712, the Committee

reconvened in open meeting and announced the decision.

Decision: Upon a motion by Dr. Nash and duly seconded by Ms. Garvin, the Committee unanimously voted to assess a monetary penalty against CVS/Pharmacy #3508 and place the pharmacy on probation under additional terms and conditions.

COMMONWEALTH EMS
Permit No. 0220-001729

No one appeared as a representative of Commonwealth EMS, to discuss allegations that it may have violated certain laws and regulations governing the conduct a business CSR as stated in the September 2, 2022, Notice. They were not represented by counsel.

Closed Meeting: Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Commonwealth EMS, additionally, she moved that Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Dr. Nash and duly seconded by Ms. Garvin, the Committee unanimously voted to refer the matter to a Formal Hearing.

ADJOURNED: 3:15 p.m.

Cheryl Garvin, Chair

Mykl D. Egan
Discipline Case Manager

_____ _____

Date Date

Agenda Item: Discussion with Department of Labor and Industry regarding Adoption of

Guidance Document

Included in Agenda:

- Draft Guidance Document

Staff Notes:

- At the September 6, 2022 Board meeting, the Board voted unanimously to table the adoption of the draft guidance document recommending that pharmacy technician trainees under the age of 18 only handle Schedule VI drugs and to invite a representative from the Department of Labor and Industry to a future meeting to discuss the matter.

Action needed:

- Following discussion with representative from DOLI regarding background information for possibly adopting Guidance Document:
  - Adopt Guidance Document as presented or amended; OR
  - Take no action.

Virginia Board of Pharmacy

Minors Working as Pharmacy Technician Trainees

Virginia Code § 54.1-3321 and 18VAC110-21-135 govern registration of pharmacy technician trainees. There is no age requirement for registration. However, applicants must be enrolled in a pharmacy technician training program. The Virginia Department of Education oversees pharmacy technician training programs for high school students. Students enrolled in the program register as pharmacy technician trainees and work in pharmacies as part of the program.

Due to concerns raised by the Virginia Department of Labor and Industry related to the application of Virginia Code § 40.1-100(A)(4) and 16VAC15-30-200(4) to minors working in pharmacies, the Board of Pharmacy recommends that pharmacy technician trainees under the age of 18 handle only Schedule VI drugs in the course of their training.

Board of Pharmacy
Current Regulatory Actions
As of November 14, 2022

In the Governor's Office

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	5/23/2018	Governor 1636 days	Addresses a patient safety concern.
18VAC110-20	Exempt/ Final	September 2022 scheduling of chemicals in Schedule I	11/7/2022	Governor 7 days	Chemicals scheduled in Schedule I pursuant to DFS request
18VAC110-20	Exempt/ Final	September 2022 action conforming schedules to federal scheduling actions	11/7/2022	Governor 7 days	Chemicals scheduled pursuant to federal actions 2021 – July 2022

In the Secretary's Office

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 225 days	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 225 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and

					registration of pharmacy technicians
18VAC110-20	Proposed	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	8/31/2022	Secretary 75 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals

At DPB/OAG

VAC	Stage	Subject Matter	Date submitted*	Office; time in office**	Notes
18VAC110-20	Emergency/ NOIRA	Pharmacy working conditions	11/7/2022	DPB 7 days	Implements emergency regulations related to work environments for pharmacy personnel
18VAC110-21	Emergency/ NOIRA	2022 Pharmacists initiating treatment	9/16/2022	OAG 59	Implements 2022 legislation regarding pharmacists initiating treatment
18VAC110-60	Exempt/ Final	Pharmaceutical processor regulations	10/5/2022	OAG 40 days	Implements changes to processor regulations pursuant to 2022 legislation

* Date submitted to current location
** As of August 11, 2022

Recently effective/awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date
18VAC110-20	Exempt/Final	Implementation of HB193/SB759 regarding Scheduled drugs	10/24/2022	11/23/2022
18VAC110-20	NOIRA	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements onf 18VAC110-20-555	11/7/2022	Public comment period ends 12/7/2022. Board can consider proposed regulations after the close of comments.
18VAC110-20	Final	Use of medication carousels and RFID technology	11/7/2022	12/7/2022
18VAC110-20	Proposed	Implementation of 2021 legislation for pharmacists initiating treatment	11/21/2022	Public comment period will run from 11/21/2022 to 1/20/2023. Board can vote on final regulations after the close of comments.
18VAC110-20	Final	Pharmacists initiating treatment – 2020 legislation	11/21/2022	12/21/2022
18VAC110-21	Final	Implementation of legislation for registration of pharmacy technicians	11/21/2022	12/21/2022
18VAC110-30	NOIRA	Implementation of 2021 Periodic Review	12/5/2022	Public comment period will run 12/5/2022 to 1/4/2023. Board can consider proposed regulations after the close of comments.

Agenda Item: Adoption of final regulations – placement of chemicals in Schedule I

Included in your agenda package are:

- Letter from DFS requesting additions to Schedule I.
- Copy of notice of public hearing listing chemicals to be placed in Schedule I.
- Amendments to 18VAC110-20-322.

Staff Note: Public hearing held before the meeting.

Action needed:

- Motion to adopt exempt final changes to 18VAC110-20-322.

COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
A Nationally Accredited Laboratory

700 NORTH 5TH ST.
RICHMOND, VIRGINIA 23219
(804) 786-2281 FAX (804) 786-6857

To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: October 14, 2022
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 five (5) 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-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.

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.

2. **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.

3. **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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

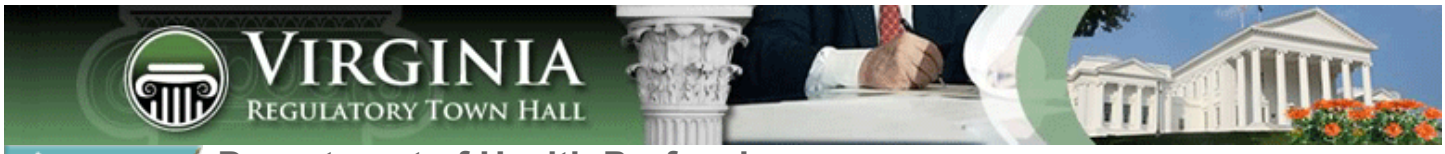
4. **7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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.

5. **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.

Robyn Weimer
Chemistry Program Manager

Virginia.gov Agencies | Governor



Agency Department of Health Professions

Board Board of Pharmacy

Edit Notice

General Notice

Notice for scheduling chemicals in Schedule I pursuant to 54.1-3443

Date Posted: 10/14/2022

Expiration Date: 12/6/2022

Submitted to Registrar for publication: YES

No comment forum defined for this notice.

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The virtual public hearing will be conducted at **9:05 a.m. on December 6, 2022.** Instructions will be included in the agenda for the board meeting, also on December 6th. Public comment may also be submitted electronically or in writing prior to December 6th to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified five (5) compounds for recommended inclusion into Schedule I of the Drug Control Act.

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-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.

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.

2. **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.

3. **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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

4. **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.

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.

5. **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.

Contact Information

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

This general notice was created by Erin Barrett on 10/14/2022 at 1:16pm

Project 7427 - Exempt Final

Board of Pharmacy

December 2022 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-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

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

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

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

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

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

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

3. Compounds expected to have depressant properties.

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

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

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

4. Cannabimimetic agents.

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

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

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

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

1. Synthetic opioids.

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

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

c. 2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene), its isomers, esters, ethers, salts, and salts of isomers,

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

d. N,N-diethyl-2-{[(4-ethoxyphenyl) methyl]-1H-benzimidazol-1-yl}-ethan-1-amine (other name: Etazene, Desnitroetonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Depressant. 5-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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. Compound expected to have hallucinogenic properties. 4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone), 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. Cannabimimetic agents.

a. Ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-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 March 14, 2023, 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. 1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline), 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. Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), 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. Cannabimimetic agents.

a. Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), 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 August 16, 2023, 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. Synthetic opioid. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), 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-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl 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.

b. 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone), 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. 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone), 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.

d. 3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone), 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.

e. 3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl 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.

f. 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone), 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.

g. 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin), 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. Central nervous system stimulant. 4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers, and salts of isomers.

4. Cannabimimetic agent. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until March 14, 2024, 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. 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 depressive 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 [September 15], 2024, unless enacted into law in the Drug Control Act.

Agenda Items: Adoption of Guidance Document 110-45

Included in your agenda package are:

- Proposed Guidance Document 110-45
- Proposed 18VAC110-60-281, awaiting approval.

Staff Note: If approved, Guidance Document 110-45 will not be submitted for publication until pharmaceutical processor regulations are approved by OAG and Executive Branch.

Action needed:

- Motion to adopt Guidance Document 110-45.

Virginia Board of Pharmacy

Approved Chemicals for use as Hydrocarbon or Other Flammable Solvents by Pharmaceutical Processors

Pursuant to 18VAC110-60-281(H), the Board approves the following chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products. These approvals are based on the availability of testing for residual material of individual solvents.

- Ethanol
- Ethyl acetate
- Ethyl ether
- Heptane
- Hexane
- Pentane
- 2-propanol (IPA)

Project 7283 - Final

Board of Pharmacy

Pharmaceutical processor regulation changes pursuant to 2022 legislation

18VAC110-60-281. Use of hydrocarbon-based solvents or other flammable solvents.

A. The following words and phrases used in this section have the following meaning:

1. "Closed-loop system" means machinery in which volatile hydrocarbon substances are self-contained without the loss or escape of those substances.

2. "Flammable solvent" means a liquid that has a flash point below 100 degrees Fahrenheit. Flammable solvents include, but are not limited to, hydrocarbon-based solvents.

3. "Hydrocarbon-based solvent" means a type of solvent composed of hydrogen and carbon compounds, such as N-butane, isobutene, propane, or any isomer or combination thereof.

B. Hydrocarbon-based solvents may be used in the cultivation, extraction, production, or manufacturing of cannabis products provided that:

1. A pharmaceutical processor complies with all requirements in this section.

2. A pharmaceutical processor using hydrocarbon-based solvents in general industrial use as promulgated by the Occupational Safety and Health Administration and published in 29 C.F.R. § 1910 or any subsequent regulation governing such use, including, but not limited to, regulations governing:

a. ventilation requirements;

b. air contaminants; and

c. hazard communication.

3. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Labor and Industry regarding use of hydrocarbon-based solvents.

4. A pharmaceutical processor using hydrocarbon-based solvents shall comply with any requirements issued by the Virginia Department of Environmental Quality regarding use of hydrocarbon-based solvents.

5. A pharmaceutical processor using hydrocarbon-based solvents maintains sole responsibility for any adverse outcomes or violations of federal or Virginia state laws or regulations caused by such use.

6. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that all equipment, counters, and surfaces used in the cultivation, extraction, production, or manufacturing of cannabis products are food-grade and do not react adversely with any hydrocarbon solvent used. All counters and surface areas shall be constructed in a manner that reduces the potential development of microbials, molds, and fungi and can be easily cleaned.

7. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any room in which hydrocarbon-based solvents will be used contains an emergency eye-wash station.

8. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that a professional grade, closed-loop extraction system capable of recovering solvent is used in the cultivation, extraction, production, or manufacturing of cannabis products.

a. Closed-loop extraction systems must be commercially manufactured and bear a permanently affixed and visible serial number.

b. A pharmaceutical processor using a closed-loop extraction system must obtain a certification from a licensed engineer that certifies that the system was commercially manufactured, is safe for its intended use, and built to codes of recognized and generally accepted good engineering practices, such as: (i) the American Society of Mechanical Engineers ("ASME"); (ii) American National Standards Institute ("ANSI"); (iii) Underwriters Laboratories ("UL"); or (iv) the American Society for Testing and Materials ("ASTM").

c. The certification must contain the signature and stamp of a professional engineer and include the serial number of the extraction unit certified.

9. A pharmaceutical processor using hydrocarbon-based solvents shall obtain a safety data sheet for each hydrocarbon-based solvent used and store such data sheet on the premises. All such records shall be subject to inspection by the board.

10. A pharmaceutical processor using hydrocarbon-based solvents shall develop standard operating procedures, good manufacturing practices, and a training plan prior to using such solvents. Standard operating procedures shall specifically address the following:

a. Safe and proper handling and use of hydrocarbon-based solvents;

b. Safe and proper operation of machinery and equipment;

c. Adequate cleaning and maintenance of machinery and equipment;

d. Incident reporting for any instances where the operator does not follow the stated standard operating procedures which identifies: (i) the operator's name; (ii) the date and time of the incident; (iii) the supervising employees to which the incident report will be sent; and (iv) an incident summary, which includes whether any cannabis products or other substances escaped from the closed-loop system, the amount of

escaped material, whether the material was destroyed, and how the incident was resolved; and

e. Safe and proper disposal of waste created during processes using hydrocarbon-based solvents.

11. A pharmaceutical processor using hydrocarbon-based solvents shall ensure that any person using such solvents in a closed-loop system:

a. Is fully trained on how to use the system;

b. Has direct access to applicable material safety data sheets; and

c. Handles and stores the solvents safely.

C. If a pharmaceutical processor intends to use a flammable solvent, then a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must:

1. Establish a maximum amount of flammable solvents and other flammable materials that may be stored within the pharmaceutical processor facility in accordance with applicable laws and regulations;

2. Determine what type of electrical equipment must be installed within the room or rooms in which flammable solvents are to be stored in accordance with applicable laws and regulations;

3. Determine whether a gas monitoring system must be installed within the room in which flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations;

4. Determine whether a fire suppression system must be installed within the room in which the flammable solvents are to be used or stored, and, if required, the system's specifications in accordance with applicable laws and regulations; and

5. Determine whether a fume vent hood or exhaust system must be installed within the room or rooms in which a flammable solvent will be used, and, if required, the system's specifications in accordance with applicable laws and regulations.

D. If a pharmaceutical processor makes a material change to its use of flammable solvents in any part of the manufacturing process, a designated industrial hygienist or professional engineer that is not an employee of the pharmaceutical processor must re-certify the standard operating procedures for use of flammable solvents determined under subsection C.

E. A pharmaceutical processor shall maintain copies of all reports generated by or received from the designated industrial hygienist or professional engineer for inspection by the board.

F. A pharmaceutical processor shall not store an amount of flammable solvents on site which exceeds the maximum amount allowable as identified by the designated industrial hygienist or professional engineer.

G. A pharmaceutical processor shall ensure that all appropriate safety and sanitary equipment, including personal protective equipment, is provided to, and appropriately used by, each employee handling a flammable solvent.

H. The board shall approve chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products based on availability of testing for residual material of individual solvents.

Agenda Items: Revision of Guidance Document 110-10

Included in your agenda package are:

- Guidance Document 110-10, with proposed changes in redline and a clean copy.

Action needed:

- Motion to adopt revisions to Guidance Document 110-10.

Virginia Board of Pharmacy
Mobile Units for Dispensing for the Indigent or Underserved Population

For good cause shown, and pursuant to Virginia Code § 54.1-3304, the Board of Pharmacy may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. ~~–~~The Board ~~has recently interpreted~~interprets Virginia Code § 54.1-3304 to mean that the indigent and medically underserved ~~may~~ represent a population for which pharmacy services are not reasonably available. ~~–~~As such, a physician desiring to dispense drugs only to an indigent or underserved population from a mobile unit may apply for this license as a ~~"~~"permitted physician,"~~"~~ which will allow~~s~~ him to practice pharmacy pursuant to Board of Pharmacy regulations as set forth in 18VAC110-20-410. ~~–~~For purposes of this guidance document, the Board defines ~~"~~"indigent"~~"~~ ~~is defined~~ as those persons whose income is not more than 200% above the federal poverty guidelines, and defines a medically underserved area or population ~~is defined~~ by criteria established by the Health Resources ~~and~~ & Services Administration of the U.S. Department of Health and Human Resources.

Additionally, pursuant to ~~-~~18 VAC 110-20-410~~-~~(B) and 18VAC110-20-120, the Board may issue a special or limited-use permit to a permitted physician~~,~~ when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a regular pharmacy service. ~~–~~The Board ~~has been made~~is aware of at least two physicians who use or have used mobile units traveling throughout a community to offer medical assistance to the indigent or underserved and who would like to include the dispensing of prescription drugs. ~~-~~Mobile units do not meet all physical requirements of 18VAC110-20-150 for security and appropriate storage conditions for drugs, and possibly do not meet the alarm requirements of 18VAC110-20-180. Additionally, ~~They~~mobile units ~~also~~ may not meet the traditional enclosure requirements of 18VAC110-20-190.

The Board recognizes that there is a growing need to ~~be able to~~ provide pharmacy services to ~~this~~ the indigent or medically underserved population. ~~–~~Therefore, if a physician applies for a permitted physician license to provide services to the indigent or medically underserved by mobile unit~~for this purpose~~, he may request a waiver of sections A, B, and C of 18VAC110-20-150. The physician~~, but~~ must be able to meet the other requirements of this section, however, including temperature control. ~~–~~The enclosure requirements in a mobile unit may, if approved after inspection, be met by a separate lockable room, compartment, or cabinet. ~~-~~In order for the Board to consider waiving sections A, B, and C of 18VAC110-20-150~~these requirements~~ for a mobile unit, the following criteria must be met in addition to all other legal requirements for a permitted physician:

- The mobile unit shall not stock any Schedule II-V controlled substances for dispensing.
- The mobile unit shall be parked daily during its off-hours at the same designated location as specified to the Board during the application process.
- When parked during the off-hours, the mobile unit shall be under camera surveillance or within a secure parking area with around-the-clock security staff, and in an area that is affiliated with the physician's practice location.
- The mobile unit shall at all times provide a controlled temperature environment pursuant to 18VAC110-20-150.

- The mobile unit shall have an alarm system that complies with the requirements of 18VAC110-20-180 and capable of alerting the alarm company or security staff to any breaking. It shall fully protect the drug storage area and shall only be controlled by the physician or designated personnel authorized to dispense medications. It shall be activated and operational at all times the mobile van is not in use to include any breaks during the day when it is not staffed.
- The mobile unit shall only be used to serve the indigent or underserved consistent with the permitted physician application.
- If the mobile unit is to be parked and not used for more than seven consecutive days, all drugs for dispensing must be removed from the unit and stored in a permanent location where access is restricted to the permitted physician.

An application for a limited-use pharmacy permit for a mobile unit to provide services to the indigent or medically underserved~~for~~ this same purpose ~~would also have to~~should meet the same requirements.

Virginia Board of Pharmacy
Mobile Units for Dispensing for the Indigent or Underserved Population

For good cause shown, and pursuant to Virginia Code § 54.1-3304, the Board of Pharmacy may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. The Board interprets Virginia Code § 54.1-3304 to mean that the indigent and medically underserved represent a population for which pharmacy services are not reasonably available. As such, a physician desiring to dispense drugs only to an indigent or underserved population from a mobile unit may apply for this license as a "permitted physician," which will allow him to practice pharmacy pursuant to Board of Pharmacy regulations as set forth in 18VAC110-20-410. For purposes of this guidance document, the Board defines "indigent" as those persons whose income is not more than 200% above the federal poverty guidelines, and defines a medically underserved area or population by criteria established by the Health Resources & Services Administration of the U.S. Department of Health and Human Resources.

Additionally, pursuant to 18 VAC 110-20-410(B) and 18VAC110-20-120, the Board may issue a special or limited-use permit to a permitted physician when the scope, degree, or type of pharmacy practice or service to be provided is of a special, limited, or unusual nature as compared to a regular pharmacy service. The Board is aware of at least two physicians who use or have used mobile units traveling throughout a community to offer medical assistance to the indigent or underserved and who would like to include the dispensing of prescription drugs. Mobile units do not meet all physical requirements of 18VAC110-20-150 for security and appropriate storage conditions for drugs, and possibly do not meet the alarm requirements of 18VAC110-20-180. Additionally, mobile units may not meet the traditional enclosure requirements of 18VAC110-20-190.

The Board recognizes that there is a growing need to provide pharmacy services to the indigent or medically underserved population. Therefore, if a physician applies for a permitted physician license to provide services to the indigent or medically underserved by mobile unit, he may request a waiver of sections A, B, and C of 18VAC110-20-150. The physician must be able to meet the other requirements of this section, however, including temperature control. The enclosure requirements in a mobile unit may, if approved after inspection, be met by a separate lockable room, compartment, or cabinet. In order for the Board to consider waiving sections A, B, and C of 18VAC110-20-150 for a mobile unit, the following criteria must be met in addition to all other legal requirements for a permitted physician:

- The mobile unit shall not stock any Schedule II-V controlled substances for dispensing.
- The mobile unit shall be parked daily during its off-hours at the same designated location as specified to the Board during the application process.
- When parked during the off-hours, the mobile unit shall be under camera surveillance or within a secure parking area with around-the-clock security staff, and in an area that is affiliated with the physician's practice location.
- The mobile unit shall at all times provide a controlled temperature environment pursuant to 18VAC110-20-150.
- The mobile unit shall have an alarm system that complies with the requirements of 18VAC110-20-180 and capable of alerting the alarm company or security staff to any breaking. It shall fully protect the drug storage area and shall only be controlled by the

physician or designated personnel authorized to dispense medications. It shall be activated and operational at all times the mobile van is not in use to include any breaks during the day when it is not staffed.

- The mobile unit shall only be used to serve the indigent or underserved consistent with the permitted physician application.
- If the mobile unit is to be parked and not used for more than seven consecutive days, all drugs for dispensing must be removed from the unit and stored in a permanent location where access is restricted to the permitted physician.

An application for a limited-use pharmacy permit for a mobile unit to provide services to the indigent or medically underserved this same purpose should meet the same requirements.

Agenda Items: Adopt revisions to Guidance Document 110-11

Included in your agenda package are:

- Proposed revisions to Guidance Document 110-11 in both redline and clean version

Action needed:

- Motion to revise Guidance Document 110-11

Formatted: Font: Times New Roman, Not Bold
Formatted: Font: Times New Roman, Not Bold
Formatted: Font: Times New Roman, Not Bold
Formatted: Right
Formatted: Left: 1", Right: 1", Top: 1", Bottom: 1"

Virginia Board of Pharmacy

Proof of Identity when Dispensing Schedule II Drugs

~~Section~~ Virginia Code § 54.1-3420.1 ~~of the Drug Control Act (see below) has always authorized~~authorizes a pharmacist to request proof of identity prior to dispensing or refilling prescriptions written for drugs in Schedules II through V.

~~Effective July 1, 2011, s~~Subsection B of § 54.1-3420.1 requires that a pharmacist or his agent obtain proof of identity at the time of delivery anytime the pharmacist or his agent does not know the patient or the person picking up or "~~"~~seeking to take delivery~~"~~" of ~~the~~ a Schedule II dispensed drug prescribed for the patient. Subsection B of § 54.1-3420.1 defines "proof of identity" (hereafter referred to as "~~"~~ID~~"~~") ~~is defined to mean~~as "a driver's license, government-issued identification card, or other photo identification with documentation of the person's current address." ~~With~~ With the inclusion of ~~the word~~ "other~~"~~ photo identification,~~"~~ the Board interprets the statute to mean that a photo is also required on the driver's license or government-issued identification card. A special identification card without a photo may be accepted provided it is issued by the Department of Motor Vehicles in accordance with Virginia Code § 46.2-345.2 ~~of the Code of Virginia~~.

Formatted: Font: Not Italic, Underline
Formatted: Not Strikethrough
Formatted: Not Strikethrough

Additionally, § 54.1-3420.1 requires the pharmacist or his agent ~~there is a requirement~~ to ~~either~~ make a photocopy or an electronic copy of the person's identification or record the full name and address whenever someone other than the patient for whom the drug was prescribed *is not known* to the pharmacist or his agent and is picking up or seeking to take delivery of the Schedule II dispensed prescription.

In summary:

- If any person picking up or "~~"~~seeking to take delivery~~"~~" of a Schedule II dispensed prescription is known to the pharmacist or his agent, then the pharmacist or his agent is not required to obtain ID.
- If the person picking up the Schedule II dispensed prescription is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID.
- If anyone other than the patient for whom the prescription is written seeks to take delivery of the drug, and the pharmacist or his agent does not know the person, then the pharmacist or his agent must either make a photocopy or an electronic copy of such person's ID *or* record the full name and address of such person. ~~–~~The pharmacist must keep ~~the~~ a record or copy of the ID for at least one month.

~~Also, s~~Subsection C of § 54.1-3420.1 states that when a pharmacy delivers a Schedule II drug by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

~~*Code of Virginia:*~~
~~§ 54.1-3420.1. Identification required for filling prescriptions.~~
~~A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.~~

~~*B. A pharmacist, or his agent, shall require proof of identity at the time of delivery from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription, unless such person is known to the pharmacist or to his agent. If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, and the person is not known to the pharmacist or his agent, the pharmacist or his agent either make a photocopy or electronic copy of such person's identification or record the full name and address of such person. The pharmacist shall keep records of the names and addresses or copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one month. For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.*~~
~~*C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.*~~

Formatted: Font: Times New Roman, Not Bold
Formatted: Font: Times New Roman, Not Bold
Formatted: Font: Times New Roman, Not Bold
Formatted: Right
Formatted: Normal

Virginia Board of Pharmacy

Proof of Identity when Dispensing Schedule II Drugs

Virginia Code § 54.1-3420.1 authorizes a pharmacist to request proof of identity prior to dispensing or refilling prescriptions written for drugs in Schedules II through V.

Subsection B of § 54.1-3420.1 requires that a pharmacist or his agent obtain proof of identity at the time of delivery anytime the pharmacist or his agent does not know the patient or the person picking up or "seeking to take delivery" of a Schedule II dispensed drug prescribed for the patient. Subsection B of § 54.1-3420.1 defines "proof of identity" (hereafter referred to as "ID") as "a driver's license, government-issued identification card, or other photo identification with documentation of the person's current address." With the inclusion of "other photo identification," the Board interprets the statute to mean that a photo is also required on the driver's license or government-issued identification card. A special identification card without a photo may be accepted provided it is issued by the Department of Motor Vehicles in accordance with Virginia Code § 46.2-345.2.

Additionally, § 54.1-3420.1 requires the pharmacist or his agent to make a photocopy or an electronic copy of the person's identification or record the full name and address whenever someone other than the patient for whom the drug was prescribed *is not known* to the pharmacist or his agent and is picking up or seeking to take delivery of the Schedule II dispensed prescription.

In summary:

- If any person picking up or "seeking to take delivery" of a Schedule II dispensed prescription is known to the pharmacist or his agent, then the pharmacist or his agent is not required to obtain ID.
- If the person picking up the Schedule II dispensed prescription is the patient for whom the prescription is written, and the pharmacist or his agent does not know that person, then the pharmacist or his agent must require ID.
- If anyone other than the patient for whom the prescription is written seeks to take delivery of the drug, and the pharmacist or his agent does not know the person, then the pharmacist or his agent must either make a photocopy or an electronic copy of such person's ID *or* record the full name and address of such person. The pharmacist must keep a record or copy of the ID for at least one month.

Subsection C of § 54.1-3420.1 states that when a pharmacy delivers a Schedule II drug by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

Agenda Items: Reaffirmation of Guidance Document 110-24

Included in your agenda package are:

- Guidance Document 110-24 for reaffirmation.

Staff Note: Only formatting changes made to previous version, therefore no redline provided.

Action needed:

- Motion to adopt revisions to Guidance Document 110-24.

Virginia Board of Pharmacy

Competency Examination Required for Licensure as a Pharmacist
NAPLEX Passing Score

In addition to other requirements of law or regulation, pharmacists applying for licensure by examination or endorsement must pass a competence assessment examination approved by the Board.

Pharmacists examined after June 1, 1979 must pass or have passed the National Association of Boards of Pharmacy Licensure Examination (NABPLEX) or its successor examination, the North American Pharmacist Licensure Examination (NAPLEX). The Board determines that the minimum acceptable passing score for the NAPLEX is 75 on the NAPLEX scale and adopts by reference the method for calculating the score as outlined in the current edition of the NAPLEX Registration Bulletin.

For pharmacists applying for licensure by endorsement, who were initially examined prior to June 1, 1979, the Board will accept the originating state's competence assessment examination and passing score as satisfactory evidence of meeting the same standard of competence required for licensure by examination in Virginia at that time.

Agenda Items: Adopt revisions to Guidance Document 110-28

Included in your agenda package are:

- Proposed revisions to Guidance Document 110-28 in both redline and clean version

Action needed:

- Motion to revise Guidance Document 110-28

Formatted: Tab stops: 6.5", Right + Not at 6.25"

Formatted: Right

Virginia Board of Pharmacy
Guidance for Free Clinic Pharmacy Applicants

Free clinics applying for a pharmacy permit which do not have a need for a full service pharmacy should apply for a special or limited-use permit as described in ~~section~~ 18-VAC1-10-20-120 of the Virginia Board of Pharmacy Regulations and submit the required information with the application and fee. While waivers are granted by the Board on an individual case basis after considering the merit of each such request, the Board will normally waive certain provisions of the below regulation for free clinic pharmacies:

18 VAC 110-20-150-Physical Standards

Formatted: Normal

- ~~t~~The size requirement of 240 square feet, provided there is adequate room inside the enclosure for ~~both~~ storage of drug inventory, equipment, and records and for working space. *See* 18VAC110-20-150(A).

- T~~t~~he sink being inside the pharmacy, provided there is a sink with hot and cold running water in close proximity which is not a bathroom sink. *See* 18VAC110-20-150(F).

Formatted: Bulleted + Level: 1 + Aligned at: 0.25" + Tab after: 0.5" + Indent at: 0.5"

The Board typically requires that the provisions of 18-VAC-110-20-180 concerning the burglar alarm system and 18-VAC-110-20-190 concerning enclosures be met. A free clinic pharmacy may request a waiver of 18-VAC-110-20-190-(C): (1) for the purpose of securing a drug order in the pharmacy if it is absolutely necessary that drugs be delivered in the absence of a pharmacist; or (2) for the purpose of repairing or upgrading essential pharmacy equipment when those repairs or upgrades cannot be reasonably performed while a pharmacist is present. A request for this waiver will be very closely scrutinized and granted at the discretion of the Board~~,~~ if deemed necessary and appropriate, and only then under the specific conditions of 18-VAC-110-20-120 (B).

Virginia Board of Pharmacy
Guidance for Free Clinic Pharmacy Applicants

Free clinics applying for a pharmacy permit which do not have a need for a full service pharmacy should apply for a special or limited-use permit as described in 18VAC110-20-120 of the Virginia Board of Pharmacy Regulations and submit the required information with the application and fee. While waivers are granted by the Board on an individual case basis after considering the merit of each such request, the Board will normally waive certain provisions of the below regulation for free clinic pharmacies:

18 VAC 110-20-150-Physical Standards

- The size requirement of 240 square feet, provided there is adequate room inside the enclosure for storage of drug inventory, equipment, and records and for working space. *See* 18VAC110-20-150(A).

- The sink being inside the pharmacy, provided there is a sink with hot and cold running water in close proximity which is not a bathroom sink. *See* 18VAC110-20-150(F).

The Board typically requires that the provisions of 18VAC110-20-180 concerning the burglar alarm system and 18VAC110-20-190 concerning enclosures be met. A free clinic pharmacy may request a waiver of 18VAC110-20-190(C): (1) for the purpose of securing a drug order in the pharmacy if it is absolutely necessary that drugs be delivered in the absence of a pharmacist; or (2) for the purpose of repairing or upgrading essential pharmacy equipment when those repairs or upgrades cannot be reasonably performed while a pharmacist is present. A request for this waiver will be very closely scrutinized and granted at the discretion of the Board if deemed necessary and appropriate, and only then under the specific conditions of 18VAC110-20-120(B).

Agenda Items: Repeal Guidance Document 110-37

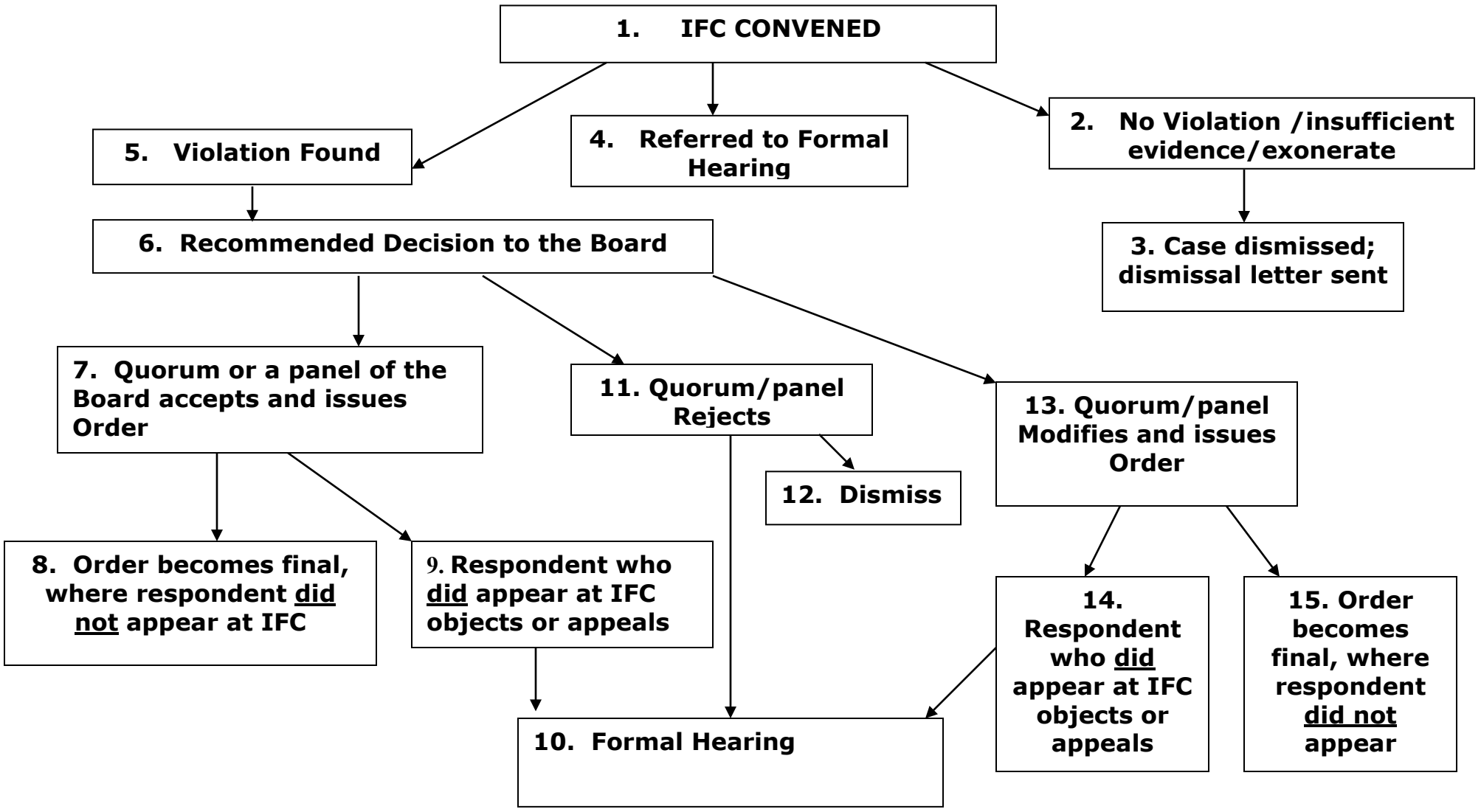
Included in your agenda package are:

- Guidance Document 110-37
- DHP agency Guidance Document 76-10.01

Action needed:

- Motion to repeal Guidance Document 110-37

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



Narrative explanation of Flow Chart on Delegation to an Agency Subordinate

This describes the process in which a subordinate hears a case at an informal conference up to a case that may be referred to a formal hearing.

1. Pursuant to a notice, the designated agency subordinate ("subordinate") will convene the informal conference ("IFC"). An IFC before a subordinate is conducted in the same manner as an IFC before a committee of the board. Following the presentation of information by the parties, the subordinate will consider the evidence presented and render a recommended decision regarding the findings of fact, conclusions of law, and if appropriate, the sanction to be imposed.

2. The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory and/or regulatory violation has occurred.

3. If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4. The subordinate may decide that the case should be referred to a formal hearing. A hearing before the board would then be scheduled and notice sent to the respondent.

5. The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

6. With the assistance of APD, the subordinate drafts a recommended decision, which includes the findings of fact, conclusions of law and sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board or a panel consisting of at least five members of the board.

7. If the quorum or panel of the board accepts the recommended decision and:

8. If the respondent <u>did not appear</u> at the IFC, the board's decision becomes a final order that can only be appealed to a circuit court; or

9-10. If the respondent <u>did appear</u> at the IFC and objects to and appeals the order, he may request a

formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

11. A quorum or panel of the board may reject the recommended decision of the subordinate, in which case:

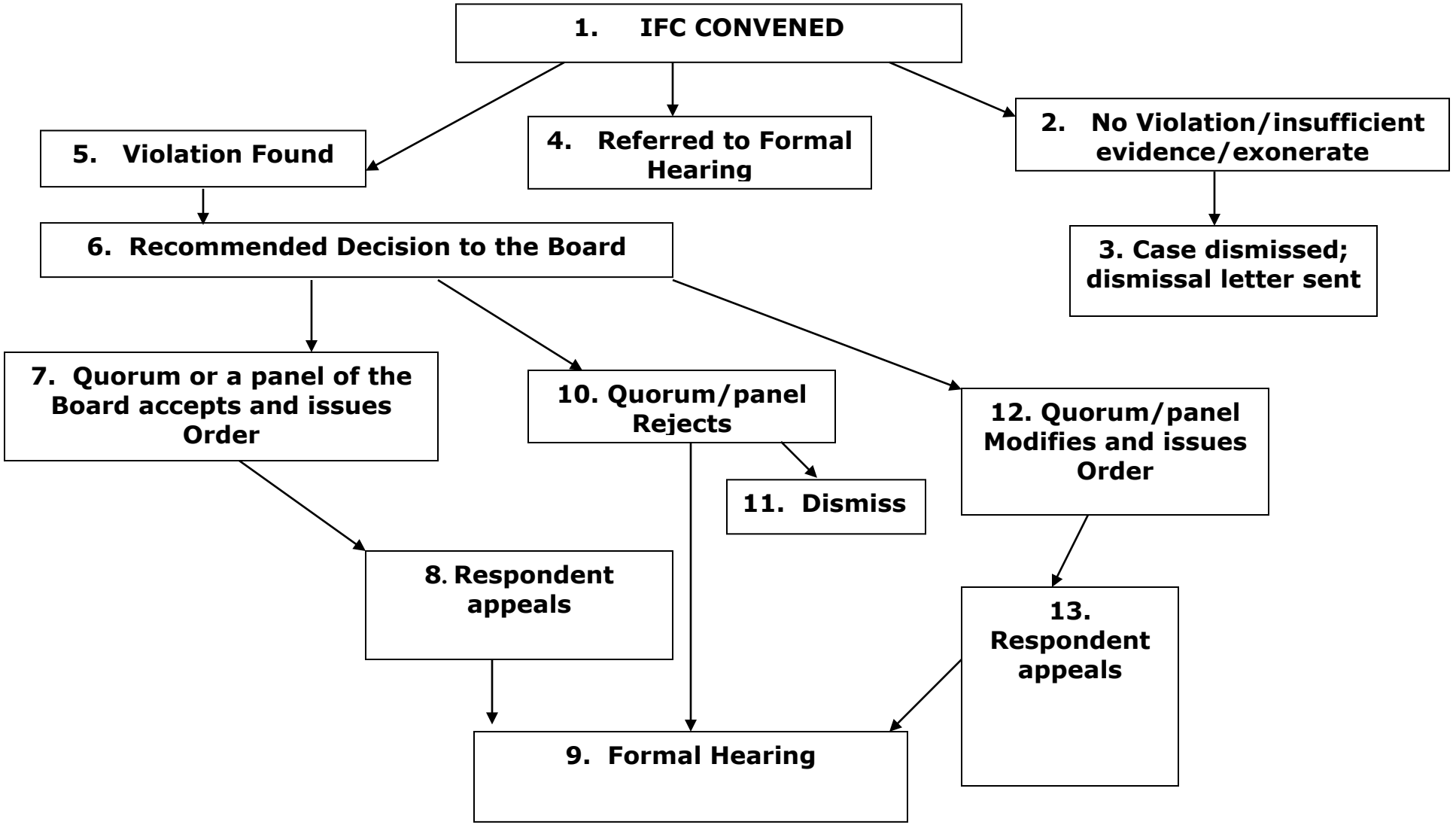
The quorum/panel may decide to refer the case for a formal hearing **(10)**; or the quorum/panel may decide to dismiss the case and a dismissal letter is issued to the respondent notifying him of the decision of the board **(12)**.

13. A quorum or panel of the board may modify the subordinate's recommended decision and issue an order reflecting the modified decision to the respondent.

15. If the respondent did not appear at the informal conference, then the board's decision becomes a final order that can only be appealed to a circuit court.

14-10. If the respondent did appear at the informal conference and objects to and appeals the order, he may request a formal hearing before the board. A case referred to a formal hearing proceeds in the same manner as cases considered by special conference committees convened pursuant to Va. Code § 54.1-2400(10). If the respondent who appeared at the IFC does not request a formal hearing, the order becomes final after a specified timeframe.

Guidance for Conduct of an Informal Conference by an Agency Subordinate of a Health Regulatory Board at the Department of Health Professions



Narrative explanation of Flow Chart on Delegation to an Agency Subordinate

This describes the process in which a subordinate hears a case at an informal conference up to a case that may be referred to a formal hearing.

1: Pursuant to a notice, the designated agency subordinate ("subordinate") will convene the informal conference ("IFC"). An IFC before a subordinate is conducted in the same manner as an IFC before a committee of the board. Following the presentation of information by the parties, the subordinate will consider the evidence presented and render a recommended decision regarding the findings of fact, conclusions of law, and if appropriate, the sanction to be imposed.

2: The subordinate may recommend that the respondent be exonerated, that there be a finding of no violation, or that insufficient evidence exists to determine that a statutory or regulatory violation has occurred.

> **3:** If the subordinate makes such a finding, the case is dismissed and a dismissal letter is issued to the respondent notifying him of the determination.

4: The subordinate may decide that the case should be referred to a formal hearing. A formal hearing before the board would then be scheduled and notice sent to the respondent.

5: The subordinate may determine that a violation has occurred and recommend the findings of fact and conclusions of law along with an appropriate sanction.

> **6**: With the assistance of APD, the subordinate drafts a recommended decision that includes findings of fact, conclusions of law and a recommended sanction. The recommendation is provided to the respondent and to the board and must be ratified by a quorum of the board or a panel consisting of at least five members of the board.

7 through 9: If the quorum or panel of the board accepts the recommended decision **(7)** and the respondent objects to and appeals the order **(8)**, the matter proceeds to a formal hearing **(9)**. A case appealed to a formal hearing proceeds in the same manner as cases considered by special conference committees and appealed to a formal hearing.

10: A quorum or panel of the board may reject the recommended decision of the subordinate, in which case:

The quorum or panel may decide to refer the case for a formal hearing **(9)**; or

The quorum or panel may decide to dismiss the case. A dismissal letter is issued to the respondent notifying him of the decision of the board **(11)**.

12: A quorum or panel of the board may modify the subordinate's recommended decision and issue an order reflecting the modified decision to the respondent.

13: If the respondent objects to and appeals the order, the matter proceeds to a formal hearing. A case appealed to a formal hearing proceeds in the same manner as cases considered by special conference committees and appealed to a formal hearing.

Agenda Items: Revision of Guidance Document 110-43

Included in your agenda package are:

- Guidance Document 110-43, with proposed changes in redline and a clean copy.

Action needed:

- Motion to adopt revisions to Guidance Document 110-43.

Guidance document: 110-43 AdoptedRevised: December 18, 20186, 2022
Effective: February 2, 2023

Virginia Board of Pharmacy

Dispensing with an Authorized Generic

The term "authorized generic" is defined in 21 CFR § 314.3 as a listed drug

> that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

Because authorized generics are identical to the branded drug product, sharing and share both the same active and inactive ingredients as the branded product, the FDA does not specifically list these drugs as a therapeutically equivalent drug product of the branded drug. However, according to the preface of the 38th edition of the FDA's Orange Book, "A[a]ny drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent to the applicant's drug product even if the applicant's drug product is single source or coded as non-equivalent (e.g., BN)."

Therefore, consistent with the provisions for dispensing therapeutically equivalent drug products as listed in 54.1-3408.03 the Board affirmsed that a pharmacist may substitute an authorized generic when dispensing a prescription written for a branded drug product unless: (i) the prescriber indicates such substitution is not authorized by specifying "brand medically necessary" on the prescription, "brand medically necessary:" or (ii) the patient insists on the dispensing of the brand-name drug product. A listing of authorized generics is provided by the FDA at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.

Related statutes:

Va. Code § 54.1-3401 (*see* definition of "therapeutically equivalent drug products")

Va. Code § 54.1-3408.03

~~Related statutes:~~
~~§54.1-3401~~
~~"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug~~

Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Right
Formatted: Font: 12 pt
Formatted: Space Before: 0 pt, After: 0 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Indent: Left: 1", Right: 1", Space Before: 0 pt, After: 0 pt
Formatted: Font: 12 pt
Formatted: Space Before: 0 pt, After: 0 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Justified
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Field Code Changed
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: (Default) Times New Roman, No underline
Formatted: Font: 12 pt
Formatted: Normal

products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.

A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.

In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.

B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.

C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.

D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.

Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Font: 12 pt
Formatted: Right
Formatted: Normal, Left

Virginia Board of Pharmacy

Dispensing with an Authorized Generic

The term "authorized generic" is defined in 21 CFR § 314.3 as a listed drug

> that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to the retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug.

Because authorized generics are identical to the branded drug product and share the same active and inactive ingredients as the branded product, the FDA does not specifically list these drugs as a therapeutically equivalent drug product of the branded drug. However, according to the preface of the 38th edition of the FDA's Orange Book, "[a]ny drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent to the applicant's drug product even if the applicant's drug product is single source or coded as non-equivalent (e.g., BN)."

Therefore, consistent with the provisions for dispensing therapeutically equivalent drug products as listed in 54.1-3408.03 the Board affirms that a pharmacist may substitute an authorized generic when dispensing a prescription written for a branded drug product unless: (i) the prescriber indicates such substitution is not authorized by specifying "brand medically necessary" on the prescription,; or (ii) the patient insists on the dispensing of the brand-name drug product. A listing of authorized generics is provided by the FDA at: http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm.

Related statutes:

Va. Code § 54.1-3401 (*see* definition of "therapeutically equivalent drug products")

Va. Code § 54.1-3408.03

Agenda Items: Revision of Guidance Document 110-47

Included in your agenda package are:

- Guidance Document 110-47, with proposed changes in redline and a clean copy.

Action needed:

- Motion to adopt revisions to Guidance Document 110-47.

Formatted: Font: (Default) Times New Roman, 12 pt
Formatted: Font: (Default) Times New Roman, 12 pt
Formatted: Font: (Default) Times New Roman, 12 pt
Formatted: Right
Formatted: Font: 14 pt
Formatted: Font: 16 pt

Virginia Board of Pharmacy

Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs

Pursuant to Chapter 114 of the 2017 Acts of Assembly ~~HB2046 passed by the 2017 General Assembly~~, the Board developed the following guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs ~~by pharmacists to patients for whom a prescription is dispensed~~. It is recommended that pharmacists verbally counsel or provide written information on the importance of proper storage and disposal of unused dispensed drugs to patients or their agents~~,~~ that receive ~~receiving~~ drugs in Schedule II-V and any drugs of concern~~, on the importance of properly storing and disposing of unused dispensed drugs~~.

Drug Storage:

Properly securing prescription drugs can decrease the risk of diversion of drugs from the medicine cabinet, a common method for obtaining drugs for abuse. Tips on safe storage may be accessed in the Medication Safety Tips flyer at https://www.upandaway.org/

Disposal Options:

- **Authorized pharmacy disposal site or collection site** – if the pharmacy is an authorized collection site as listed at http://www.dhp.virginia.gov/pharmacy/destructionsites.asp, the pharmacist should inform the patient of how to dispose of the unused drugs via the collection box at the pharmacy.
- **Collection boxes at local law enforcement agencies** – encourage patients to use a collection box for drug destruction at a local law enforcement agency, if applicable.
- **Drug take-back programs** – pharmacists should encourage patients to take their unused drugs for destruction to take-back programs organized by local, state, or federal government agencies.
- **Drug deactivation or disposal pouches** – pharmacists are encouraged to educate patients on the use of drug deactivation or disposal pouches and how to obtain them for purchase or free of charge for disposing of unwanted medications. The unwanted medications are placed in the pouch which deactivates the medication and renders the drug safe for landfills.
- **Home disposal** – if an authorized collection site or take-back program is not available, home ~~D~~disposal is a viable option despite the risk of diversion and environmental contamination.
    - **Step 1** – Remove medications from their original containers. If the medication is solid, crush it or add water to dissolve it and then mix the medication with an undesirable substance, such as kitty litter or coffee grounds. This makes the mixture

Formatted: No underline, Font color: Auto

Formatted: Font: (Default) Times New Roman, 12 pt

Formatted: Font: (Default) Times New Roman, 12 pt

Formatted: Font: (Default) Times New Roman, 12 pt

Formatted: Right

unattractive to children and pets and unrecognizable to potential abusers who may go through your trash.

- **Step 2** – Place the mixture in a container with a lid or in a sealable baggie to prevent the medication from leaking, and throw it into the trash.
- **Step 3** – When discarding the original containers, scratch out or remove identifiers on the bottle and/or packaging.
- Caution patients not to dispose of medications in the toilet or sink, unless specifically instructed to on the label, and not to give medicine to friends or family. This is not only potentially illegal, but a drug that works for the patient could be dangerous for someone else.
- For more information on home disposal, refer patients to FDA's *Disposal of Unused Medicines: What You Should Know* found at https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

Additional Resources

- Tips, educational flyers, and pharmacist resources on disposal – https://nabp.pharmacy/initiatives/awarxe/dispose-safely/

Virginia Board of Pharmacy

Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs

Pursuant to Chapter 114 of the 2017 Acts of Assembly, the Board developed the following guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs. It is recommended that pharmacists verbally counsel or provide written information on the importance of proper storage and disposal of unused dispensed drugs to patients or their agents that receive drugs in Schedule II-V and any drugs of concern.

Drug Storage:

Properly securing prescription drugs can decrease the risk of diversion of drugs from the medicine cabinet, a common method for obtaining drugs for abuse. Tips on safe storage may be accessed in the Medication Safety Tips flyer at https://www.upandaway.org/

Disposal Options:

- **Authorized pharmacy disposal site or collection site** – if the pharmacy is an authorized collection site as listed at http://www.dhp.virginia.gov/pharmacy/destructionsites.asp, the pharmacist should inform the patient of how to dispose of the unused drugs via the collection box at the pharmacy.
- **Collection boxes at local law enforcement agencies** – encourage patients to use a collection box for drug destruction at a local law enforcement agency, if applicable.
- **Drug take-back programs** – pharmacists should encourage patients to take their unused drugs for destruction to take-back programs organized by local, state, or federal government agencies.
- **Drug deactivation or disposal pouches** – pharmacists are encouraged to educate patients on the use of drug deactivation or disposal pouches and how to obtain them for purchase or free of charge for disposing of unwanted medications. The unwanted medications are placed in the pouch which deactivates the medication and renders the drug safe for landfills.
- **Home disposal** – if an authorized collection site or take-back program is not available, home disposal is a viable option despite the risk of diversion and environmental contamination.
    - **Step 1** – Remove medications from their original containers. If the medication is solid, crush it or add water to dissolve it and then mix the medication with an undesirable substance, such as kitty litter or coffee grounds. This makes the mixture unattractive to children and pets and unrecognizable to potential abusers who may go through your trash.
    - **Step 2** – Place the mixture in a container with a lid or in a sealable baggie to prevent the medication from leaking, and throw it into the trash.

- **Step 3** – When discarding the original containers, scratch out or remove identifiers on the bottle and/or packaging.
- Caution patients not to dispose of medications in the toilet or sink unless specifically instructed to on the label, and not to give medicine to friends or family. This is not only potentially illegal, but a drug that works for the patient could be dangerous for someone else.
- For more information on home disposal, refer patients to FDA's *Disposal of Unused Medicines: What You Should Know* found at https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

Additional Resources

- Tips, educational flyers, and pharmacist resources on disposal – https://nabp.pharmacy/initiatives/awarxe/dispose-safely/

Virginia Board of Pharmacy
December 06, 2022
Licenses Issued

	5/1/21 - 7/31/21	8/1/21 - 10/31/21	11/1/21 - 1/31/22	2/1/22 - 4/30/22	5/1/22 - 7/31/22	8/1/22 - 10/31/22	License Count 11/17/2022
Business CSR	44	25	28	35	30	32	1,516
Cannabis Dispensing Facility		1	2	2	1	2	7
CE Courses	1	1	0	1	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	1	6	0	0	4	3	223
Non-restricted Manufacturer	0	1	2	0	2	1	34
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	1	0	0	1
Pharmaceutical Processor	0	0	0	0	0	0	4
Pharmacist	275	279	157	187	265	252	16,527
Pharmacist Volunteer Registration	0	1	0	1	0	2	1
Pharmacy	10	9	16	9	11	10	1,768
Pharmacy Intern	59	179	87	88	56	96	1,263
Pharmacy Technician	460	353	360	360	531	430	13,702
Pharmacy Technician Trainee	1414	1280	1385	1042	777	1,226	7,544
Physician Selling Controlled Substances	19	39	14	17	33	27	622
Limited Use Practitioner Dispensing	0	0	0	0	1	1	3
Physician Selling Drugs Location	4	1	4	2	6	2	162
Pilot Programs	0	0	0	2	1	1	22
Registered Practitioner For Medical Cannabis	162	66	81	106	56	147	1,130
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	36
Third Party Logistics Provider	0	0	0	1	1	0	7
Warehouser	0	1	1	1	1	0	121
Limited Use Facility Dispensing							1
Wholesale Distributor	1	1	0	0	0	0	63
Total	**2,450**	**2,243**	**2,137**	**1,855**	**1,776**	**2,232**	**44,775**

Virginia Board of Pharmacy
December 6, 2022
Nonresident Licenses Issued

	5/1/21 - 7/31/21	8/1/21 - 10/31/21	11/1/21 - 1/31/22	2/1/22 - 4/30/22	5/1/22 - 7/31/22	8/1/22 - 10/31/22	License Count 11/15/2022
Nonresident Manufacturer	6	10	1	12	4	6	221
Nonresident Medical Equipment Supplier	6	10	5	5	7	11	365
Nonresident Outsourcing Facility	1	1	1	0	2	2	33
Nonresident Pharmacy	17	17	22	25	27	18	911
Nonresident Third Party Logistics Provider	9	4	7	1	8	11	201
Nonresident Warehouser	5	4	5	6	0	8	109
Nonresident Wholesale Distributor	18	14	14	6	7	9	644
Total	**62**	**60**	**55**	**55**	**55**	**65**	**2,484**

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Quarterly Review – Date Range 07/01/2022 ending 09/30/2022

Numbers of Inspections Completed by License Type

Insp Status	License Type	Change of Location	Compliance	New	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	7		29	3	3	130	172
	Cannabis Dispensing Facility			1	1			2
	Limited Use Facility Dispensing			1				1
	Medical Equipment Supplier			2			13	15
	Non-resident Medical Equipment Supplier			1				1
	Non-restricted Manufacturer				1			1
	Pharmaceutical Processor Permit					2		2
	Pharmacy	5	2	9	10	58	207	291
	Physician Selling Drugs Location		1	2			15	18
	Third Party Logistics Provider						1	1
	Warehouser					1	13	14
	Wholesale Distributor					1	6	7
Completed Total		12	3	45	15	65	385	525
Completed Virtual	Business CSR			1	1	1		3
	Pharmacy					1	1	2
Completed Virtual Total				1	1	2	1	5
Grand Total		12	3	46	16	67	386	530

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Date Range: 07/01/2022 ending 09/30/2022

Routine Inspections, Deficiencies by License Type

Count of Insp ID	Result					
License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	Deficiency-Response Required	No Deficiency	Grand Total
Business CSR	2	66			62	130
Medical Equipment Supplier		4			9	13
Pharmacy		43	115	1	49	208
Physician Selling Drugs Location	1	11			3	15
Third Party Logistics Provider		1				1
Warehouser		2			11	13
Wholesale Distributor		3			3	6
Grand Total	3	130	115	1	137	386

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

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Date Range: 07/01/2022 ending 09/30/2022

Categories of Deficiencies for Occurrences, Routine Inspections Only Recorded >20 Times with Examples

Description	Number of times for occurrence
110-20-180	36

Deficiency 9a: Alarm is operational but does not fully protect the prescription department
Deficiency 9a: Alarm operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.
Deficiency 9a: The alarm system does not include a feature by which any breach shall be communicated to the PIC
Security: The device is not maintained in operating order and unable to verify an auxiliary source of power. The device is not capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.
The facility is not able to send a signal to the monitoring entity
The device for the detection of breaking does not have at least one hard-wired communication method.- The facility has cellular and Wi-Fi enabled ADT lines of communication. Pharmacist-in-Charge are aware that a hard-wired line is required by the Board of Pharmacy

110-20-190	25

Deficiency 10: Unauthorized access to locking device to the prescription department
Deficiency 11: Insufficient enclosures or locking devices
Deficiency 108: Emergency access alarm code/key not maintained in compliance
Deficiency 108: Emergency access alarm code/key not maintained in compliance. The signature was not across the seal of the envelope.

110-20-240	57

Deficiency 14: No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late
Deficiency 15: Perpetual inventory not being maintained as required
Deficiency 17: Hard copy prescriptions not maintained or retrievable as required

Enforcement Division Inspections Report:
Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Description **Number of times for occurrence**

Deficiency 113: Inventory taken on time, but not in compliance
Deficiency 114: Records of receipt (e.g. invoices) not maintained as required

| 110-20-270 | 41 |

Deficiency 19: Pharmacists not verifying accuracy of dispensed prescriptions in all respects
Deficiency 19: Pharmacists failing to document verification of accuracy of dispensed prescriptions

| 110-20-275 | 24 |

Deficiency 122: Engaging in alternate delivery not in compliance
Procedure for return of any prescription medication not delivered to patient was not available for review during the inspection
There is no written contract or agreement between the two parties describing the procedures for such a delivery system
There is a policy and procedure manual on site, but the procedure and recordkeeping for undeliverable prescriptions
The written contract between the two parties does not thoroughly describe the procedures for such a delivery system and the responsibilities of each party.

| 110-20-276 | 20 |

Deficiency 123: Engaging in remote processing not in compliance

| 110-20-355 | 29 |

Deficiency 20: Pharmacist not checking and documenting repackaging
Deficiency 109: Dispensed drugs being returned to stock not in compliance
Deficiency 127: Repackaging records and labeling not kept as required or in compliance

| 110-20-418 | 30 |

Deficiency 142: No record maintained and available for 12 months from date of analysis of dispensing errors/ patient safety

| 110-20-700 | 42 |

Enforcement Division Inspections Report:
Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Description **Number of times for occurrence**

The supervising practitioner has not approved the list of drugs which may be ordered by the holder of the controlled substances registration.
Failed to notify BOP of change in Responsible Party within 14 days
List of supervising practioners approved drugs was not available at the time of inspection
Possession of controlled substances by the entity is not limited to an approved list of drugs
Supervising practioners on CSR no longer works at the facility
The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation
Access to the controlled substances is not limited to the supervision practioners or to those who are authored
The list of drugs.
Responsible party is incorrect.

110-20-710	27

Expired drugs in working stock.
Drugs are not maintained in a lockable cabinet, cart, device or other area.
Access to the alarm system is not restricted only designated and necessary persons.
Expired drugs were found in the shelter working stock.
Disposal of unwanted or expired Schedule II through VI drugs is not by the transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.
Any drug which has exceeded the expiration date shall not be administered

110-20-720	21

Records for controlled drugs were not available for review.
There were no biennial inventories available for review.
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
Not capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.
After the initial inventory is taken, every person described herein shall take a new inventory at least every two years

Enforcement Division Inspections Report:
Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Description	Number of times for occurrence
54.1-3404	55

Deficiency 13: No biennial inventory. No biennial inventory has been completed
Deficiency 16: Theft/unusual loss of drugs not reported to the Board
Deficiency 113: Inventories taken on time, but not in compliance
Deficiency 148: Unusual loss of drugs reported to board but report not maintained by pharmacy
Records of CII-V drugs does not include date of receipt
Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board.
Current biennial of all stocks on hand of Schedules 1 through V drugs was not available at the time of the inspection
The distribution record does not include the quantity of the drug dispensed
Records of receipt of CII-V drugs failed to include the date of receipt for all drugs.

54.1-3410.2	26

Deficiency 20b: Pharmacist not documenting verification of accuracy of sterile compounding
Deficiency 22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual
Deficiency 23: Certificaiton of the buffer or clean room and ante-room indicating ISO Class 7/ ISO Class 8 or better not performed by a qualifdied individual
Deficiency 26: No documentation of intial and annual media-fill testing or gloved fingertip testing for persons performing low and medial risk level compounding of sterile preporaitons
Deficiency 32: Have clean room, but not all physical standards in compliance
Deficiency 33: Low or medium-risk compounded sterile
Deficiency 130: Required compounding records not complete and properly maintained
Deficiency 130a: Compounded products not properly labeled
Deficiency 131: Temperature of drug storage area/ main pharmacy not being documented
Deficiency 132: Personnel preparing compounding sterile preparations do not comply with cleaning and garbing requirements

Enforcement Division Inspections Report:
Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Description	Number of times for occurrence
54.1-3410.2	***110***

800: Assessment of Risk has not been performed - Separated from the Section upon Board Request – Is not in full effect –Inspectors note to heighten preparedness

54.1-3434	23

Deficiency 1: No Pharmacist-in-Charge
Deficiency 1: Pharmacist-In-Charge not fully engaged in practice at the pharmacy location.
Deficiency 2: Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe
Deficiency 14: No incoming change of Pharmacist-in-Charge inventory
After the initial inventory is taken, every person describe herein has not taken a new inventory at least every two years of all stocked on hand Schedule I through V drugs
Deficiency 109. Expired drugs in working stock. 100 drugs on the shelves were reviewed. 13 of them were expired.

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Two Year Review - Date Range: 09/30/2020 ending 09/30/2022

Number of Inspections Completed by License Type

Count of Insp		Insp Type								
Insp Status	License Type	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	51			158		11	19	570	809
	Cannabis Dispensing Facility				9		3			12
	Limited Use Facility Dispensing				1					1
	Medical Equipment Supplier	14			15				92	121
	Non-resident Medical Equipment Supplier				1					1
	Non-restricted Manufacturer	1			7		5	1	3	17
	Pharmaceutical Processor Permit	1					1	12	17	31
	Pharmacy	31	9	7	77	1	35	283	1415	1858
	Physician Selling Drugs Location	5	1	1	22		5	1	118	153
	Pilot Programs					8				8
	Restricted Manufacturer	1			1				1	3
	Third Party Logistics Provider				2				4	6
	Warehouser	9			10		3	4	64	90
	Wholesale Distributor	3		1	2			4	32	42
Completed Total		116	10	9	305	9	63	324	2316	3152
Completed	Business CSR	17			66	1	6	13	212	315
	Medical Equipment Supplier	3			6			1	9	19
	Non-restricted Manufacturer						1			1
	Pharmacy	3		1	6		16	56	1	83
	Physician Selling Drugs Location	1			3		4	1	8	17
	Pilot Programs					4				4
	Third Party Logistics Provider				1					1
	Warehouser	1			3		1	1	7	13
	Wholesale Distributor				1		2	1		4
Completed Virtual Total		25		1	86	5	30	73	237	457
Grand Total		141	10	10	391	14	93	397	2553	3609

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Date Range: 09/30/2020 ending 09/30/2022

Routine Inspections, Deficiencies by License Type

Count of Insp ID	Result					
License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	Deficiency-Response Required	No Deficiency	Grand Total
Business CSR	3	362			417	782
Medical Equipment Supplier		37			64	101
Non-restricted Manufacturer					3	3
Pharmaceutical Processor Permit		17				17
Pharmacy		437	642	1	336	1416
Physician Selling Drugs Location	3	101			22	126
Restricted Manufacturer		1				1
Third Party Logistics Provider		2			2	4
Warehouser		14			57	71
Wholesale Distributor		11			21	32
Grand Total	6	982	642	1	922	2553

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

Enforcement Division Inspections Report:

Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Pharmaceutical Processor / Special Report – Board Requested
Date Range: 09/30/2020 ending 09/30/2022

Examples of Deficiencies Recorded >10 Times with Examples

Count of Result	InspStatus	
Description	Completed	Grand Total
110-60-240	10	10
110-60-290	10	10
54.1-3442.7	17	17
Grand Total	81	81

Description **Number of times for occurrence**

110-60-240	10

Cultivation employees have the alarm code to access to the facility for cultivation duties
Restrict access to keys or codes to other approved areas to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility
A cannabis dispensing facility shall properly secure cannabis products
The monitoring entity did not receive alarm signals on the secondary line of communication for the dispensary area

110-60-290	10

Labeling of Batch of CBD or THC-A Products require the name and address of the pharmaceutical processor
111.560 The facility does not maintain written procedures that must be established and followed regarding that a qualified person
111.260 The processor is not maintaining documentation, at the time of performance, of the manufacture of the batch, including: the initials of the person responsible for weighing
The Production Record form is used as a Batch Record. Reviewed approximately fifty batch records

Enforcement Division Inspections Report:
Prepared for the December 6, 2022 - Board of Pharmacy Meeting

Description	Number of times for occurrence
54-1.3442.7	17

The Processor has not completed background checks on five new employees to ensure that no person who has been convicted
Sanitation: The facility does not conduct all manufacturing operations in accordance with adequate sanitation principles
The facility's refrigerators are equipped with an internal thermometer, but the refrigerators cannot record temperatures
The batch record did not include the signature of the person reviewing the record in accordance with cGMP 111.65
There is no documentation on the records that visual examination occurred before packaging or labeling a product that determines if specifications were met in accordance with cGMP 111.75
Standards are not in place for personnel to prevent microbial contamination. Employees were eating candy in the manufacturing area, wearing earrings not covered by a hairnet, and possessing cell phones in the manufacturing area.
The batch record does not have documentation of a visual examination to ensure that specifications under cGMP 111.70
The facility does not have a stability testing schedule established
The facility does not have a policy and procedure for returned dietary supplements
The facility does not investigate and review complaints
The facility does not have a sanitation supervisor per cGMP 111.15
Physical plant facilities were not maintained or repaired sufficient to prevent components, dietary supplements, or contact surfaces from becoming contaminated
According to cGMP for a subset of finished dietary supplement batches that you identify through a sound statistical sampling plan

Staffing Announcement -

- Andy Inge from our on Enforcement Division took a lateral transfer from a Case Intake Analyst and accepted the position of Senior Inspector for Central Virginia. We are delighted to have Andy in this new role and he is progressing very nicely since he already had 11 years with our agency.

Reports Extracted on 11/15/2022 -

- Data extrapolated from My License Office (MLO) / Inspection Completed Detail Reports /Inspection Result Detail Reports

Report prepared by: Melody J. Morton, Inspections Manager Enforcement Division

Executive Director's Report – December 6, 2022

Staffing:

- Records administrative assistant position filled
- Executive Assistant returned from extended leave
- Ongoing discussions regarding workload balance
- Volunteering day and holiday celebration on 12/9
- Annual performance evaluations

IT-related Updates:

- Recent agency migration to Microsoft 365
- Recent agency upgrade to Windows 11
- Recent agency migration to Cardinal (new payroll/attendance software)
- Continued transition to digital case files via Box, DocuSign
- Continued implementation of BioTrack (new medical cannabis licensing software)
- Ongoing development of application document upload feature
- Upcoming migration in January to new agency recruitment platform, Page Up
- Conference Center A/V equipment en route; installation likely in January

Agency Reports Recently Completed and Posted Online:

- Strategic Plan 2022-2024
- Biennial Report 2021-2022
- Code of Ethics

Ongoing Activities:

- Upcoming renewal cycle
- Pharmacy technician training high school initiative

Recent Meetings Attended:

- Tri-Regulator Meeting
- Tri-Regulator Symposium – Panelist on Misinformation
- SAMHSA Region 3 Meeting regarding Buprenorphine Access
- FDA 50-State Intergovernmental Meeting on Compounding – Panelist on Non-pharmacist Compounding
- International Pharmaceutical Federation
- NABP Executive Officer Interactive Forum and Leadership Academy
- NABP/AACP Districts 1 & 2 Meeting
- Virginia Society of Health-Systems Pharmacist – Law Update
- USP 795/797 Training
- NABP Interim Planning/Budget & Finance Subcommittee Meeting
- NABP Executive Committee Meeting
- VACDS – Law Update

Upcoming Meetings:

- Opioid Regulatory Collaborative
- Virginia Pharmacists Association Annual Meeting, Roanoke
- NABP Executive Committee Meeting