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
September 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	**55-59**
• Conforming Drug Schedules to Federal Scheduling Action	**67-71**
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:	
• May 23, 2022, Formal Hearings	**1-3**
• May 24, 2022, Innovative Pilot Program Committee	**4-5**
• May 25, 2022, Special Conference Committee	**6-9**
• June 6, 2022, Formal Hearings	**10-11**
• June 6, 2022, Full Board Meeting	**12-19**
• June 6, 2022, Public Hearing	**20-23**
• June 13, 2022, Formal Hearings	**24-26**
• June 14, 2022, Special Conference Committee	**27-29**
• June 29, 2022, Telephone Conference Call	**30-32**
• July 13, 2022, Special Conference Committee	**33-35**
• July 13, 2022, Telephone Conference Call	**36-38**
• July 28, 2022, Formal Hearings	**39-41**
• August 11, 2022, Drug Donation Workgroup Meeting	**Handout**
• August 17, 2022, Special Conference Committee	**42-45**
• August 18, 2022, Telephone Conference Call	**46-47**
• August 23, 2022, Formal Hearings	**48-51**
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: David Brown, DC	
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh	
• Chart of Regulatory Actions	**52-54**
• Adoption of Exempt Final Regulation to Place Certain Chemicals into Schedule I	**55-66**
• Adoption of Exempt Final Regulation to Conform Drug Schedules to Federal Scheduling Action	**67-75**
• Adoption of Exempt Final Regulations to Remove Chemicals Recently Scheduled in Code	**76-97**

• Adoption of Emergency Regulations/NOIRA for Pharmacists Initiating Treatment	**98-111**
• Amend Current Statewide Protocols	**112-138**
• Adoption of Exempt Regulations for Pharmaceutical Processors	**139-218**
• Adoption of Emergency Regulations/NOIRA for Pharmacy Working Conditions	**219-224**
• Consider Ability for Pharmacy Technicians Trainees to Administer Vaccines	**225-237**
• Amend Guidance Documents 110-25 to Address Life of Written Certification when Prescriber No Longer in Practice	**238-241**
• Amend Guidance Document 110-6 (Guidance for Pharmacies within Opioid Treatment Programs)	**242-251**
• Amend Guidance Document 110-35 (Guidance on Virginia Prescription Requirements)	**252-257**
• Amend Guidance Document 110-45 (Minors Working as Pharmacy Technician Trainees) and Guidance Document 110-20 (Criminal Background Checks for Material Owners)	**258-260**

New Business:

- Election of Vice-Chairman, September 6, 2022 through June 30, 2023

Reports:

• Chairman's Report –Dale St.Clair, PharmD	**verbal**
• Report on Board of Health Professions – Sarah Melton, PharmD	**verbal**
• Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh	**261**
• Report on Nonresident Facilities – Beth O'Halloran, RPh	**262**
• Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division	**263-270**
• Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C.	**271**
• Report on Disciplinary Program – Ellen B. Shinaberry, PharmD	**272**
• Executive Director's Report – Caroline D. Juran, RPh	**273**

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 A QUOROM OF THE BOARD

Monday, May 23, 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 9:13 AM.

PRESIDING: Cheryl Nelson, Chair

MEMBERS PRESENT:
Sarah Melton
Bernie Henderson
Kris Ratliff
Cheri Garvin
James Jenkins
Bill Lee
Glenn Bolyard
Dale St. Clair

STAFF PRESENT:
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General

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

TIME & PURPOSE:
Case No. 214575

James Schliessmann, Assistant Attorney General for the Commonwealth, presented evidence for a possible summary suspension. Mr. Schliessmann was assisted by Jess Weber, DHP Adjudication Specialist.

CLOSED MEETING: Upon a motion by Dr. St. Clair, and duly seconded by Mr. Jenkins, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Dina Liuzzi. Additionally, he moved that Ellen Shinaberry and Jim Rutkowski attend the closed meeting.

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

DECISION:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Garvin, the Board voted 9-0 to summarily suspend the pharmacy technician registration of Dina Liuzzi. Upon a motion by Mr. Bolyard, and duly seconded by Ms. Garvin, the Board voted 8-1 (Henderson - Nay) to notice for a formal hearing, and offer a consent order for in lieu of the formal hearing with certain terms and conditions.
CONSIDERATION OF CONSENT ORDERS:	
CASE NO. 201687	Mr. Lee recused himself prior to the start of this presentation. Jess Weber, Adjudication Specialist, presented a consent order in the matter of case number 201687.
CLOSED MEETING:	Upon a motion by Dr. St. Clair, and duly seconded by Mr. Bolyard, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the consent order. Additionally, he moved that Ellen Shinaberry and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision. Mr. Lee returned for open session.
DECISION:	Upon a motion by Ms. Garvin, and duly seconded by Mr. Henderson, the Board voted 8-0 to deny the consent order.
CASE NO. 211648	Dr. Ratliff and Mr. Henderson recused themselves prior to the start of this presentation. Jess Weber, Adjudication Specialist, presented a consent order in the matter of case number 211648.
CLOSED MEETING:	Upon a motion by Dr. St. Clair, and duly seconded by Mr. Jenkins, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the consent order. Additionally, he moved that Ellen Shinaberry and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision. Dr. Ratliff and Mr. Henderson returned for open session. Upon a motion by Ms. Garvin, and duly seconded by Mr. Bolyard, the Board voted 7-0 to accept the consent order.

	Caroline Juran, Executive Director and Krista Samuels, Assistant Attorney General, arrived for the formal hearing for case number 201687. Mr. Lee recused himself from the formal hearing and left the building.
PASCALE EL HAYEK License No. 0202-207815	A formal hearing was held in the matter of Pascal El Hayak to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy in Virginia. Jess Weber, DHP Adjudication Specialist, presented the case. Ms. El Hayek was not represented by counsel and Ms. Cotter testified on her own behalf. Victoria McGee, DHP Inspector, testified in person for the Commonwealth.
CLOSED MEETING:	Upon a motion by Ms. Garvin, and duly seconded by Dr. St. Clair, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Pascale El Hayek. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, and Krista Samuels attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.
DECISION:	Upon a motion by Dr. St. Clair, and duly seconded by Dr. Melton, the Board voted 8-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board. Upon a motion by Dr. St. Clair, and duly seconded by Dr. Melton, the board voted 8-0 to revoke the pharmacist license of Pascale El Hayek.
ADJOURN:	1:35 PM

Cheryl Nelson, Chair	Caroline D. Juran, Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Tuesday, May 24, 2022
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 9:14 AM.
PRESIDING:	Cheryl Nelson, Committee Chairman
MEMBER PRESENT:	Dale St.Clair, Committee Member
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Jess Weber, DHP Adjudication Specialist
NEW RIVER COMMUNITY SERVICES BOARD Naloxone Automated Dispensing Machine	Charlie Tarasidis, PharmD, Carillon Health Services, Sohyun Park, Pharmacy Resident, and Tiffani Wells, DBHDS Harm Reduction Coordinator, appeared in person on behalf of New River Community Services Board and Dr. Circe Cook, Medical Director, New River Community Services Board, participated remotely to discuss the proposed innovative pilot program "Naloxone Automated Dispensing Machine" as stated in the April 28, 2022 Notice.
DISCUSSION:	Representatives of the New River Community Services Board and Virginia Department of Behavioral Health & Developmental Services presented information about the need for and use of an automated dispensing system for dispensing of naloxone.
DECISION:	Upon a motion by Dr. St. Clair, and duly seconded by Dr. Nelson, the Committee voted unanimously to approve the innovative pilot program for one year with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 1:20 PM.

Cheryl Nelson
Committee Chairman

Date

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, May 25, 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:	Kristopher Ratliff, Committee Chair
MEMBERS PRESENT:	Bernard Henderson, Committee Member
STAFF PRESENT:	Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jessica Weber, DHP Adjudication Specialist Christine Andreoli, DHP Adjudication Specialist
FRANK LUCAS License No. 0202-004585	Frank Lucas appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 7, 2022, Notice. Mr. Lucas was not represented by Counsel.
Closed Meeting:	Upon a motion by Mr. Henderson, 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 Frank Lucas. 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 Mr. Henderson and duly seconded by Mr. Ratliff, the Committee voted unanimously to order Mr. Lucas to undergo a mental health assessment pursuant to 54.1-2400(15).
LINDY M. KNIGHT, Reinstatement Applicant Registration No. 0230-008701	Lindy M. Knight appeared to discuss her application for reinstatement/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 March 24, 2022 Notice. Ms. Knight was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Henderson, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(16) for the purpose of reviewing confidential medical and substance abuse records. Additionally, he moved that Mykl Egan, Ileita Redd, Jess Weber and Christine Andreoli 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.
Closed Meeting:	Upon a motion by Mr. Henderson, 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 Lindy M. Knight. 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 Mr. Henderson and duly seconded by Mr. Ratliff, the Committee voted unanimously to grant her request for reinstatement under terms and conditions.
AKINA PHARMACY Permit No. :0201-004538	Bassem Girgis, Pharmacist-in-Charge of Akina 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 March 24, 2022 Notice. They were not represented by counsel. The pharmacy was not represented by counsel.
Closed Meeting:	Upon a motion by Mr. Henderson, 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 Akina 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 Mr. Henderson and duly seconded by Mr. Ratliff, the Committee unanimously voted to assess a monetary penalty against Akina Pharmacy.
CVS/Pharmacy #7558 Permit No. 0201-002605	Joseph Levino, Senior Legal Counsel for Regulatory Affairs and Nancy Lee Frye, Pharmacist-in-Charge,

appeared as representatives of CVS/Pharmacy #7558 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the January 12, 2022 Notice. They were represented by Roger Morris, Esquire.

Closed Meeting: Upon a motion by Mr. Ratliff, and duly seconded by Mr. Henderson, 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 #7558. Additionally, he moved that Ellen Shinaberry, Mykl Egan and Ileita Redd attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Ratliff and duly seconded by Mr. Henderson, the Committee voted unanimously to refer the matter to a Formal Administrative Hearing.

ADJOURNED: 5:15 p.m.

_____ _____

Kristopher Ratliff, Chair

Mykl Egan
Discipline Case Manager

_____ _____

Date

Date

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

Monday, June 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 1:42pm.

PRESIDING: Cheryl Nelson, PharmD, Chair

MEMBERS PRESENT: Glenn Bolyard, RPh
Cheri Garvin, RPh
James Jenkins, Jr., RN
Dale St. Clair, PharmD
Kristopher Ratliff, DPh

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

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

JACKIE MCCALL
0202212502

A formal hearing was held in the matter of Jackie McCall, Jr. to discuss violations of certain laws and regulations governing the practice of pharmacy in Virginia and his request for reinstatement of his pharmacist license.

David Robinson, DHP Adjudication Specialist, presented the case on behalf of the Commonwealth.

Jackie McCall, Jr. did not have legal counsel and represented himself.

Gayle Miller, DHP Senior Investigator, testified in person on behalf of the Commonwealth.

Jackie McCall testified on behalf of himself.

CLOSED MEETING: Upon a motion by Dale St. Clair, and duly seconded by Glenn Bolyard, 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 Jackie McCall, Jr. Additionally, he moved that Caroline Juran, James Rutkowski, and Sorayah Haden attend the closed meeting.

RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Dale St. Clair, second by Cheri Garvin)
DECISION:	Upon a motion by James Jenkins, Jr. and duly seconded by Glenn Bolyard, the Board unanimously voted that with the evidence presented, the Board denies the reinstatement application for the pharmacist license of Jackie McCall, Jr.
ADJOURN:	With all business concluded, the meeting adjourned at 4:24pm.

Cheryl Nelson, Chair

Caroline Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

June 6, 2022

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

CALL TO ORDER:	A full board meeting was called to order at 9:12AM.
PRESIDING:	Cheryl Nelson, PharmD, Chairman
MEMBERS PRESENT:	Kristopher Ratliff, DPh Dale St. Clair, PharmD James Jenkins, Jr., RN Cheri Garvin, RPh Glenn Bolyard, RPh William Lee, DPh Patricia Richards-Spruill, RPh
MEMBERS ABSENT:	Sarah Melton, PharmD Bernard Henderson
STAFF PRESENT:	Caroline Juran, RPh, Executive Director, Board of Pharmacy Sorayah Haden, Executive Assistant, Board of Pharmacy David Brown, DC, DHP Director Erin Barrett, JD, DHP Senior Policy Analyst James Rutkowski, JD, Assistant Attorney General Ryan Logan, RPh, Deputy Executive Director, Board of Pharmacy Beth O'Halloran, RPh, Deputy Executive Director, Board of Pharmacy Annette Kelley, MS, CSAC, Deputy Executive Director, Board of Pharmacy Delisa Turner, Licensing Specialist, Board of Pharmacy Rose DeMatteo, MHSA, MPA, Compliance Manager, Board of Pharmacy
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	Glenn Bolyard

QUORUM: With 8 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 March 15, 2022 and May 3, 2022 as presented. (Motion by Jenkins, seconded by Richards-Spruill)**

PUBLIC COMMENT: Christina Barrille, Executive Director of VPhA, provided public comment thanking the chairman, vice-chairman, Dr. Brown, and Dr. Allison-Bryan for their service to the Virginia Board of Pharmacy and Commonwealth. She stated COVID-19 is still creating a strain on the profession and encouraged the Board to continue addressing pharmacy working conditions. She thanked Sen. Dunnavant for introducing SB632 and referenced the authority for new statewide protocol allowances for vaccines and tobacco cessation. She stated VPhA is supportive of a legislative proposal to add a pharmacy technician member to the Board of Pharmacy and commends efforts to address cannabis drug-drug interactions in the draft guidance document. VPhA invites all to their annual convention in Virginia Beach scheduled in August.

DHP DIRECTOR'S REPORT: Dr. David Brown provided an update regarding the change in administration. Appointment for DHP Director has not yet been determined, but a strong team across the Secretariat is being assembled. Supply chain issues has caused delays in upgrades to the AV system in the Conference Center located on the second floor. Dr. Brown anticipates the updates will take place this upcoming summer. He commented that DMAS is reviewing reimbursement rates for buprenorphine to address concerns with access.

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF REGULATORY ACTIONS: Erin 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.

REPORT OF THE 2022 GENERAL ASSEMBLY: Erin Barrett referenced the legislative report included in the agenda packet regarding relevant bills considered or passed by the 2022 General Assembly. Ms. Barrett reviewed and explained the requirements for emergency regulations, proposed regulations requiring exempt regulatory actions, and required non-regulatory actions.

ADOPTION OF FINAL

EXEMPT REGULATIONS TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

MOTION: **The Board voted unanimously to adopt the final exempt regulations to place certain chemicals in Schedule I as presented. (Motioned by St. Clair, seconded by Bolyard)**

ADOPTION OF PROPOSED REGULATIONS FOR CENTRALIZED WAREHOUSER OR WHOLESALE DISTRIBUTOR TO VERIFY SCHEDULE VI DRUGS FOR AUTOMATED DISPENSING DEVICES IN HOSPITALS:

The Board discussed expectations for scanning rate and offered an amendment to the draft language. Dr. Nelson stated that a "unit" as referenced in the amendment is intended to be an intact product, e.g., a loose individual unit dose or an intact blister card of 10 unit doses. It was mentioned that a guidance document capturing this understanding could be drafted in the future, if necessary, and if the proposed amendment becomes final. The adopted language will be published for public comment to ensure the proposed language is not problematic.

MOTION: **The Board voted 7-1 to adopt the proposed regulations as presented and amended to read "each unit should be scanned before placement" into the automated dispensing device. (motion by Nelson, seconded by Jenkins; opposed by Lee)**

ADOPTION OF FINAL REGULATIONS FOR IMPLEMENTATION OF LEGISLATION FOR REGISTRATION OF PHARMACY TECHNICIAN TRAINEES:

Erin Barrett explained the proposed final regulations for implementation of legislation for registration of pharmacy technician trainees and requirement for accredited pharmacy technician training programs. Ms. Barrett also referenced the Frequently Asked Questions for Pharmacy Technician Training Program and Registration which was provided as a handout. Ms. Juran confirmed for Ms. Garvin that the board will stop renewing board-approval of pharmacy technician training programs as of July 1, 2022.

MOTION: **The Board voted 7-1 to adopt the final regulations for implementation of legislation for registration of pharmacy technician trainees as presented and recommended by the Regulation Committee. (opposed by Garvin)**

CONSIDERATION OF PETITION FOR RULEMAKING CONCERNING AUTOMATED DISPENSING DEVICES IN NURSING HOMES EXCLUSIVELY STOCKED WITH EMERGENCY OR STAT

Erin Barrett explained the consideration of petition for rulemaking concerning automated dispensing systems. The Board discussed the petition to determine whether to accept the Regulatory Committee's recommendation or take no action on the petition. Ms. Juran stated it has come to her attention recently that DEA requires pharmacist verification of a valid order prior to releasing the drug in the automated dispensing device intended for emergency or stat use. Therefore, the petitioner's request appears to conflict with federal requirements for drugs in Schedules II-V. It could potentially be considered for Schedule VI drugs.

DRUGS:

MOTION: **The Board voted 7-1 to adopt a Notice of Intended Regulatory Action for possibly amending 18VAC110-20-555 regarding pharmacist verification of a valid order prior to a drug being obtained from an automated dispensing device stocking only drugs for emergency or stat use as recommended by the Regulation Committee. (opposed by Nelson)**

ADOPTION OF FINAL REGULATIONS FOR PHARMACISTS INITIATING TREATMENT:

Erin Barrett explained the adoption of the final regulations for implementation of 2020 legislation regarding pharmacists initiating treatment.

MOTION **The Board voted unanimously to adopt the final regulations for implementation of the 2020 legislation regarding pharmacists initiating treatment. (motion by Richards-Spruill, seconded by Jenkins)**

CONSIDERATION OF LEGISLATIVE PROPOSALS FOR EXPANDING USE OF TECHNOLOGY FOR STORING AND DISPENSING DRUGS IN CERTAIN FACILITIES; AUTHORIZING PHARMACY TECHNICIANS TO ADMINISTER VACCINES, AND AUTHORIZING PHARMACY TECHNICIANS TO CLARIFY REFILLS AND QUANTITY OF CERTAIN SCHEDULE VI PRESCRIPTIONS

Ms. Juran reviewed a handout of a draft legislative proposal for 2023 that would expand allowances for certain facilities to stock a supply of drug and use various forms of technology to store, label, and dispense drugs for residents.

MOTION: **The Board voted unanimously to decline the Regulation Committee's recommendation to adopt the 2023 legislative proposal for expanding use of technology for storing and dispensing drugs in certain facilities as presented, because it wanted to amend the language in a separate motion. (motion by St. Clair, seconded by Richards-Spruill)**

MOTION: **The Board voted unanimously to adopt the 2023 legislative proposal for expanding use of technology for storing and dispensing drugs in certain facilities as presented and amended by changing 54.1-3434.02 (A)(7) to read "Except as authorized in Board regulation," a pharmacy not located in the facility that provides services to the facility for use of an automated drug dispensing system or remote dispensing system shall first obtain a**

controlled substances registration issued in the name of the pharmacy at the address of the facility and a registration from the Drug Enforcement Administration, if required, prior to stocking drugs in Schedules II through VI." (motion by St. Clair, seconded by Garvin)

Ms. Juran reviewed the draft legislative proposal for 2023 included in the agenda packet authorizing pharmacy technicians to clarify refills and quantity of certain Schedule VI prescriptions. It was noted that because HB1323 was passed and includes authorization for pharmacy technicians to administer vaccines, there is no need to include this allowance in a 2023 legislative proposal.

MOTION: **The Board voted unanimously to adopt the 2023 legislative proposal authorizing pharmacy technicians to clarify refills and quantity of certain Schedule VI prescriptions as presented by the Regulation Committee and amended by striking the language for vaccine administration since that authority was recently passed by the General Assembly in HB1323.**

CONSIDERATION OF LEGISLATIVE PROPOSAL TO ADD PHARMACY TECHNICIAN MEMBER TO BOARD OF PHARMACY

The Board reviewed the draft legislative proposal included in the agenda packet. It was discussed that any member of the Board has the same rights as any other Board member and therefore, may participate in disciplinary hearings or be elected as an officer. It was noted that this issue was discussed at the NABP annual meeting. Approximately twelve states have one pharmacy technician member on the Board; one of these states has two positions for pharmacy technicians. Additional states are considering the allowance given the discussions to expand the scope of duties for pharmacy technicians and the important role they play in the practice of pharmacy.

MOTION: **The Board voted unanimously to adopt the 2023 legislative proposal for adding one pharmacy technician member position to the Board of Pharmacy. (motion by Ratliff, seconded by Bolyard)**

ADOPTION OF GUIDANCE DOCUMENT REGARDING CANNABIS DRUG-DRUG INTERACTIONS:

The Board reviewed the draft guidance document included in the agenda packet which was prepared by Board Member Sarah Melton and associated students/residents.

MOTION: **The Board voted unanimously to adopt the guidance document regarding cannabis drug-drug interactions as presented. (motion by Jenkins, seconded by Garvin)**

NEW BUSINESS:

AMEND 2022 PHARMACIST WORKFORCE SURVEY

The Board reviewed the amended questions in the agenda packet for the 2022 pharmacist healthcare workforce survey regarding additional medical

conditions authorized for statewide protocols.

MOTION: **The Board adopted the amended questions for the 2022 pharmacist healthcare workforce survey regarding collaborative practice agreements and the additional medical conditions authorized for statewide protocols. (motion by St. Clair, seconded by Garvin)**

ELECTIONS OF CHAIRMAN AND VICE-CHAIRMAN

Mrs. Richards-Spruill recommended Dale St. Clair for 2022-2023 Chairman of the Virginia Board of Pharmacy. Term is for July 1, 2022 through June 30, 2023. No other nominations were recommended.

MOTION: **The Board voted unanimously to close nominations for election of the 2022-2023 Chairman of the Virginia Board of Pharmacy. (motion by Lee, seconded by Bolyard)**

MOTION: **The Board voted unanimously to elect Dale St. Clair as the 2022-2023 Chairman of the Virginia Board of Pharmacy.**

Mr. James Jenkins, Jr. recommended Glenn Bolyard for Vice-Chairman of the Virginia Board of Pharmacy. Term is for July 1, 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 Garvin)**

MOTION: **The Board voted unanimously to elect Glenn Bolyard as the 2022-2023 Vice-Chairman of the Virginia Board of Pharmacy.**

REPORTS:

CHAIRMAN'S REPORT

Dr. Nelson provided an update from the 2022 NABP annual meeting in Phoenix, AZ that she and Dr. St. Clair attended, along with Ms. Juran. She recognized Ms. Juran for her work serving as NABP President and congratulated her for transitioning to Chairman of NABP. She encouraged other board members to attend the NABP meetings, if able, to network with colleagues from other states grappling with similar issues. She also expressed appreciation for the Board's support while serving as Chairman.

BOARD OF HEALTH PROFESSIONS

Ms. Juran provided a brief report on behalf of Dr. Melton from the last Board of Health Professions meeting.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES

Ryan Logan presented the Licensing Report of Individuals and In-State Facilities which included data from November 2020 through May 9, 2022. As of May 9, 2022, the Virginia Board of Pharmacy currently has 41,170 licensees.

LICENSURE OF NONRESIDENT FACILITIES

Beth O'Halloran presented the Licensing Report of Nonresident Facilities which included data from November 2020 through May 3, 2022. As of May 3, 2022, the Virginia Board of Pharmacy has 2,366 licensed nonresident facilities.

INSPECTION PROGRAM

Melody Morton, Inspections Manager with the Enforcement Division presented the Inspections Report including data from March 2020 through March 2022.

PHARMACEUTICAL PROCESSORS

Annette Kelley presented the Pharmaceutical Processors Report. As of May 3, 2022, the Virginia Board of Pharmacy currently has 827 registered practitioners, 50,935 registered patients, 260 registered parents/guardians, 172 registered agents, and 1,375 registered cannabis oil products. No additional cannabis dispensing facilities have been permitted during the last quarter. The Board receives an average of 1,000 applications per week. The Board has been developing regulations and procedures to address the 2022 legislative changes impacting the Pharmaceutical Processors Program.

DISCIPLINARY PROGRAM

Caroline Juran presented the Disciplinary Program Report on behalf of Dr. Ellen B. Shinaberry. As of May 5, 2022, the Virginia Board of Pharmacy currently has 373 open cases consisting of 215 patient care related cases and 158 non-patient care related cases.

EXECUTIVE DIRECTOR'S REPORT

Caroline Juran provided an operational report of the board staff's teleworking allowance which will likely be restricted to one day per week effective July 5, 2022. The board is recruiting for a vacant licensing administrative assistant position. A Licensing Administrative Assistant and Licensing Supervisor were recently hired for the Pharmaceutical Processor Program.

There are ongoing efforts to acquire a new licensing software for the Pharmaceutical Processors Program. Board staff is also are preparing for digital disciplinary evidence packets and meeting agendas.

Mrs. Juran highlighted meetings she has recently attended and presentations offered at NASPA and JCPP.

MEETING ADJOURNED: With all business concluded, the meeting adjourned at 12:48PM

Cheryl Nelson, Chairman	Caroline Juran, Executive Director
DATE:	DATE:

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

Monday, June 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 consider placement of certain chemicals into Schedule I at 9:07 am.
PRESIDING:	Cheryl Nelson, PharmD, Chair
MEMBERS PRESENT:	Glenn Bolyard Patricia Richards-Spruill (arrived 9:09am) Cheri Garvin Bill Lee Dale St. Clair Kristopher Ratliff James Jenkins Jr.
MEMBERS ABSENT	Bernard Henderson Sarah Melton
STAFF PRESENT:	Caroline D. Juran, Executive Director David Brown, DHP Director Erin Barrett, DHP Senior Policy Analyst Ryan Logan, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Annette Kelley, Deputy Executive Director James Rutkowski, Assistant Attorney General Sorayah Haden, Executive Assistant Rose DeMatteo, Compliance Manager Delisa Turner, Licensing Specialist
QUORUM:	With eight (8) members of the Board present, a quorum of the board was established.
PUBLIC COMMENT	Dr. Nelson invited members of the public to offer comment on the subject. Pursuant to article § 54.1-3443(D), the Virginia Department of Forensic Science (DFS) has identified ten (10) 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-(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.

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-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alphapropylaminobutiophenone; 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.

3. **2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alphaethylaminopentiophenone),** 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. **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.

5. **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.

6. **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.

7. **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.

8. **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.

The following compound is classified as a central nervous system stimulant. Compounds of this type have been placed in Schedule I (§ 54.1-3446(5)) in previous legislative sessions.

9. **4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA)**, including its salts, isomers and salts of isomers.

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.

10. **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.

No public comments were offered.

MEETING ADJOURNED	The Public Hearing was adjourned at 9:12am.

Cheryl Nelson, Chair

Caroline D. Juran, Executive Director

Date

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

Monday, June 13, 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 quorum of the Board of Pharmacy ("Board") was called to order at 9:08 AM.

PRESIDING: Cheryl Nelson, Chair

MEMBERS PRESENT:
Sarah Melton
Bernie Henderson
Kris Ratliff
Cheri Garvin
Patricia Richards-Spruill
Bill Lee
Dale St.Clair
Glenn Bolyard

STAFF PRESENT:
Ellen B. Shinaberry, Deputy Executive Director
Caroline D. Juran, Executive Director
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant

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

POSSIBLE SUMMARY SUSPENSION PRESENTATIONS
CASE NO.: 215907

The Board considered the summary suspension of the license of Edward Breslow to practice as a pharmacist in the Commonwealth of Virginia.

Sean Murphy, Assistant Attorney General for the Commonwealth, presented the evidence in this case.

CLOSED MEETING: Upon a motion by Mr. Bolyard, and duly seconded by Mr. Henderson, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Edward Breslow. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Sorayah Haden, and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Bolyard/St. Clair).

DECISION:

Upon a motion by Mr. Henderson, and duly seconded by Dr. Ratliff, the Board voted 9-0 to summarily suspend the pharmacist license of Edward Breslow.

CASE NO.: 219558

The Board considered the summary suspension of the registration of Ashleigh Bowman to practice as a technician trainee in the Commonwealth of Virginia.

Sean Murphy, Assistant Attorney General for the Commonwealth, presented the evidence in this case.

CLOSED MEETING:

Upon a motion by Mr. Bolyard, and duly seconded by Mrs. Richards-Spruill, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Ashleigh Bowman. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Sorayah Haden, and Jim Rutkowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Bolyard/St. Clair).

DECISION:

Upon a motion by Mr. Bolyard, and duly seconded by Mrs. Patricia Richards-Spruill, the Board voted 9-0 to summarily suspend the technician trainee registration of Ashleigh Bowman, and to offer a consent order for revocation in lieu of a formal hearing.

FORMAL HEARING
BRYAN WADE LEWIS
License No. 0202-210300

A formal hearing was held in the matter of Bryan W. Lewis to discuss allegations he may have violated certain laws and regulations governing the practice of pharmacy in Virginia and to consider his application for reinstatement.

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

Mr. Lewis was present and testified on his own behalf. He was not represented by legal counsel.

Jermia Gray, DHP Senior Investigator, testified in person on behalf of the Commonwealth.

CLOSED MEETING:	Upon a motion by Dr. St. Clair, and duly seconded by Mr. Bolyard, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(16) of the Code of Virginia ("Code"), for the purpose of discussing the medical records and mental health records of Bryan W. Lewis. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Sorayah Haden, Jim Rutkowski, and the court reporter 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 (St.Clair/Bolyard).
CLOSED MEETING:	Upon a motion by Dr. St. Clair, and duly seconded by Mr. Garvin, the Board voted 9-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Bryan W. Lewis. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Sorayah Haden, and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (St.Clair/Lee).
DECISION:	Upon a motion by Dr. St. Clair, and duly seconded by Dr. Ratliff, the panel voted 9-0 to accept the Findings and Facts and Conclusion of Law proposed by Ms. Joseph and amended by the Board. Upon a motion by Dr. Melton, and duly seconded by Dr. Lee, the panel voted 9-0 to reinstate the pharmacist license of Bryan W. Lewis with certain terms and conditions.
RECONVENE:	Upon a motion by Dr. Melton, and duly seconded by Mr. Henderson, the panel voted 6-0 to revoke the pharmacist license of Lisa K. Cotter.
ADJOURN:	11:57 AM

Cheryl Nelson, Chair

Caroline D. Juran, Executive Director

Date

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, June 14, 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 9:08 am.
PRESIDING:	Glenn Bolyard, Committee Chair
MEMBERS PRESENT:	Patricia Richards-Spruill, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist David Robinson, DHP Adjudication Specialist
CYNTHIA N. GLOVER, Applicant Registration No.	Cynthia Glover, did not appear to discuss her application for registration as a pharmacy technician trainee 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 March 17 2022 Notice. Ms. Glover was not represented by counsel.
Closed Meeting:	Upon a motion by Mrs. Richards-Spruill, and duly seconded by Mr. Bolyard, 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 Cynthia Glover. 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 Mrs. Richards-Spruill, and duly seconded by Mr. Bolyard, the Committee unanimously voted to deny Ms. Glover's application

FEDAH S. ABOABDO
License No. 0230-217102

Fedah S. Aboabdo, pharmacist, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the May 5, 2022, Notice. She was not represented by counsel.

Closed Meeting: Upon a motion by Mrs. Richards-Spruill, and duly seconded by Mr. Bolyard, 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 Fedah S. Aboabdo. 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 Mrs. Richards-Spruill, and duly seconded by Mr. Bolyard, the Committee unanimously voted to refer the matter to a formal hearing

ADJOURNED: 10:48 a.m.

Glenn Bolyard, Chair

Mykl D. Egan
Discipline Case Manager

_____ _____

Date Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, June 29, 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 June 29, 2022, at 09:02 AM, to consider the summary suspensions in case no. 217280, case no. 220054, and case no. 214635.

PRESIDING: Cheryl Nelson, Chair

MEMBERS PRESENT:
Glenn Bolyard
Cheri Garvin
James Jenkins
William Lee
Kristopher Ratliff
Dale St. Clair
Bernie Henderson
Patricia Richards-Spruill

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Wayne Halbleib, Senior Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Davis Robinson, 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 nine (9) members participating and one (1) member unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

TYESHA MALONE
Registration No. 0245-002282

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in case no. 217280 regarding the pharmacy technician trainee registration of Tyesha Malone.

CLOSED SESSION:

Upon a motion by Dr. St. Clair, and duly seconded by Ms. Richards-Spruill, the board voted 9-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Tyesha Malone. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.

OPEN SESSION:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the board reconvened an open meeting and announced the decision. (St. Clair/Rogers)

DECISION:

Upon a motion by Mr. Jenkins and duly seconded by Mr. Henderson, the Board unanimously voted (9-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Tyesha Malone poses a substantial danger to the public; and therefore, the registration of Ms. Malone shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Malone for the revocation of her registration in lieu of the formal hearing.

HANNAH N. HUDSON
Registration No. 0245-000598

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 220054 regarding the pharmacy technician trainee registration of Hannah N. Hudson.

DECISION:

Upon a motion by Mr. Henderson and duly seconded by Mr. Ratliff, the Board unanimously voted (9-0) that,

with the evidence presented, the practice as a pharmacy technician trainee by Hannah N. Hudson poses a substantial danger to the public; and therefore, the registration of Ms. Hudson shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Hudson for the revocation of her registration in lieu of the formal hearing.

MICHELLE A. BIBY
Registration No. 0230-034252

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 214635 regarding the pharmacy technician registration of Michelle A. Biby.

Upon a motion by Mr. Jenkins and duly seconded by Mr. Henderson, the Board unanimously voted (9-0) that, with the evidence presented, the practice as a pharmacy technician by Michelle A. Biby poses a substantial danger to the public; and therefore, the registration of Ms. Biby shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Biby for the revocation of her registration in lieu of the formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 09:51 AM.

Cheryl Nelson, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, July 13, 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 9:21 am.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	William Lee, Committee Member Cheryl Garvin, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Rose DeMatteo, Compliance Case Manager Jess Weber, DHP Adjudication Specialist
Jeffrey Chodrow, Pharmacist License No. 0202-207482	Jeffrey Chodrow, pharmacist, did not appear to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the May 19, 2022, Notice. He was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Jeffrey Chodrow. Additionally, he moved that Mykl Egan and Rose DeMatteo 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 Mrs. Richards-Spruill, the Committee unanimously voted to issue Mr. Chodrow a REPRIMAND and order him to take additional hours in continuing education.
CVS/Pharmacy #2691 Permit No. 0201-003705	Justin Clouse, District Leader and Joseph Levino, Senior Legal Counsel for Regulatory Affairs, appeared as representatives of CVS/Pharmacy #2691 to discuss allegations that it may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the March 24, 2022 Notice. They were represented by George Parcells, Esquire.
Closed Meeting:	Upon a motion by Dr. Lee, and duly seconded by Mrs. Richards-Spruill, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of CVS/Pharmacy #2691. Additionally, he moved that Mykl Egan and Rose DeMatteo 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 Mrs. Richards-Spruill, the Committee unanimously voted to issue a monetary penalty to CVS/Pharmacy #2691 and order additional terms and conditions placed on the Pharmacy.
ADJOURNED:	4:05 p.m.

_____ _____

Patricia Richards-Spruill, Chair Mykl D. Egan

Discipline Case Manager

_____ _____

Date Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, July 13, 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 July 13, 2022, at 12:33 AM, to consider the summary suspensions in case no. 218856 and case no. 218439.

PRESIDING: Dale St. Clair, Chair

MEMBERS PRESENT:
Cheri Garvin
James Jenkins
William Lee
Kristopher Ratliff
Sarah Melton
Patricia Richards-Spruill

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Erin Weaver, Assistant Attorney General
Sean J. Murphy, Assistant Attorney General
Davis Robinson, 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. Four Board members stated that they would not have been able to attend; three Board members (Richards-Spruill, Lee, and Garvin) were in the Board office to participate in informal conferences.

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

JESSICA TAYLOR
Registration No. 0245-002763

Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case no. 218856 regarding the pharmacy technician trainee registration of Jessica Taylor.

DECISION:

Upon a motion by Mr. Jenkins and duly seconded by Mr. Ratliff, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Jessica Taylor poses a substantial danger to the public; and therefore, the registration of Ms. Taylor shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Taylor for the revocation of her registration in lieu of the formal hearing.

WARREN MCCANN
License No. 0202-204817

Erin Weaver, Assistant Attorney General, presented a summary of the evidence in case no. 218439 regarding the pharmacist license of Warren McCann.

Upon a motion by Mr. Ratliff and duly seconded by Mr. Jenkins, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacist by Warren McCann poses a substantial danger to the public; and therefore, the license of Mr. McCann shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Mr. McCann for the revocation of his license in lieu of the formal hearing.

ADJOURN:	With all business concluded, the meeting adjourned at 12:54 PM.

Dale St. Clair, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

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

Thursday, July 28, 2022
Commonwealth Conference Center
Second Floor
Board Room 3

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 quorum of the Board of Pharmacy ("Board") was called to order at 9:04 AM.

PRESIDING: Dale St. Clair, Chairman

MEMBERS PRESENT:
Ling Yuan
Larry Kocot
Kris Ratliff
Cheri Garvin
Wendy Nash
Bill Lee
Jim Jenkins

STAFF PRESENT:
Ellen B. Shinaberry, Deputy Executive Director
Caroline D. Juran, Executive Director
James Rutkowski, Assistant Attorney General

QUORUM: With nine (8) members of the Board present, a quorum of the board was established.

POSSIBLE SUMMARY SUSPENSION PRESENTATION
CASE NO.: 220049

The Board considered the summary suspension of the license of Susan Waters to practice as a pharmacist in the Commonwealth of Virginia.

Sean Murphy, Assistant Attorney General for the Commonwealth, presented the evidence in this case. Mr. Murphy was assisted by Anne Joseph, Sr. Adjudication Specialist

CLOSED MEETING: Upon a motion by Ms. Garvin, and duly seconded by Dr. Lee, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Susan Waters. Additionally, she moved that Ellen Shinaberry, Caroline Juran, and Jim Rutkowski attend the closed meeting.

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

decision (Garvin/Lee).

DECISION: Upon a motion by Mr. Jenkins, and duly seconded by Dr. Yuan, the Board voted 8-0 to summarily suspend the pharmacist license of Susan Waters and to offer a consent order in lieu of a formal hearing.

FORMAL HEARINGS

PRESIDING: Kris Ratliff, Chairman

MEMBERS PRESENT: Ling Yuan
Larry Kocot
Cheri Garvin
Wendy Nash
Bill Lee
Jim Jenkins

FALLS CHURCH PHARMACY
Permit No. 0201-003833

ASHLEIGH BOWMAN
Registration No. 0245-004089

EDWARD BRESLOW
License No. 0202-011951

CLOSED MEETING: Upon a motion by Ms. Garvin, and duly seconded by Dr. Nash, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(7) of the Code of Virginia ("Code"), for the purpose of consultation with legal counsel. Additionally, she moved that Ellen Shinaberry, Caroline Juran and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting (Garvin/Nash).

MOTION TO CONTINUE: Upon a motion by Mr. Jenkins, and duly seconded by Dr. Lee, the Board voted 7-0, to continue the formal hearings in the matter of Falls Church Pharmacy, Ashleigh Bowman, and Edward Breslow, to a another date.

ADJOURN: 1:12 PM

Kris Ratliff, Chairman (Formal Hearing)

Date

Dale St. Clair, Chairman (Sum Susp)

Date

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, August 17, 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 9:15 am.
PRESIDING:	William Lee, Committee Chair
MEMBERS PRESENT:	Ling Yuan, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Case Specialist Jess Weber, DHP Adjudication Specialist Christine Andreoli, DHP Adjudication Specialist
Michael Lewis, Pharmacist License No. 0202-214196	Michael Lewis, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the June 23, 2022, Notice. He was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Dr. Lee, 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 Michael Lewis. 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. Yuan, and duly seconded by Dr. Lee, the Committee unanimously voted to order Mr. Lewis to complete additional hours in continuing education.
Nesreen Henien, Pharmacist License No. 0202-216891	Nesreen Henien, pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacist as stated in the July 19, 2022, Notice. She was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Dr. Lee, 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 Nesreen Henien. 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. Yuan, and duly seconded by Dr. Lee, the Committee unanimously voted to reprimand Ms. Henien and order her to complete additional hours in continuing education.
Ehab Zarif Aziz Tadrous, Pharmacist License No. 0202-208080	Ehab Zarif Aziz Tadrous, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing his practice as a pharmacist as stated in the July 19, 2022, Notice. He was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Dr. Lee, 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 Ehab Zarif Aziz Tadrous. 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. Yuan, and duly seconded by Dr. Lee, the Committee unanimously voted to reprimand Mr. Tadrous, assess a monetary penalty, and order him to complete additional hours in continuing education.
St. Theodore, LLC d/b/a TED Pharmacy Permit No. 0201-004844	Ehab Zarif Aziz Tadrous, Owner and PIC of St. Theodore LLC d/b/a/ TED Pharmacy ("TED Pharmacy"), appeared as a representative of TED Pharmacy to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy as stated in the July 19, 2022 Notice. The pharmacy was not represented by counsel.
Closed Meeting:	Upon a motion by Dr. Yuan, and duly seconded by Dr. Lee, 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 TED Pharmacy. 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. Yuan and duly seconded by Dr. Lee, the Committee unanimously voted to assess a monetary penalty to TED Pharmacy and order additional terms and conditions placed on the Pharmacy.
ADJOURNED:	2:33 p.m.

_____ _____

William Lee, Chair

Mykl D. Egan
Discipline Case Manager

_____ _____

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, August 18, 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 § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on March 30, 2022, at 11:01 AM, to consider terms of a settlement proposal for case no. 210816.

PRESIDING: Dale St. Clair, Chair

MEMBERS PRESENT: Cheri Garvin
Larry Kocot
William Lee
Patricia Richards-Spruill
Wendy Nash
Ling Yuan

STAFF PRESENT: Caroline Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Senior Assistant Attorney General

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

QUORUM: With seven (7) members participating a quorum was established. Board member Kris Ratliff was recused from the conference call.

CLOSED MEETING:	Upon a motion by Mrs. Richards-Spruill, and duly seconded by Mr. Kocot, the Board voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(13) of the Code of Virginia ("Code"), for the purpose of deliberation regarding a possible settlement in the matter of Case No 210816. Additionally, he moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.
RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Motion by Richards-Spruill/Second by Lee).
DECISION:	Upon a motion by Mr. Kocot and duly seconded by Ms. Garvin, the Board unanimously voted (7-0) to instruct staff to revise the proposed settlement terms as agreed upon by the Board.
ADJOURN:	With all business concluded, the meeting adjourned at 12:46 PM.

Dale St.Clair, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

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

Tuesday, August 23, 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 quorum of the Board of Pharmacy ("Board") was called to order at 9:13 AM.

PRESIDING: Kris Ratliff, Chair

MEMBERS PRESENT:
Larry Kocot
Wendy Nash
Cheri Garvin
Patricia Richards-Spruill
Bill Lee
Ling Yuan

STAFF PRESENT:
Ellen B. Shinaberry, Deputy Executive Director
Caroline D. Juran, Executive Director
James Rutkowski, Assistant Attorney General

FORMAL HEARING
SHERONDA DRUMGOLE
Registration No. 0230-029919

A formal hearing was held in the matter of Sheronda Drumgole to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

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

Ms. Drumgole was not present at the formal hearing and was not represented by legal counsel.

CLOSED MEETING: Upon a motion by Mrs. Richards-Spruill, and duly seconded by Dr. Lee, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Sheronda Drumgole. Additionally, she moved that Ellen Shinaberry, Caroline Juran, and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Richards-Spruill/Garvin).

DECISION: Upon a motion by Dr. Nash, and duly seconded by Dr. Yuan, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by the Commonwealth. Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the panel voted 7-0 to revoke Ms. Drumgole's right to renew her pharmacy technician registration.

FORMAL HEARING
AMANDA PELLETIER
Registration No. 0230-033145

A formal hearing was held in the matter of Amanda Pelletier to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Anne Joseph, Adjudication Specialist, presented the case on behalf of the Commonwealth. Anna Badgely, former DHP Sr. Investigator, testified in person on behalf of the Commonwealth.

Ms. Pelletier was not present at the formal hearing and was not represented by legal counsel.

CLOSED MEETING: Upon a motion by Mrs. Richards-Spruill, and duly seconded by Ms. Garvin, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Amanda Pelletier. Additionally, she moved that Ellen Shinaberry, Caroline Juran, and Jim Rutkowski attend the closed meeting.

RECONVENE: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Richards-Spruill/Garvin).

DECISION: Upon a motion by Dr. Nash, and duly seconded by Dr. Yuan, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by the Commonwealth. Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the panel voted 7-0 to revoke Ms. Pelletier's right to renew her pharmacy technician registration.

FORMAL HEARING
TYESHA MALONE
Registration No. 0245-002282

A formal hearing was held in the matter of Tyesha Malone to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia.

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

Investigator, and Richard Waddell, Walgreens Asset Protection Manager, testified in person on behalf of the Commonwealth.

Ms. Malone was not present at the formal hearing and was not represented by legal counsel.

CLOSED MEETING:

Upon a motion by Dr. Lee, and duly seconded by Mrs. Richards-Spruill, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Tyesha Malone. Additionally, he moved that Ellen Shinaberry, Caroline Juran, and Jim Rutkowski attend the closed meeting.

RECONVENE:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Lee/Richards-Spruill).

DECISION:

Upon a motion by Dr. Nash, and duly seconded by Dr. Yuan, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law proposed by the Commonwealth. Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the panel voted 7-0 to revoke Ms. Malones's pharmacy technician trainee registration.

FORMAL HEARING
MICHELLE BIBY
Registration No. 0230-034252

A formal hearing was held in the matter of Michelle Biby to discuss allegations she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Jess Weber, Adjudication Specialist, presented the case on behalf of the Commonwealth. Richard Waddell, Walgreens Asset Protection Manager, testified in person on behalf of the Commonwealth. Amy Caliguiri, Walgreens Pharmacist in charge, testified by telephone on behalf of the Commonwealth.

Ms. Biby was not present at the formal hearing and was not represented by legal counsel.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Dr. Lee, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Michelle Biby. Additionally, she moved that Ellen Shinaberry, Caroline Juran, and Jim Rutkowski attend the closed meeting.

RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Garvin/Lee).
DECISION:	Upon a motion by Dr. Nash, and duly seconded by Dr. Yuan, the panel voted 7-0 to accept the Findings and Facts and Conclusion of Law as proposed by the Commonwealth and amended by the Board. Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the panel voted 7-0 to revoke Ms. Biby's right to renew her pharmacy technician registration.
ADJOURN:	11:41 AM

Kris Ratliff, Chair

Caroline D. Juran, Executive Director

Date

Date

Board of Pharmacy
Current Regulatory Actions
As of August 10, 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 1541 days	Addresses a patient safety concern.
18VAC110-30	NOIRA	Implementation of 2021 Periodic Review	3/30/2022	Governor 135 days	Implementation of changes identified during 2021 periodic review of regulations governing practitioners selling controlled substances
18VAC110-20	Proposed	Implementation of 2021 legislation for pharmacists initiating treatment	5/12/2022	Governor 91 days	Amendments to include additional drugs, devices, and treatment that can be initiated by pharmacists pursuant to 2021 legislation.
18VAC110-20	Final	Use of medication carousels and RFID technology	4/25/2022	Governor 59 days	Incorporation into regulation certain allowances that have been approved by the Board for pilot programs in several hospital systems.
18VAC110-20	NOIRA	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain	6/16/2022	Governor 56 days	Response to a petition for rulemaking.

		requirements onf 18VAC110-20-555			

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 130 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 130 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-21	Final	Implementation of legislation for registration of pharmacy technicians	6/30/2022	Secretary 42 days	Establishes requirements for registration of a pharmacy technician trainee and sets out the requirement for accreditation of training programs in accordance with law.
18VAC110-20	Final	Pharmacists initiating treatment – 2020 legislation	7/18/2022	Secretary 24 days	Implements 2020 legislation for pharmacists initiating treatment

* 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	Additions of drugs to Schedule I	8/15/2022	9/14/2022
18VAC110-60	Exempt final	Changes to access and labeling requirements	4/25/2022	5/25/2022

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: July 5, 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. **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.

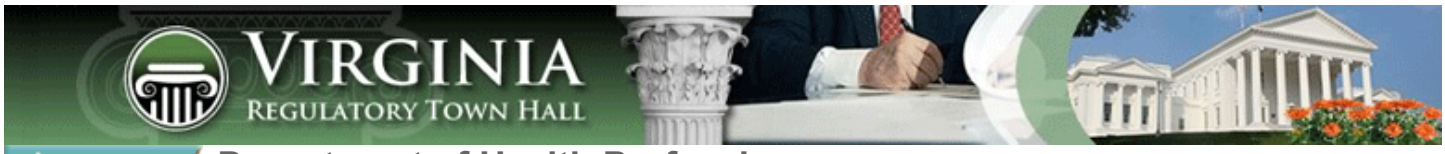
3. **8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific 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.

Robyn Weimer
Chemistry Program Manager



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: 7/11/2022

Expiration Date: 9/6/2022

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 September 6, 2022.** Instructions will be included in the agenda for the board meeting, also on September 6th. Public comment may also be submitted electronically or in writing prior to September 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. **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.

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 07/11/2022 at 3:47pm

Project 7337 - Exempt Final

Board of Pharmacy

September 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.

N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters,

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

2. Compounds expected to have hallucinogenic properties.

1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties.

8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until [May 1,] 2024, unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of final regulations – placement and removal of chemicals in Schedules to conform to federal Scheduling

Included in your agenda package are:

- List of schedule changes to conform to federal scheduling actions from 2021 to July 6, 2022.
- Copy of notice of public hearing.
- Amendments to 18VAC110-20-323.

Staff Note: Public hearing held before the meeting.

Action needed:

- Motion to adopt exempt final changes to 18VAC110-20-323.

Drugs that need to be Scheduled to Conform with Federal Scheduling Actions Taken in 2021 thru 7/6/2022

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:

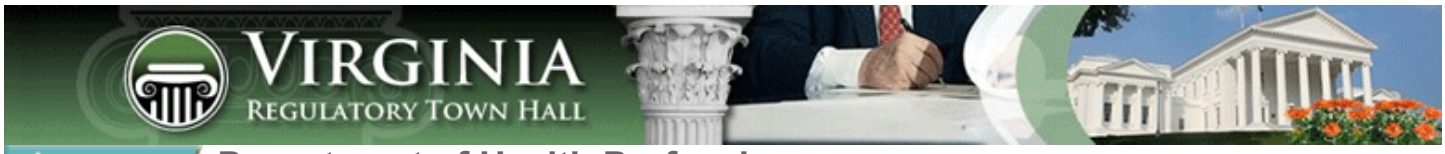
1. Removal of Samidorphan

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



Agency **Department of Health Professions**

Board **Board of Pharmacy**

Edit Notice

General Notice

Drugs to be Scheduled and De-Scheduled to Conform with Federal Scheduling Actions

Date Posted: 8/10/2022

Expiration Date: 9/7/2022

Submitted to Registrar for publication: NO

No comment forum defined for this notice.

Notice of Public Hearing

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

Pursuant to article § 54.1-3443(E), **the following drugs will be placed in Schedule I** to conform with federal scheduling actions taken during 2021 through July 6, 2022:

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)

Pursuant to article § 54.1-3443(E), **the following drugs will be placed in Schedule II** to conform with federal scheduling actions taken during 2021 through July 6, 2022:

1. Oliceridine

Pursuant to article § 54.1-3443(E), **the following drugs will be placed in Schedule IV** to conform with federal scheduling actions taken during 2021 through July 6, 2022:

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

Pursuant to article § 54.1-3443(E), **the following drugs will be placed in Schedule V** to conform with federal scheduling actions taken during 2021 through July 6, 2022:

1. Ganaxolone

Pursuant to article § 54.1-3443(E), **the following drugs will be removed from Schedule II** to conform with federal scheduling actions taken during 2021 through July 6, 2022:

1. Samidorphan

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 08/10/2022 at 1:25pm

Project 7344 - Exempt Final

Board of Pharmacy

September 2022 action conforming schedules to federal scheduling actions 2021 - July 6, 2022

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

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

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

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

3. Deletes naldemedine from Schedule II;

4. Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I;

5. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV;

6. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II;

7. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V;

8. Adds brexanolone (3α-hydroxy-5α-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule IV;

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

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

11. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I; ~~and~~

12. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I.

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

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

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

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

17. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl) to Schedule I;

18. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;

19. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;

20. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;

21. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;

22. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β-methyl fentanyl) to Schedule I;

23. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl) to Schedule I;

24. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetylfentanyl; 2-methyl acetylfentanyl) to Schedule I;

25. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetylfentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;

26. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl) to Schedule I;

27. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;

28. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl) to Schedule I;

29. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;

30. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene) to Schedule I;

31. Adds Oliceridine to Schedule II;

32. Deletes Samidorphan from Schedule II;

33. Adds Remimazolam to Schedule IV;

34. Adds Serdexmethylphenidate to Schedule IV;

35. Adds Lemborexant to Schedule IV;

36. Adds Daridorexant to Schedule IV; and

37. Adds Ganaxolone to Schedule V.

Agenda Item: Adoption of final regulations – removal of chemicals from Schedules

Included in your agenda package are:

- Amendments to 18VAC110-20-322 and 18VAC110-20-323.
- HB193, placing certain chemicals in 54.1-3446.

Action needed:

- Motion to adopt exempt final changes to 18VAC110-20-322 and 18VAC110-20-323, removing Scheduled substances which are now in the Code of Virginia.

Project 7143 - Exempt Final

Board of Pharmacy

Implementation of HB193/SB759 regarding Scheduled drugs

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.

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

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

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

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

3. Deletes naldemedine from Schedule II;

4. ~~Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I;~~

~~5. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV;~~

~~6. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II;~~

~~7. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V;~~

~~8. Adds brexanolone (3α-hydroxy-5α-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule IV;~~

~~9.~~ Deletes naloxegol and 6β-naltrexol from Schedule II; and

~~10.~~5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP)~~;~~.

~~11. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-~~

~~carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I; and~~

~~12. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I.~~

CHAPTER 114

An Act to amend and reenact §§ 54.1-3446, 54.1-3448, 54.1-3452, and 54.1-3454 of the Code of Virginia, relating to Drug Control Act; Schedule I; Schedule II; Schedule IV; Schedule V.

[H 193]

Approved April 6, 2022

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3446, 54.1-3448, 54.1-3452, and 54.1-3454 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3446. Schedule I.

The controlled substances listed in this section are included in Schedule I:

1. Any of the following opiates, including their 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:

1-{1-[1-(4-bromophenyl)ethyl]-4-piperidinyl}-1,3-dihydro-2H-benzimidazol-2-one (other name: Brorphine);

1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237);

1-(2-phenylethyl)-4-phenyl-4-acetyloxypiperidine (other name: PEPAP);

1-methyl-4-phenyl-4-propionoxypiperidine (other name: MPPP);

2-[(4-methoxyphenyl)methyl]-N,N-diethyl-5-nitro-1H-benzimidazole-1-ethanamine (other name: Metonitazene);

2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl);

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

3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921);

Acetyl fentanyl (other name: desmethyl fentanyl);

Acetylmethadol;

Allylprodine;

Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM);

Alphameprodine;

Alphamethadol;

Benzethidine;

Betacetylmethadol;

Betameprodine;

Betamethadol;

Betaprodine;

Clonitazene;

Dextromoramide;

Diampromide;

Diethylthiambutene;

Difenoxin;

Dimenoxadol;

Dimepheptanol;

Dimethylthiambutene;

Dioxaphetylbutyrate;

Dipipanone;

Ethylmethylthiambutene;

Etonitazene;

Etoxeridine;

Furethidine;

Hydroxypethidine;

Ketobemidone;

Levomoramide;

Levophenacylmorphan;

Morpheridine;

MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine);

N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl);

N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (other name: Tetrahydrofuranyl

fentanyl);

N-[1-[1-methyl-2-(2-thienyl)ethyl]-4-piperidyl]-N-phenylpropanamide (other name: alpha-methylthiofentanyl);

N-[1-(1-methyl-2-phenylethyl)-4-piperidyl]-N-phenylacetamide (other name: acetyl-alpha-methylfentanyl);

N-{1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl}-N-phenylpropanamide (other name: beta-hydroxythiofentanyl);

N-[1-(2-hydroxy-2-phenyl)ethyl-4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxyfentanyl);

N-[1-(alpha-methyl-beta-phenyl)ethyl-4-piperidyl]propionanilide (other names: 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine, alpha-methylfentanyl);

N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl);

N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl);

N-[3-methyl-1-(2-hydroxy-2-phenylethyl)4-piperidyl]-N-phenylpropanamide (other name: beta-hydroxy-3-methylfentanyl);

N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide (other name: 3-methylfentanyl);

N-[3-methyl-1-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);

N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl);

N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl);

N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl);

N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluorofentanyl);

N,N-diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine (other name: Isotonitazene);

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

N,N-diethyl-2-[(4-methoxyphenyl)methyl]-1H-benzimidazole-1-ethanamine (other name: Metodesnitazene);

N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl);

N-phenyl-N-(4-piperidinyl)-propanamide (other name: Norfentanyl);

Noracymethadol;

Norlevorphanol;

Normethadone;

Norpipanone;

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl);

N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide (other name: thiofentanyl);

Phenadoxone;

Phenampromide;

Phenomorphan;

Phenoperidine;

Piritramide;

Proheptazine;

Properidine;

Propiram;

Racemoramide;

Tilidine;

Trimeperidine;

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl);

3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900);

2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-48800);

2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methyl acetamide (other name: U-51754);

N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Ocfentanil);

N-(4-methoxyphenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: 4-methoxybutyrylfentanyl);

N-phenyl-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: Isobutyryl fentanyl);

N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-cyclopentanecarboxamide (other name: Cyclopentyl fentanyl);
N-phenyl-N-(1-methyl-4-piperidinyl)-propanamide (other name: N-methyl norfentanyl);
N-[2-(dimethylamino)cyclohexyl]-N-methyl-1,3-benzodioxole-5-carboxamide (other names: 3,4-methylenedioxy U-47700 or 3,4-MDO-U-47700);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl fentanyl);
N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl);
N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl fentanyl);
N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17);
N-[2-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17);
3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700).

2. Any of the following opium derivatives, their salts, isomers and salts of isomers, unless specifically excepted, whenever the existence of these salts, isomers and salts of isomers is possible within the specific chemical designation:
Acetorphine;
Acetyldihydrocodeine;
Benzylmorphine;
Codeine methylbromide;
Codeine-N-Oxide;
Cyprenorphine;
Desomorphine;
Dihydromorphine;
Drotebanol;
Etorphine;
Heroin;
Hydromorphinol;
Methyldesorphine;
Methyldihydromorphine;
Morphine methylbromide;
Morphine methylsulfonate;
Morphine-N-Oxide;
Myrophine;
Nicocodeine;
Nicomorphine;
Normorphine;
Pholcodine;
Thebacon.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of 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 (for purposes of this subdivision only, the term "isomer" includes the optical, position, and geometric isomers):
Alpha-ethyltryptamine (some trade or other names: Monase; a-ethyl-1H-indole-3-ethanamine; 3-2-aminobutyl] indole; a-ET; AET);
4-Bromo-2,5-dimethoxyphenethylamine (some trade or other names: 2-4-bromo-2,5-dimethoxyphenyl]-1-aminoethane;alpha-desmethyl DOB; 2C-B; Nexus);
3,4-methylenedioxy amphetamine;
5-methoxy-3,4-methylenedioxy amphetamine;
3,4,5-trimethoxy amphetamine;
Alpha-methyltryptamine (other name: AMT);
Bufotenine;
Diethyltryptamine;
Dimethyltryptamine;
4-methyl-2,5-dimethoxyamphetamine;
2,5-dimethoxy-4-ethylamphetamine (DOET);
4-fluoro-N-ethylamphetamine;
2,5-dimethoxy-4-(n)-propylthiophenethylamine (other name: 2C-T-7);
Ibogaine;
5-methoxy-N,N-diisopropyltryptamine (other name: 5-MeO-DIPT);
Lysergic acid diethylamide;
Mescaline;
Parahexyl (some trade or other names:

3-Hexyl-1-hydroxy-7,8,9,10-tetrahydro-6,6,9-trimethyl-6H-dibenzo [b,d] pyran; Synhexyl);

Peyote;

N-ethyl-3-piperidyl benzilate;

N-methyl-3-piperidyl benzilate;

Psilocybin;

Psilocyn;

Salvinorin A;

Tetrahydrocannabinols, except as present in (i) industrial hemp, as defined in § 3.2-4112, that is possessed by a person registered pursuant to subsection A of § 3.2-4115 or his agent; (ii) a hemp product, as defined in § 3.2-4112, containing a tetrahydrocannabinol concentration of no greater than 0.3 percent that is derived from industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law; (iii) marijuana; (iv) dronabinol in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the U.S. Food and Drug Administration; or (v) industrial hemp, as defined in § 3.2-4112, that is possessed by a person who holds a hemp producer license issued by the U.S. Department of Agriculture pursuant to 7 C.F.R. Part 990;

2,5-dimethoxyamphetamine (some trade or other names: 2,5-dimethoxy-a-methylphenethylamine; 2,5-DMA);

3,4-methylenedioxymethamphetamine (MDMA), its optical, positional and geometric isomers, salts and salts of isomers;

3,4-methylenedioxy-N-ethylamphetamine (also known as N-ethyl-alpha-methyl-3,4 (methylenedioxy)phenethylamine, N-ethyl MDA, MDE, MDEA);

N-hydroxy-3,4-methylenedioxyamphetamine (some other names: N-hydroxy-alpha-methyl-3,4(methylenedioxy)phenethylamine, and N-hydroxy MDA);

4-bromo-2,5-dimethoxyamphetamine (some trade or other names: 4-bromo-2,5-dimethoxy-a-methylphenethylamine; 4-bromo-2,5-DMA);

4-methoxyamphetamine (some trade or other names: 4-methoxy-a-methylphenethylamine; paramethoxyamphetamine; PMA);

Ethylamine analog of phencyclidine (some other names: N-ethyl-1-phenylcyclohexylamine, (1-phenylcyclohexyl) ethylamine, N-(1-phenylcyclohexyl) ethylamine, cyclohexamine, PCE);

Pyrrolidine analog of phencyclidine (some other names: 1-(1-phenylcyclohexyl)-pyrrolidine, PCPy, PHP);

Thiophene analog of phencyclidine (some other names: 1-[1-(2-thienyl)-cyclohexyl]-piperidine, 2-thienyl analog of phencyclidine, TPCP, TCP);

1-1-(2-thienyl)cyclohexyl]pyrrolidine (other name: TCPy);

3,4-methylenedioxypyrovalerone (other name: MDPV);

4-methylmethcathinone (other names: mephedrone, 4-MMC);

3,4-methylenedioxymethcathinone (other name: methylone);

Naphthylpyrovalerone (other name: naphyrone);

4-fluoromethcathinone (other names: flephedrone, 4-FMC);

4-methoxymethcathinone (other names: methedrone; bk-PMMA);

Ethcathinone (other name: N-ethylcathinone);

3,4-methylenedioxyethcathinone (other name: ethylone);

Beta-keto-N-methyl-3,4-benzodioxolylbutanamine (other name: butylone);

N,N-dimethylcathinone (other name: metamfepramone);

Alpha-pyrrolidinopropiophenone (other name: alpha-PPP);

4-methoxy-alpha-pyrrolidinopropiophenone (other name: MOPPP);

3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (other name: MDPPP);

Alpha-pyrrolidinovalerophenone (other name: alpha-PVP);

6,7-dihydro-5H-indeno-(5,6-d)-1,3-dioxol-6-amine (other name: MDAI);

3-fluoromethcathinone (other name: 3-FMC);

4-Ethyl-2,5-dimethoxyphenethylamine (other name: 2C-E);

4-Iodo-2,5-dimethoxyphenethylamine (other name: 2C-I);

4-Methylethcathinone (other name: 4-MEC);

4-Ethylmethcathinone (other name: 4-EMC);

N,N-diallyl-5-methoxytryptamine (other name: 5-MeO-DALT);

Beta-keto-methylbenzodioxolylpentanamine (other names: Pentylone, bk-MBDP);

Alpha-methylamino-butyrophenone (other name: Buphedrone);

Alpha-methylamino-valerophenone (other name: Pentedrone);

3,4-Dimethylmethcathinone (other name: 3-,4-DMMC);

4-methyl-alpha-pyrrolidinopropiophenone (other name: MPPP);

4-Iodo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 25-I, 25I-NBOMe, 2C-I-NBOMe);

Methoxetamine (other names: MXE, 3-MeO-2-Oxo-PCE);

4-Fluoromethamphetamine (other name: 4-FMA);

4-Fluoroamphetamine (other name: 4-FA);
2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (other name: 2C-D);
2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (other name: 2C-C);
2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-2);
2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (other name: 2C-T-4);
2-(2,5-Dimethoxyphenyl)ethanamine (other name: 2C-H);
2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (other name: 2C-N);
2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (other name: 2C-P);
(2-aminopropyl)benzofuran (other name: APB);
(2-aminopropyl)-2,3-dihydrobenzofuran (other name: APDB);
4-chloro-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-C-NBOMe, 25C-NBOMe, 25C);
4-bromo-2,5-dimethoxy-N-[(2-methoxyphenyl)methyl]-benzeneethanamine (other names: 2C-B-NBOMe, 25B-NBOMe, 25B);
Acetoxydimethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);
Benocyclidine (other names: BCP, BTCP);
Alpha-pyrrolidinobutiophenone (other name: alpha-PBP);
3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA);
4-bromomethcathinone (other name: 4-BMC);
4-chloromethcathinone (other name: 4-CMC);
4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25I-NBOH);
Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP);
Alpha-Pyrrolidinoheptiophenone (other name: PV8);
5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT);
Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB);
Beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B);
1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone);
1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP);
1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP);
4-Chloroethcathinone (other name: 4-CEC);
3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone);
1-propionyl lysergic acid diethylamide (other name: 1P-LSD);
(2-Methylaminopropyl)benzofuran (other name: MAPB);
1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);
1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);
3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: TH-PVP);
4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);
4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25B-NBOH);
4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone);
4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);
4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);
4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT);
4-methyl-alpha-ethylaminopentiophenone;
4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);
5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT);
5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT);
6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD);
6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD);
(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB);
2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine);
2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine);
2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP);
Alpha-ethylaminohexanophenone (other name: N-ethylhexedrone);
N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE);
4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP);
N-ethyl-1,2-diphenylethylamine (other name: Ephenidine);
2,5-dimethoxy-4-chloroamphetamine (other name: DOC);
3,4-methylenedioxy-N-tert-butylcathinone;
Alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP);
1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP);
4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT);
4-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT);
3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP);

5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT);
1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other names: Eutylone, bk-EBDB);
1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone);
N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA);
1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone);
1-cyclopropionyl lysergic acid diethylamide (other name: 1cP-LSD);
2-(ethylamino)-1-phenylheptan-1-one (other name: N-ethylheptedrone);
(2-ethylaminopropyl)benzofuran (other name: EAPB);
4-ethyl-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (other name: 25E-NBOH);
2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone);
4-hydroxy-N-ethyl-N-propyltryptamine (other name: 4-hydroxy-EPT);
2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, alpha-isobutylaminohexanphenone);
1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: para-Methoxymethamphetamine, PMMA);
N-ethyl-1-(3-hydroxyphenyl)cyclohexylamine (other name: 3-hydroxy-PCE);
N-heptyl-3,4-dimethoxyamphetamine (other ~~names:~~ *name:* N-heptyl-3,4-DMA);
N-hexyl-3,4-dimethoxyamphetamine (other ~~names:~~ *name:* N-hexyl-3,4-DMA)*;*
4-fluoro-3-methyl-alpha-pyrrolidinovalerophenone (other name: 4-fluoro-3-methyl-alpha-PVP);
4-fluoro-alpha-methylamino-valerophenone (other name: 4-fluoropentedrone);
N-(1,4-dimethylpentyl)-3,4-dimethoxyamphetamine (other name: N-(1,4-dimethylpentyl)-3,4-DMA);
4,5-methylenedioxy-N,N-diisopropyltryptamine (other name: 4,5-MDO-DiPT);
Alpha-pyrrolidinocyclohexanophenone (other name: alpha-PCYP);
3,4-methylenedioxy-alpha-pyrrolidinoheptiophenone (other name: MDPV8);
4-chloro-alpha-methylaminobutiophenone (other name: 4-chloro Buphedrone).

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including 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-(2-chlorophenyl)-1,3-dihydro-3-methyl-7-nitro-2H-1,4-benzodiazepin-2-one (other name: Meclonazepam);
7-chloro-5-(2-fluorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one (other name: Norfludiazepam);
Bromazolam;
Clonazolam;
Deschloroetizolam;
Etizolam;
Flualprazolam;
Flubromazepam;
Flubromazolam;
Gamma hydroxybutyric acid (some other names include GHB; gamma hydroxybutyrate; 4-hydroxybutyrate; 4-hydroxybutanoic acid; sodium oxybate; sodium oxybutyrate);
Mecloqualone;
Methaqualone.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers and salts of isomers:

2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine);
Aminorex (some trade or other names; aminoxaphen; 2-amino-5-phenyl-2-oxazoline; 4,5-dihydro-5-phenyl-2-oxazolamine);
Cathinone (some trade or other names: 2-amino-1-phenyl-1-propanone, alpha-aminopropiophenone, 2-aminopropiophenone, norephedrone), and any plant material from which Cathinone may be derived;
Cis-4-methylaminorex (other name: cis-4,5-dihydro-4-methyl-5-phenyl-2-oxazolamine);
Ethylamphetamine;
Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate);
Fenethylline;
Methcathinone (some other names: 2-(methylamino)-propiophenone; alpha-(methylamino)-propiophenone; 2-(methylamino)-1-phenylpropan-1-one; alpha-N-methylaminopropiophenone; monomethylpropion; ephedrone; N-methylcathinone; methylcathinone; AL-464; AL-422; AL-463 and UR 1432);
N-Benzylpiperazine (some other names: BZP, 1-benzylpiperazine);
N,N-dimethylamphetamine (other names: ~~N, N-alpha-trimethyl-benzeneethanamine, N, N-alpha-trimethylphenethylamine)~~ *N,N-alpha-trimethyl-benzeneethanamine, N,N-alpha-trimethylphenethylamine)*;
Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 4-fluoromethylphenidate);

Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate);

4-chloro-N,N-dimethylcathinone;

3,4-methylenedioxy-N-benzylcathinone (other name: BMDP).

6. Any substance that contains one or more cannabimimetic agents or that contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, and any preparation, mixture, or substance containing, or mixed or infused with, any detectable amount of one or more cannabimimetic agents.

a. "Cannabimimetic agents" includes any substance that is within any of the following structural classes:

2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent;

3-(1-naphthoyl)indole or 1H-indol-3-yl-(1-naphthyl)methane with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent;

3-(1-naphthoyl)pyrrole with substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the pyrrole ring to any extent, whether or not substituted on the naphthoyl ring to any extent;

1-(1-naphthylmethyl)indene with substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent;

3-phenylacetylindole or 3-benzoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent;

3-cyclopropoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the cyclopropyl ring to any extent;

3-adamantoylindole with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent;

N-(adamantyl)-indole-3-carboxamide with substitution at the nitrogen atom of the indole ring, whether or not further substituted on the indole ring to any extent, whether or not substituted on the adamantyl ring to any extent; and

N-(adamantyl)-indazole-3-carboxamide with substitution at a nitrogen atom of the indazole ring, whether or not further substituted on the indazole ring to any extent, whether or not substituted on the adamantyl ring to any extent.

b. The term "cannabimimetic agents" includes:

5-(1,1-Dimethylheptyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497);

5-(1,1-Dimethylhexyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C6 homolog);

5-(1,1-Dimethyloctyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C8 homolog);

5-(1,1-Dimethylnonyl)-2-[3-hydroxycyclohexyl]-phenol (other name: CP 47,497 C9 homolog);

1-pentyl-3-(1-naphthoyl)indole (other names: JWH-018, AM-678);

1-butyl-3-(1-naphthoyl)indole (other name: JWH-073);

1-pentyl-3-(2-methoxyphenylacetyl)indole (other name: JWH-250);

1-hexyl-3-(naphthalen-1-oyl)indole (other name: JWH-019);

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (other name: JWH-200);

(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol (other name: HU-210);

1-pentyl-3-(4-methoxy-1-naphthoyl)indole (other name: JWH-081);

1-pentyl-3-(4-methyl-1-naphthoyl)indole (other name: JWH-122);

1-pentyl-3-(2-chlorophenylacetyl)indole (other name: JWH-203);

1-pentyl-3-(4-ethyl-1-naphthoyl)indole (other name: JWH-210);

1-pentyl-3-(4-chloro-1-naphthoyl)indole (other name: JWH-398);

1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (other name: AM-694);

1-((N-methylpiperidin-2-yl)methyl)-3-(1-naphthoyl)indole (other name: AM-1220);

1-(5-fluoropentyl)-3-(1-naphthoyl)indole (other name: AM-2201);

1-[(N-methylpiperidin-2-yl)methyl]-3-(2-iodobenzoyl)indole (other name: AM-2233);

Pravadoline ~~(4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-y l]methanone (other name: WIN 48,098)~~ *(4-methoxyphenyl)-[2-methyl-1-(2-(4-morpholinyl)ethyl)indol-3-yl]methanone (other name: WIN 48,098);*

1-pentyl-3-(4-methoxybenzoyl)indole (other names: RCS-4, SR-19);

1-(2-cyclohexylethyl)-3-(2-methoxyphenylacetyl)indole (other names: RCS-8, SR-18);

1-pentyl-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: UR-144);

1-(5-fluoropentyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other names: XLR-11, 5-fluoro-UR-144);

N-adamantyl-1-fluoropentylindole-3-carboxamide (other name: STS-135);
N-adamantyl-1-pentylindazole-3-carboxamide (other names: AKB48, APINACA);
1-pentyl-3-(1-adamantoyl)indole (other name: AB-001);
(8-quinolinyl)(1-pentylindol-3-yl)carboxylate (other name: PB-22);
(8-quinolinyl)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);
(8-quinolinyl)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: AB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)indazole-3-carboxamide (other name: AB-FUBINACA);
1-(5-fluoropentyl)-3-(1-naphthoyl)indazole (other name: THJ-2201);
N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentylindazole-3-carboxamide (other name: ADB-PINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AB-PINACA);
~~N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxam ide~~ *N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide* (other names: ADB-CHMINACA, MAB-CHMINACA);
Methyl-2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);
1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);
1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);
1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl)indole (other name MAM-2201);
~~N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole- 3-carboxamide~~ *N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide* (other name: ADB-FUBINACA);
Methyl ~~2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-di methylbutanoate (other name: MDMB-FUBINACA)~~ *2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA)*;
Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA);
Methyl ~~2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoat e (other names: AMB-FUBINACA, FUB-AMB)~~ *2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB)*;
N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other ~~name:~~ *names:* FUB-AKB48, *5F-APINACA*);
N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);
N-(adamantanyl)-1-(5-chloropentyl) indazole-3-carboxamide (other name: 5-chloro-AKB48);
Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005);
N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA);
1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006);
Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22);
Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (other name: MMB-CHMICA);
~~N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamid e~~ *N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide* (other name: 5-fluoro-ADB-PINACA);
1-(4-cyanobutyl)-N-(1-methyl-1-phenylethyl)-1H-indazole-3-carboxamide (other name: 4-cyano CUMYL-BUTINACA);
Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other ~~name: 5-Fluoro-MDMB-PICA)~~ *names: 5-fluoro MDMB-PICA, 5F-MDMB-PICA)*;
~~Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoat e~~ *Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate* (other name: EMB-FUBINACA);
Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA);
1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA);
Methyl 2-[1-(pent-4-enyl)-1H-indazole-3-carboxamindo]-3,3-dimethylbutanoate (other name: MDMB-4en-PINACA);
Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indole-3-carbonyl}amino)-3-methylbutanoate (other names:

MMB-FUBICA, AMB-FUBICA);

Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA);

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201);

Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butylindazole-3-carboxamide (other name: ADB-BUTINACA);

N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-chloropentyl)indazole-3-carboxamide (other name: 5-chloro-AB-PINACA)*;*

1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other names: 5F-CUMYL-PINACA, 5-fluoro CUMYL-PINACA, CUMYL-5F-PINACA);

Ethyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5F-EDMB-PINACA, 5-fluoro EDMB-PINACA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3-methylbutanoate (other names: 5-fluoro-EMB-PINACA, 5F-AEB);

Ethyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: 5-fluoro-EMB-PICA);

Ethyl-2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-fluoro EDMB-PICA);

Methyl 2-[1-(4-fluorobutyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTICA);

Methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other names: MDMB-CHMICA, MMB-CHMINACA);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(pent-4-enyl)indazole-3-carboxamide (other name: ADB-4en-PINACA).

§ 54.1-3448. Schedule II.

The controlled substances listed in this section are included in Schedule II:

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, naldemedine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;
Opium extracts;
Opium fluid extracts;
Powdered opium;
Granulated opium;
Tincture of opium;
Codeine;
Dihydroetorphine;
Ethylmorphine;
Etorphine hydrochloride;
Hydrocodone;
Hydromorphone;
Metopon;
Oripavine (3-O-demethylthebaine or 6,7,8,14-tetradehydro-4,
5-alpha-epoxy-6-methoxy-17-methylmorphinan-3-ol);
Morphine;
Noroxymorphone;
Oxycodone;
Oxymorphone;
Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine; cocaine or any salt or isomer thereof.

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;
Alphaprodine;
Anileridine;
Bezitramide;
Bulk dextropropoxyphene (nondosage forms);
Carfentanil;
Dihydrocodeine;
Diphenoxylate;
Fentanyl;
Isomethadone;
Levo-alphacetylmethadol (levo-alpha-acetylmethadol)(levomethadyl acetate)(LAAM);
Levomethorphan;
Levorphanol;
Metazocine;
Methadone;
Methadone — Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;
Moramide — Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylicacid;
Pethidine (other name: meperidine);
Pethidine — Intermediate — A, 4-cyano-1-methyl-4-phenylpiperidine;
Pethidine — Intermediate — B, ethyl-4-phenylpiperidine-4-carboxylate;
Pethidine — Intermediate — C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;
Phenazocine;
Piminodine;
Racemethorphan;
Racemorphan;
Remifentanil;
Sufentanil;
Tapentadol;
Thiafentanil.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

Amphetamine, its salts, optical isomers, and salts of its optical isomers;
Phenmetrazine and its salts;
Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;
Methylphenidate;
Lisdexamfetamine, its salts, isomers, and salts of its isomers.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including 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:

Amobarbital;
Glutethimide;
Secobarbital;
Pentobarbital;
Phencyclidine.

5. The following hallucinogenic substances:

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

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are:

a. Immediate precursors to amphetamine and methamphetamine:
Phenylacetone.
b. Immediate precursor to phencyclidine:
1-phenylcyclohexylamine;
1-piperidinocyclohexanecarbonitrile (other name: PCC).
c. Immediate precursor to fentanyl:
4-anilino-N-phenethyl-4-piperidine (ANPP).

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically

excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alfaxalone (5[alpha]-pregnan-3[alpha]-ol-11, 20-dione), previously spelled "alphaxalone," including its salts, isomers, and salts of isomers;

Alprazolam;

Barbital;

Brexanolone;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Suvorexant ([(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2- (2H-1, 2, 3-triazol-2-yl) phenyl]methanone), including its salts, isomers, and salts of isomers;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine;

Lorcaserin.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproprex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

Solriamfetol (2-amino-3-phenylpropyl carbamate);

SPA (-)-1-dimethylamino-1,2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1,2-diphenyl-3-methyl-2-propionoxybutane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit;

2-[(dimethylamino) methyl]-1-(3-methoxyphenyl) cyclohexanol, its salts, optical and geometric isomers, and salts of such isomers, including tramadol.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Eluxadoline (including its optical isomers and its salts, isomers, and salts of isomers);

Pentazocine.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

§ 54.1-3454. Schedule V.

The controlled substances listed in this section are included in Schedule V:

1. Any compound, mixture, or preparation containing limited quantities of any of the following narcotic drugs, which also contains one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture, or preparation, valuable medicinal qualities other than those possessed by the narcotic drug alone:

Not more than 200 milligrams of codeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of dihydrocodeine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 100 milligrams of ethylmorphine, or any of its salts, per 100 milliliters or per 100 grams;

Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit;

Not more than 100 milligrams of opium per 100 milliliters or per 100 grams;

Not more than 0.5 milligrams of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter and such substances so excepted may be dispensed pursuant to § 54.1-3416.

2. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers:

Pyrovalerone.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the

central nervous system, including its salts:

Brivaracetam ((2S)-2-[(4R)-2-oxo-4-propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact);

Ezogabine [N-[2-amino-4-(4-fluorobenzylamino)-phenyl]-carbamic acid ethyl ester]-2779;

Gabapentin [1-(aminomethyl)cyclohexaneacetic acid];

Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide];

Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide];

Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

2. That the provisions of this act may result in a net increase in periods of imprisonment or commitment. Pursuant to § 30-19.1:4 of the Code of Virginia, the estimated amount of the necessary appropriation is $0 for periods of imprisonment in state adult correctional facilities and $0 for periods of commitment to the custody of the Department of Juvenile Justice.

Agenda Item: Adoption of emergency regulations/NOIRA regarding pharmacists initiating treatment from 2022 legislation

Included in your agenda package are:

- HB1323
- Draft emergency regulations regarding pharmacists initiating treatment pursuant to 2022 legislation

Action needed:

- Motion to promulgate emergency regulations as presented OR amended; and
- Motion to issue a notice of intended regulatory action pursuant to HB1323.

CHAPTER 791

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

[H 1323]

Approved May 27, 2022

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-325. Board to submit plan for medical assistance services to U.S. Secretary of Health and Human Services pursuant to federal law; administration of plan; contracts with health care providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto. The Board shall include in such plan:

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed $5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;

5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such family planning services shall begin with delivery and continue for a period of 24 months, if the woman continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions;

8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant for medical assistance with information about advance directives pursuant to Article 8 (§ 54.1-2981 et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a breast for any medical reason. Breast reductions shall be covered, if prior authorization has been obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any supporting verifiable documentation shall be signed, dated, and returned by the physician, physician assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 days from the time the ordered durable medical equipment and supplies are first furnished by the durable medical equipment provider;

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen;

16. A provision for payment of medical assistance for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast;

17. A provision, when in compliance with federal law and regulation and approved by the Centers for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program and may be provided by school divisions, regardless of whether the student receiving care has an individualized education program or whether the health care service is included in a student's individualized education program. Such services shall include those covered under the state plan for medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § 38.2-3418.16. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and

restore a range of physical and social functioning in the activities of daily living;

19. A provision for payment of medical assistance for colorectal cancer screening, specifically screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in accordance with the most recently published recommendations established by the American College of Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and frequencies referenced in such recommendations;

20. A provision for payment of medical assistance for custom ocular prostheses;

21. A provision for payment for medical assistance for infant hearing screenings and all necessary audiological examinations provided pursuant to § 32.1-64.1 using any technology approved by the United States Food and Drug Administration, and as recommended by the national Joint Committee on Infant Hearing in its most current position statement addressing early hearing detection and intervention programs. Such provision shall include payment for medical assistance for follow-up audiological examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss;

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. 106-354), for certain women with breast or cervical cancer when such women (i) have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise eligible for medical assistance services under any mandatory categorically needy eligibility group; and (v) have not attained age 65. This provision shall include an expedited eligibility determination for such women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and services delivery, of medical assistance services provided to medically indigent children pursuant to this chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the FAMIS Plan program in § 32.1-351. A single application form shall be used to determine eligibility for both programs;

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

25. A provision for the payment of medical assistance for otherwise eligible pregnant women during the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. 111-3);

26. A provision for the payment of medical assistance for medically necessary health care services provided through telemedicine services, as defined in § 38.2-3418.16, regardless of the originating site or whether the patient is accompanied by a health care provider at the time such services are provided. No health care provider who provides health care services through telemedicine services shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is located, including any medical care facility or office of a health care provider, the home of the patient, the patient's place of employment, or any public or private primary or secondary school or postsecondary institution of higher education at which the person to whom telemedicine services are provided is located;

27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not impose any utilization controls or other forms of medical management limiting the supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time or (ii) exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § 38.2-3418.16, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic health condition who have had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" means the use of digital technologies to collect medical and other forms of health data from patients in one location and electronically transmit that information securely to health care providers in a different location for analysis, interpretation, and recommendations, and management of the patient. "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence monitoring, and interactive videoconferencing with or without digital image upload.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § 2.2-4007.05, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § 38.2-3407.4:2 be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § 38.2-3407.4:2, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ 2.2-4006 et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § 2.2-4002, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when

such corporation has been convicted of or otherwise pled guilty to any violation of § 32.1-314, 32.1-315, 32.1-316, or 32.1-317, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § 32.1-162.13.

For the purposes of this subsection, "provider" may refer to an individual or an entity.

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ 2.2-4000 et seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection D, the Director may determine the period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

F. When the services provided for by such plan are services which a marriage and family therapist, clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for covered services as provided in the state plan. The Board shall promulgate regulations which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers, licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria, including the professional credentials required for licensure.

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

1. Include in its provider networks and all of its health maintenance organization contracts a provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for medically necessary assessment and treatment services, when such services are delivered by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable expertise, as determined by the Director.

2. Amend the Medallion II waiver and its implementing regulations to develop and implement an exception, with procedural requirements, to mandatory enrollment for certain children between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors and enrolled providers for the provision of health care services under Medicaid and the Family Access to Medical Insurance Security Plan established under § 32.1-351.

4. Require any managed care organization with which the Department enters into an agreement for the provision of medical assistance services to include in any contract between the managed care organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of the pharmacy benefits manager from conducting spread pricing with regards to the managed care organization's managed care plans. For the purposes of this subdivision:

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a managed care plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible recipients with special needs. The Board shall promulgate regulations regarding these special needs patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board.

J. Except as provided in subdivision A 1 of § 2.2-4345, the provisions of the Virginia Public Procurement Act (§ 2.2-4300 et seq.) shall not apply to the activities of the Director authorized by subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law

and regulation.

K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § 54.1-3303.1, the Department shall provide reimbursement for such service.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older *with whom the pharmacist has a bona fide pharmacist-patient relationship and* in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ *and vaccines for COVID-19*;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention*;*

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; and

11. Tests for COVID-19 and other coronaviruses.

B. *Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:*

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.).* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

~~C.~~ *D.* A pharmacist who administers a vaccination pursuant to ~~subdivision~~ *subdivisions* A 7 *and B 1* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*

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

B. To be registered as a pharmacy technician, a person shall submit:

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A

when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health, shall establish a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2022, and the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq., as amended.

3. That the provisions of subdivisions B 1 and 2 of § 54.1-3303.1 of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

Project 7339 - Emergency/NOIRA

Board of Pharmacy

2022 Pharmacists Initiating Treatment

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

18VAC110-21-46. Initiation of treatment by a pharmacist.

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older with whom the pharmacist has a bona fide pharmacist-patient relationship:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs and devices as defined in § 54.1-3401 of the Code of Virginia, controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia, and other supplies and equipment available over the counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Tuberculin purified protein derivative for tuberculosis testing;

8. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and

10. Nicotine replacement and other tobacco-cessation therapies, including controlled substances as defined in the Drug Control Act, § 54.1-3400 *et seq.*, together with appropriate patient counseling.

B. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older:

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

C. Pharmacists who initiate treatment with, dispense, or administer a drug, device, controlled paraphernalia, or other supplies or equipment pursuant to subsections A and B of this section shall:

1. Follow the statewide protocol adopted by the board for each drug, device, controlled paraphernalia, or other supplies or equipment.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d *et seq.* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

5. Obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

6. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

D. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

Board Item: Amend Current Statewide Protocols

Staff Note:

1) Line 365 of HB 1323 strikes "upon request". Current statewide protocols need to be amended to strike this phrase to conform to law.
2) Suggested edits were offered to a future vaccine protocol for patients 3 years old and above during the recently held Statewide Protocol Workgroup meeting hosted by the Board of Medicine. Ms. Juran informed the workgroup that she would offer similar suggested edits to the existing vaccine protocol for patients 18 years old and above.

Action needed:

1) Adopt the amended statewide protocols as presented (can take as a block).

Adopted: 9/9/2020
Revised: 9/6/2022
Effective Date: ~~1/3/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Emergency Contraception Statewide Protocol

A pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Self-administered hormonal emergency contraception (EC) provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING
Prior to issuing a prescription to initiate treatment with, or dispensing of a self-administered hormonal EC under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use or standard protocol and shall have completed at least one hour of continuing education specific to the prescribing of EC.

PATIENT INCLUSION CRITERIA
Patients eligible for self-administered hormonal EC under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Emergency Contraception Self-Screening Questionnaire** indicating the last day of unprotected intercourse was within the previous 5 days (120 hours) and who the pharmacist has determined is eligible for a hormonal emergency contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *US Medical Eligibility Criteria for Contraceptive Use, Classifications for Emergency Contraception.*

*****Note: A pharmacy may create and use an electronic emergency contraception self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Emergency Contraception Self-Screening Questionnaire.

PROCESS FOR HANDLING INELIGIBLE PATIENTS
Patients identified by the pharmacist to NOT be eligible for EC shall be referred to a healthcare practitioner and may not receive EC under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

DRUG INCLUSION CRITERIA
The following drug formulations are included in this EC statewide protocol:

Dedicated Approved EC – One Tablet Regimens

Plan B One-Step	1 tablet	1.5mg levonorgestrel	OTC
Levonorgestrel	1 tablet	1.5mg levonorgestrel	OTC
Next Choice One Dose	1 tablet	1.5mg levonorgestrel	OTC
Ella	1 tablet	30mg ulipristal	Rx only

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed.

Oral Contraceptive Pills

Brand	Tablets per dose (2 doses 12 hours apart*)	Ethinyl Estradiol per dose (mcg)	Levonorgestrel per dose (mg)*	Status
Alesse	5 pink tablets	100	0.50	Rx only
Aviane	5 orange tablets	100	0.5	Rx only
Levlen	4 light-orange tablets	120	0.6	Rx only
Levlite	5 pink tablets	100	0.5	Rx only
Levora	4 white tablets	120	0.60	Rx only
Lo/Ovral	4 white tablets	120	0.60	Rx only
Low-Ogestrel	4 white tablets	120	0.60	Rx only
Nordette	4 light-orange tablets	120	0.60	Rx only
Ogestrel	2 white tablets	100	0.50	Rx only
Ovral	2 white tablets	100	0.50	Rx only
Tri-Levlen	4 yellow tablets	100	0.50	Rx only
Triphasil	4 yellow tablets	120	0.50	Rx only
Trivora	4 pink tablets	120	0.50	Rx only
Ovrette	20 yellow tablets	0	0.75	Rx only

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrol, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in the above chart, generic equivalent products may be prescribed and dispensed. Estrogen containing regimens are not preferred and should be used only when other options are not available.

Anti-nausea Treatment Options for use with EC

Drug	Dose	Timing of Administration	Status
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25mg tablets	1 hour before first EC dose; repeat if needed in 24 hours	OTC
Diphenhydramine hydrochloride (Benadryl)	One or two 25mg tablets or capsules	1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Dimenhydrinate (Dramamine)	One or two 50mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first EC dose; repeat as needed every 4-6 hours	OTC
Cyclizine hydrochloride (Marezine)	One 50mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours	OTC

ADDITIONAL PRESCRIBING AND DISPENSING CONSIDERATIONS

- For women who weigh more than 165 lbs, levonorgestrel may be less effective than ulipristal acetate.*****
- Levonorgestrel may be preferable for women who need EC due to missed or late pills, patch, or ring.*****
- Starting hormonal birth control immediately after taking ulipristal acetate may make it ineffective.*****
- For women with prescription insurance coverage, OTC drugs may be covered by the health carrier when prescribed for the patient.*****
- Ella may be more effective if it has been more than 72 hours since the last day of unprotected intercourse.
- Pharmacist must counsel the patient on the proper use of the EC and side effects, to include providing written educational materials.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER AND COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a self-administered hormonal EC, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,
2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

***Per the American Society for Emergency Contraception.**

Adopted: 9/9/2020
Revised: 9/24/2021, 9/6/2022
Effective Date: ~~12/22/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses

For the purpose of lowering a patient's out-of-pocket health care costs, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following to persons 18 years of age or older:

- Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and follow any relevant evidence-based guidelines.

PATIENT INCLUSION CRITERIA

Patients eligible for drugs, devices, controlled paraphernalia, and other supplies and equipment under this protocol:

- An individual, 18 years of age or older, whose over-the-counter drug, device, controlled paraphernalia, and other supply or equipment is covered by the patient's health carrier and when the patient's out-of-pocket cost for the prescribed item is lower than the out-of-pocket cost to purchase the same drug over-the-counter;
- An individual, 18 years of age or older, whose over-the-counter drug would cost more out-of-pocket than a prescribed prescription-only drug that is a therapeutically equivalent drug product[1], as defined in § 54.1-3401, as the over-the-counter drug.

EXAMPLES OF INCLUDED DEVICES AND CONTROLLED PARAPHERNALIA

Examples of devices and controlled paraphernalia for which a pharmacist may issue a prescription to initiate treatment under the qualifying conditions of this protocol include:

- Diabetic blood sugar testing supplies,
- Injection supplies;
- Hypodermic needles and syringes;
- Nebulizers and associated supplies;
- Inhalation spacers;
- Peak flow meters;
- International Normalized Ratio (INR) testing supplies;
- Enteral nutrition supplies;
- Ostomy products and supplies

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Drug Control Act, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

[1]"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 U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book.", § 54.1-3401.

Adopted: 9/24/2021
Revised: 9/6/2022
Effective: ~~12/22/2021~~

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Records documenting completion of required training shall be maintained by the pharmacist for a minimum of six years following the last patient encounter pursuant to this protocol or subsequent iterations for which the training is required. The training records may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either onsite or offsite. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Prior to initiating the dispensing, administration, and interpretation of TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing
- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

[3] Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations

- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who:

- Are at increased risk for latent or active tuberculosis disease
- Need TST documented for school attendance, occupational requirements, insurance purposes, or other administrative purposes

EXCLUSION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[6] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)
- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccination and not remember, this should be considered when administering the TST.

(NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification shall be made to the local health department. TST may still be performed.

MEDICATIONS

This protocol authorizes pharmacists to administer TST antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in the American Thoracic Society (ATC)/CDC Guideline.[1] A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-administered by the client. The Report of Tuberculosis Screening in Appendix B must be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix C for detailed procedures for placing the TST).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021) [3] (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required counseling and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. The Report of TB Screening is included in Appendix B. The individual should sign a release of information indicating the individual's consent that this information can be shared (refer to the Patient Authorization section in Appendix A).
4. Certain laws or regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist who administers PPD for a TST shall notify the patient's primary health care provider that the pharmacist has administered a TST and inform the provider of the test results within three (3) business days, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~,~~ ~~upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the

area in which the patient is located.

Note: A pharmacy may create and use an electronic format of this protocol if the questions and process are identical to the Board-adopted protocol.

Adopted: 9/24/2021
Revised: 9/6/2022
Effective: ~~12/22/2021~~

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING TWO-STEP PROTOCOL: FOR INITIAL TESTING IN ADULTS WHO MAY BE UNDERGOING ANNUAL TESTING

PURPOSE

This protocol specifies the criteria and procedures for pharmacists to initiate the dispensing, administration, and interpretation of the Tuberculin Skin Test (TST) to assist in tuberculosis prevention and control. The two-step testing will help in reducing the likelihood that a boosted reaction to a subsequent TST will be misinterpreted as a recent infection.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must successfully complete the following training:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing[1] from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection[2] or from a comparable provider approved by the Virginia Board of Pharmacy

Records documenting completion of required training shall be maintained by the pharmacist for a minimum of six years following the last patient encounter pursuant to this protocol or subsequent iterations for which the training is required. The training records may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either onsite or offsite. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Prior to initiating the dispensing, administration, and interpretation of a TST under this protocol, the pharmacist(s) must understand and follow procedures as specified by:

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing

[1] Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection ATS/CDC Statement Committee on Latent Tuberculosis Infection, June 2000. Available at **https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4906a1.htm.**

[2] CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf

- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations[3]: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019[4]
- High Burden TB Country List, Virginia Department of Health[5]

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who are receiving initial TB skin testing and may continue to receive an annual TST for employment purposes. The 2020 CDC Guidelines for Screening, Testing and Treatment of Healthcare Personnel no longer include a recommendation for serial screening for the majority of healthcare personnel after the initial screening, unless they fall into a particular high risk group (e.g., pulmonologists) or there is an exposure or on-going transmission at the healthcare facility[6].

EXCLUSTION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month[7] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST

[3]Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations (NTCA/NTSC, 2021). Available at: https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration

[4] Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019. Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[5] High Burden TB Country List, Virginia Department of Health. Available at: https://www.vdh.virginia.gov/tuberculosis/screening-testing/

[6] Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, Available at: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

[7] Fact Sheets: Tuberculin Skin Testing. Centers for Disease Control and Prevention. Available at: https://www.cdc.gov/tb/publications/factsheets/testing/skintesting.htm

- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccine and not remember, this should be considered when administering the TST.
- Individuals with a suppressed immune system (HIV, other acute/chronic infections, those on certain medications, etc.) may not react to a TST in the way an immunocompetent person does. In this instance, a false negative result may be possible.
- Individuals who are contacts of a confirmed positive TB case may seek testing from a pharmacist. If a pharmacist becomes aware of this during the risk assessment, notification shall be made to the local health department. TST may still be performed.

MEDICATIONS

This protocol authorizes pharmacists to administer tuberculin skin test antigen, also known as purified protein derivative (PPD), read, and interpret the TST. TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

Product	Mfr. / Dist.	NDCs*
Tubersol	Sanofi Pasteur	1mL (10 tests) = 49281-752-21 5mL (50 tests) = 49281-752-22
Aplisol	Parkdale	1 mL (10 tests) = 42023-104-05 5mL (50 tests) = 42023-104-05

**or any other FDA-approved tuberculin skin test antigen*

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in the American Thoracic Society (ATS)/CDC Guideline.[1] In addition, the need for periodic retesting and the presence of individual risk factors for occupational exposures will be used to determine the need for two-step testing. A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-

administered by the client. The Report of Tuberculosis Screening in Appendix B must be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions

The TST is performed by injecting 0.1mL of tuberculin PPD in the inner surface of the forearm. The injection should be made with a tuberculin syringe, with the needle bevel facing upward. The TST is an intradermal injection. When placed correctly, the injection should produce a pale elevation of the skin (a wheal) 6 to 10 mm in diameter (see Appendix C for detailed procedures for placing the TST).

PROCEDURES FOR MONITORING AND FOLLOW UP

The skin test reaction should be read between 48 and 72 hours after administration. Schedule an appointment for the reading at the time the TST is administered. An individual who does not return within 72 hours will need to be rescheduled for another skin test. The reaction should be measured in millimeters of the induration (palpable, raised, hardened area or swelling). The reader should not measure erythema (redness). The diameter of the indurated area should be measured across the forearm (perpendicular to the long axis) and recorded as millimeters of induration.

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline[1] (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

An initial positive reaction is considered a TB infection and a second TST is not required. The patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case a TST can be repeated annually, if required. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. A referral is required for this follow-up and so that treatment considerations can be made if latent TB infection is diagnosed (see Appendix E)[2].

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

- Need to return in 48-72 hours for interpretation of the TST
- If mild itchiness occurs, avoid scratching the site. Do not use creams or other treatments to treat the itchiness.
- Redness may develop. This is a normal reaction, avoid using creams or other treatments.
- Result of the TST
- Need for a second TST in 1-3 weeks if the initial result is negative
- Need for confirmatory evaluation and a chest X-ray following a positive TST result
- Between an initial positive TST and confirmatory evaluation, the patient may carry on normal activity unless showing signs and symptoms of active TB disease.
- If active TB symptoms are present or indicated on the TB risk assessment documentation (Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

DOCUMENTATION

Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

1. Documentation for the dispensing of prescription medication; and documentation that the individual receiving the TST was provided with the required education and referral information pursuant to this protocol.
2. Documentation of the completion of the risk assessment, date and time of test placement, date and time of test reading, results and interpretation must be maintained by the pharmacist and provided to the patient and shall include both the millimeters of induration and interpretation of the test (negative or positive).
3. Individual test results, either positive or negative, may be provided to others upon the individual's request. This can include employers when testing is provided as a requirement of employment. The Report of TB Screening is included in Appendix B. The individual should sign a release of information indicating their consent that this information can be shared (refer to the Patient Authorization section in Appendix A).
4. Certain laws or regulations may preclude a pharmacist from signing documentation for an individual to certify the individual has been examined and is free of tuberculosis. This should be ascertained prior to administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist who administers PPD for a TST shall notify the patient's primary health care provider that the pharmacist has administered a TST and inform the provider of the test results within three (3) business days, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~,~~ ~~upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Note: A pharmacy may create and use an electronic format of this protocol if the questions and process are identical to the Board-adopted protocol.

Adopted: 9/9/2020
Revised: 9/6/2022
Effective Date: ~~1/3/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Epinephrine Statewide Protocol

Consistent with the epinephrine manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Epinephrine auto-injector; or,
- Injectable epinephrine, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING
Prior to issuing a prescription to initiate treatment with, dispensing, or administering epinephrine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognition and management of anaphylaxis.

PATIENT INCLUSION CRITERIA
Patients eligible for epinephrine under this protocol:

- Any person, 18 years of age or older, demonstrating signs and symptoms of anaphylaxis or at risk for experiencing anaphylaxis, e.g., patients reporting having previously been prescribed epinephrine for treatment of possible anaphylaxis or reporting a diagnosis of allergies that may result in anaphylaxis.

COUNSELING
The pharmacist shall counsel the patient or the patient's agent on how to properly recognize and mangage anaphylaxis, including proper administration of the epinephrine.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Adopted: 9/9/2020
Revised: 9/6/2022
Effective Date: ~~1/3/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Naloxone Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

Patients eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law. Refer patient to primary care provider to determine if naloxone appropriate.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and counsel the patient or the patient's agent on how to properly

identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Adopted: 9/9/2020
Revised: 9/6/2022
Effective Date: ~~1/3/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Prenatal Vitamin Statewide Protocol

Consistent with the prenatal vitamin manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs to persons 18 years of age or older:

- Prenatal vitamins for which a prescription is required.

PHARMACIST EDUCATION AND TRAINING
Prior to issuing a prescription to initiate treatment with, dispensing, or administering prenatal vitamins under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use and evidence-based guidelines.

PATIENT INCLUSION CRITERIA
Patients eligible for prenatal vitamins under this protocol:

- An individual, 18 years of age or older, who is considering pregnancy, attempting to become pregnant, or pregnant.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider and obstetrician/gynecologist (OB/GYN). If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Adopted: 9/9/2020
Revised: 9/6/2022
Effective Date: ~~1/3/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Hormonal Contraceptive Statewide Protocol
(Excluding Emergency Contraception)

Consistent with the hormonal contraceptive manufacturer's instructions for use approved by the US Food and Drug Administration (FDA), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- Injectable or self-administered hormonal contraceptives provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering injectable or self-administered hormonal contraceptive under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited educational training program related to the prescribing of contraceptives by a pharmacist.

PATIENT INCLUSION CRITERIA

Patients eligible for injectable or self-administered hormonal contraceptives approved by the FDA under this protocol:

- An individual, 18 years of age or older, who has completed the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire** and who the pharmacist has determined is eligible for a hormonal contraceptive, consistent with the most current version of the Centers for Disease Control and Prevention *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use*, i.e., the prescribed drug is assessed at a "1" or "2" for all conditions applicable to the patient.

*Note: A pharmacy may create and use an electronic routine hormonal contraceptive self-screening questionnaire if the collection of patient information and assessment process is identical to the Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

1. Obtain from each new patient and, at a minimum of every twelve months for each returning patient, a completed *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire**; and,
2. Utilize and follow the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives* or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate* to perform the patient assessment.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients identified by the pharmacist to NOT be eligible for a hormonal contraceptive as indicated by the *Summary Chart of US Medical Eligibility Criteria for Contraceptive Use* and the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptive*s or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, shall be referred to a healthcare practitioner and may not receive a hormonal contraceptive under this statewide protocol. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

FURTHER CONDITIONS

1. For each new patient requesting a contraceptive service a participating pharmacist must provide the patient with a visit summary.
2. A pharmacist shall not:
    a. Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit. Such evidence may be obtained by the response on the *Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire* regarding the date of the patient's last women's health clinical visit.
    b. Prescribe in instances that the *Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptive*s or the *Virginia Algorithm for Pharmacists to Prescribe and Administer Depot Medroxyprogesterone Acetate*, as applicable, requires referral to a provider.

DRUG INCLUSION CRITERIA

The following drug formulations approved by the FDA to prevent pregnancy are included in this statewide protocol:

- injectable depot medroxyprogesterone acetate;
- transdermal patches;
- vaginal rings; and,
- contraceptives intended to be taken orally.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18 VAC 110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER; COUNSELING

1. If the pharmacist initiates treatment with or dispenses or administers a hormonal contraceptive, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider and obstetrician/gynecologist (OB/GYN), the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located; and,

2. Additionally, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

Adopted: 9/24/2021
Revised: 9/6/2022
Effective: ~~12/22/2021~~

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) or current emergency use authorization from the U.S. Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the vaccines to persons 18 years of age or older.

PHARMACIST EDUCATION AND TRAINING
Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine under this protocol, the pharmacist shall be knowledgable of the manufacturer's instructions for use or instructions indicated in the emergency use authorization, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions.

PATIENT INCLUSION CRITERIA
Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination;
- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who ~~is fully vaccinated~~ has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING

The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Item: Adoption of final regulations – Pharmaceutical Processors

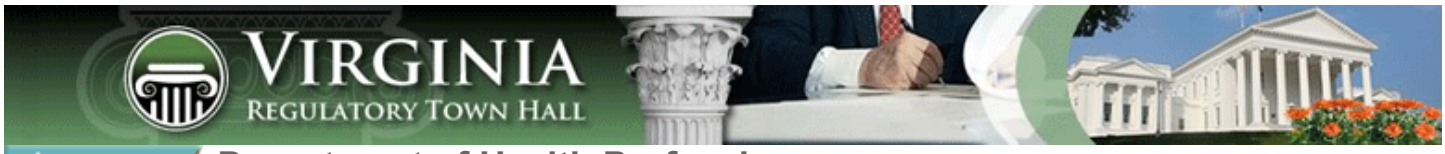
Included in your agenda package are:

- Copy of notice of exempt action for pharmaceutical processor regulations.
- Summary of amendments required by HB933/SB671.
- Copy of HB933 (identical to SB671).
- Revised draft of proposed language. Changes made for clarifications and in response to comments are highlighted.
- Copy of comments received.

Action needed:

- Motion to adopt exempt final changes to regulations governing pharmaceutical processors as presented or amended by the Board.

Virginia.gov Agencies | Governor



Agency **Department of Health Professions**

Board **Board of Pharmacy**

Edit Notice

General Notice

Notice of Public Comment Period

Date Posted: 6/13/2022

Expiration Date: 9/6/2022

Submitted to Registrar for publication: YES

59 Day Comment Forum is underway. Began on 7/8/2022 and will end on 9/5/2022

Board of Pharmacy
Regulations Governing Pharmaceutical Processors

In accordance with Chapters 392 and 933 of the 2022 Acts of the Assembly, the Board of Pharmacy is providing an opportunity to comment on draft proposed regulations for pharmaceutical processors that will be considered for adoption as an exempt action.

The proposed regulations have been drafted to conform to the 2022 legislation, which includes but is not limited to the elimination of mandatory patient registration, changes in allowable manufacturing and extraction of cannabis products, wholesale transactions of bulk cannabis, and marketing of cannabis products. The proposed regulations can be found on the Board of Pharmacy's website for review:
https://www.dhp.virginia.gov/Pharmacy/pharmacy_laws_regs.htm

Virginia Code § 54.1-3442.6 requires that the Board provide a 60 day comment period prior to adopting regulations related to pharmaceutical processors. The 2022 legislation requires the Board to amend regulations by September 15, 2022. Therefore, the Board of Pharmacy will adopt regulations at its scheduled meeting on September 6, 2022.

The Board will receive public comment on these proposed regulations from **July 8, 2022 to September 6, 2022**. However, commenters are strongly encouraged to submit comments by **August 12, 2022** in order to have them included in the Board's agenda package and adequately considered for the September 6th meeting.

Comments may be sent to:

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This general notice was created by Erin Barrett on 06/13/2022 at 2:14pm

Summary of Changes Required By Topic
HB933/SB671

Required change	Location
Patient Registration[1]	
Patients issued written certifications and parents/legal guardians no longer register with the Board.	• 18VAC110-60-10 • 18VAC110-60-50 • 18VAC110-60-60 • 18VAC110-60-70 • 18VAC110-60-80 • 18VAC110-60-90 • 18VAC110-60-160
Board must provide registration cards when requested by patients.	• 18VAC110-60-10 • 18VAC110-60-20 • 18VAC110-60-50(A)
Board must maintain electronic database of certified patients as reported to the Board by pharmaceutical processors.	• 18VAC110-60-310(A)(2)
Hydrocarbon Processing	
Board must amend regulations to permit hydrocarbon processing.	• 18VAC110-60-280(B), (D) • 18VAC110-60-281 • 18VAC110-60-330(F)
Operational Changes	
Only pharmacist or responsible party required to be present to witness destruction/disposal of green waste.	• 18VAC110-60-330(A), (B)
Green waste may be disposed of by incineration, inert composting, or any other means of disposal and destruction.	• 18VAC110-60-330(C)
Processor may sell or otherwise distribute inert green waste.	• 18VAC110-60-330(D)
Board shall permit processors to engage in wholesale transactions of bulk cannabis oil, botanical cannabis, and usable cannabis.	• 18VAC110-60-160(D)(6) • 18VAC110-60-220(A)(2) • 18VAC110-60-250(D)(1) • 18VAC110-60-251(F)
Board shall remove requirements that wholesale transactions must have passed tests in 18VAC110-60-300(G) and (H) and packaged and labeled for sale with expiration date in accordance with 18VAC110-60-300.	• 18VAC110-60-251(B)
Regulations will require that wholesale material be packaged in a tamper-evident container with requirements for labeling to	• 18VAC110-60-251(D) • 18VAC110-60-290 • 18VAC110-60-295

[1] Changes include numerous deletions of references to "registered" patients which are not included in this list.

include seller and buyer identifying information, quantity or weight of product, identification of contents of the container, a unique serial number, date of laboratory testing, dates of harvest and packaging, and expiration date.	
Corporate point of contact to receive copies of all investigative and disciplinary material sent to PIC or responsible party.	• Change was made to the processor application to account for this.
Advertising	
Board shall amend regulations to allow marketing except for marketing activities that include false or misleading statements, depict a person younger than 21 consuming cannabis, include images or designs likely to appeal to minors, depicts products or labeling that reasonably resembles candy products, or contains any image or insignia that would lead the public to believe that the product is made or endorsed by the Commonwealth.	• 18VAC110-60-215(A)
Product	
Board shall amend 18VAC110-60-285 to except the following: where THC concentration is less than 5 mg/dose, the concentration of THC shall be within 0.5 mg/dose; where total CBD concentration is less than 5 mg/dose, the concentration of total CBD shall be within 0.5 mg/dose	• 18VAC110-60-285(B)
Board shall amend regulations to permit labeling of cannabis products with expiration date assigned by processor of six months or less from the date of the cannabis product registration approval.	• 18VAC110-60-300(I)
Botanical cannabis that fails testing standards may be remediated except product that fails pesticide quality testing standards.	• 18VAC110-60-300(G), (H)
Stability testing not required for product which has an expiration date of six months or less from product approval date. Testing for date longer than six months limited to microbial testing on a pass/fail basis and potency testing on a 10% deviation basis.	• 18VAC110-60-300(I)

CHAPTER 391

An Act to amend and reenact §§ 54.1-3408.3, 54.1-3442.5, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to pharmaceutical processors.

[H 933]

Approved April 11, 2022

Be it enacted by the General Assembly of Virginia:

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

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

A. As used in this section:

"Botanical cannabis" means cannabis that is composed wholly of usable cannabis from the same parts of the same chemovar of cannabis plant.

"Cannabis oil" means any formulation of processed Cannabis plant extract, which may include ~~oil from~~ industrial hemp ~~extract~~ *extracts, including isolates and distillates,* acquired by a pharmaceutical processor pursuant to § 54.1-3442.6, or a dilution of the resin of the Cannabis plant that contains ~~at least five milligrams of cannabidiol (CBD) or tetrahydrocannabinolic acid (THC-A) and~~ no more than 10 milligrams of delta-9-tetrahydrocannabinol per dose. "Cannabis oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law, unless it has been *grown and processed in the Commonwealth by a registered industrial hemp processor and* acquired and formulated ~~with cannabis plant extract~~ by a pharmaceutical processor.

"Cannabis product" means a product that is (i) produced by a pharmaceutical processor, registered with the Board, and compliant with testing requirements and (ii) composed of cannabis oil or botanical cannabis.

"Designated caregiver facility" means any hospice or hospice facility licensed pursuant to § 32.1-162.3, or home care organization as defined in § 32.1-162.7 that provides pharmaceutical services or home health services, private provider licensed by the Department of Behavioral Health and Developmental Services pursuant to Article 2 (§ 37.2-403 et seq.) of Chapter 4 of Title 37.2, assisted living facility licensed pursuant to § 63.2-1701, or adult day care center licensed pursuant to § 63.2-1701.

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

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

"Usable cannabis" means any cannabis plant material, including seeds, but not (i) resin that has been extracted from any part of the cannabis plant, its seeds, or its resin; (ii) the mature stalks, fiber produced from the stalks, or any other compound, manufacture, salt, or derivative, mixture, or preparation of the mature stalks; or (iii) oil or cake made from the seeds of the plant.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabis products for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation and may employ the use of telemedicine, provided that the use of telemedicine includes the delivery of patient care through real-time interactive audio-visual technology. If a practitioner determines it is consistent with the standard of care to dispense botanical cannabis to a minor, the written certification shall specifically authorize such dispensing. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing.

C. The written certification shall be on a form provided by the ~~Office of the Executive Secretary of the Supreme Court developed in consultation with the~~ Board of ~~Medicine~~ *Pharmacy*. Such written certification shall contain the name, address, and telephone number of the practitioner~~,~~*;* the name and address of the patient issued the written certification~~,~~*;* the date on which the written certification was made~~,~~*;* and the signature or authentic electronic signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration. *A written certification shall not be issued to a patient by more than one practitioner during any given time period.*

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for the issuance of a

certification for the use of cannabis products for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board and shall hold sufficient education and training to exercise appropriate professional judgment in the certification of patients. The Board shall not limit the number of patients to whom a practitioner may issue a written certification. The Board may report information to the applicable licensing board on unusual patterns of certifications issued by a practitioner.

F. ~~A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.~~ No patient shall be required to physically present the written certification after the initial dispensing by any pharmaceutical processor or cannabis dispensing facility under each written certification, provided that the pharmaceutical processor or cannabis dispensing facility maintains an electronic copy of the written certification. *Pharmaceutical processors and cannabis dispensing facilities shall electronically transmit, on a monthly basis, all new written certifications received by the pharmaceutical processor or cannabis dispensing facility to the Board.*

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

H. Upon delivery of *a* cannabis ~~oil~~ *product* by a pharmaceutical processor or cannabis dispensing facility to a designated caregiver facility, any employee or contractor of a designated caregiver facility, who is licensed or registered by a health regulatory board and who is authorized to possess, distribute, or administer medications, may accept delivery of the cannabis ~~oil~~ *product* on behalf of a patient or resident for subsequent delivery to the patient or resident and may assist in the administration of the cannabis ~~oil~~ *product* to the patient or resident as necessary.

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

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

§ 54.1-3442.5. Definitions.

As used in this article:

"Botanical cannabis," "cannabis oil," "cannabis product," and "usable cannabis" have the same meanings as specified in § 54.1-3408.3.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabis products produced by a pharmaceutical processor to a ~~registered~~ patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Designated caregiver facility" has the same meaning as defined in § 54.1-3408.3.

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

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

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

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

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

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

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors and cannabis dispensing facilities. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling, including the potency of each botanical cannabis product and the amounts recommended by the practitioner or dispensing pharmacist, and packaging; (vii) routine inspections no more frequently than once annually; (viii) processes for safely and securely dispensing and delivering in person cannabis products to a ~~registered~~ patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) dosage limitations for cannabis oil that provide that each dispensed dose of cannabis oil not exceed 10 milligrams of delta-9-tetrahydrocannabinol; (x) a process for the wholesale distribution of and the transfer of usable cannabis, botanical cannabis, cannabis oil, and cannabis products between pharmaceutical processors, between a pharmaceutical processor and a cannabis dispensing facility, and between cannabis dispensing facilities; (xi) an allowance for the sale of devices for administration of dispensed cannabis products and hemp-based CBD products that meet the applicable standards set forth in state and federal law, including the laboratory testing standards set forth in subsection M; (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification; (xiii) a process for acquiring ~~oil from~~ industrial hemp ~~extract and formulating such oil extract with Cannabis plant extract into allowable dosages of cannabis oil~~ *extracts and formulating such extracts into cannabis products*; and (xiv) an allowance for the advertising and promotion of the pharmaceutical processor's products and operations, which shall not limit the pharmaceutical processor from the provision of educational material to practitioners who issue written certifications and ~~registered~~ patients. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabis products, (b) the secure disposal of agricultural waste, and (c) a process for registering cannabis oil products.

D. The Board shall require that, after processing and before dispensing any cannabis products, a pharmaceutical processor shall make a sample available from each batch of cannabis product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative cannabis oil sample for analysis. A minimum sample size, to be determined by the certified testing laboratory, from each batch of botanical cannabis is required to achieve a representative botanical cannabis sample for analysis. Botanical cannabis products shall only be tested for the following: total cannabidiol (CBD); total tetrahydrocannabinol (THC); terpenes; pesticide chemical residue; heavy metals; mycotoxins; moisture; and microbiological contaminants. Testing thresholds shall be consistent with generally accepted cannabis industry thresholds. The pharmaceutical processor may remediate *botanical cannabis or* cannabis oil that fails any quality testing standard *except pesticides*. Following remediation, all remediated *botanical cannabis or* cannabis oil shall be subject to laboratory testing and approved upon satisfaction of *applicable* testing standards ~~applied to cannabis oil generally~~, *which shall not be more stringent than initial testing prior to remediation*. If ~~the~~ *a* batch *of botanical cannabis* fails retesting *after remediation*, it shall be considered usable cannabis and may be processed into cannabis oil~~, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil~~. Stability testing shall not be required for any cannabis ~~oil~~ product with an expiration date assigned by the pharmaceutical processor of six months or less from the date of ~~packaging~~ *the cannabis product registration approval*. *Stability testing required for assignment of an expiration date longer than six months shall be limited to microbial testing, on a pass/fail basis, and potency testing, on a 10 percent deviation basis, of active ingredients.*

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the

Board in regulation.

F. Every pharmaceutical processor's dispensing area or cannabis dispensing facility shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor or cannabis dispensing facility. The pharmaceutical processor shall ensure that security measures are adequate to protect the cannabis from diversion at all times, and the pharmacist-in-charge shall have concurrent responsibility for preventing diversion from the dispensing area.

Every pharmaceutical processor shall designate a person who shall have oversight of the cultivation and production areas of the pharmaceutical processor and shall provide such information to the Board. The Board shall direct all communications related to enforcement of requirements related to cultivation and production of cannabis oil products by the pharmaceutical processor to such designated person.

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

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

I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabis products that have been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

J. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a pharmaceutical processor or cannabis dispensing facility.

K. Every pharmaceutical processor or cannabis dispensing facility shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

L. A pharmacist at the pharmaceutical processor's dispensing area and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time in the pharmaceutical processor's dispensing area or cannabis dispensing facility.

M. A pharmaceutical processor may acquire industrial hemp ~~extract~~ *extracts grown and* processed in Virginia, and in compliance with state or federal law, from a registered industrial hemp dealer or processor. A pharmaceutical processor may process and formulate such ~~extract with cannabis plant extract~~ *extracts* into an allowable dosage of cannabis ~~oil~~ *product*. Industrial hemp ~~extract~~ *extracts* acquired *and formulated* by a pharmaceutical processor ~~is~~ *are* subject to the same third-party testing requirements that may apply to cannabis plant extract. Testing shall be performed by a laboratory located in Virginia and in compliance with state law *governing the testing of cannabis products*. The industrial hemp dealer or processor shall provide such third-party testing results to the pharmaceutical processor before industrial hemp ~~extract~~ *extracts* may be acquired.

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

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

§ 54.1-3442.7. Dispensing cannabis products; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis products only in person to (i) a patient who is a Virginia resident or temporarily resides in Virginia ~~as made evident to the Board,~~ *and* has been issued a valid written certification~~, and is registered with the Board pursuant to § 54.1-3408.3~~; (ii) such patient's registered agent; or (iii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident or temporarily resides in Virginia ~~as made evident to the Board and is registered with the Board pursuant to § 54.1-3408.3~~. A companion may accompany a ~~registered~~ patient into a pharmaceutical processor's dispensing area or cannabis dispensing facility. Prior to the initial dispensing of cannabis ~~oil~~ *products* pursuant to each written certification, a pharmacist or pharmacy technician employed by the pharmaceutical processor or cannabis dispensing facility shall make and maintain, on site or remotely by electronic means, for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view, in person or by audiovisual means, a current photo identification of the patient, registered agent, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding ~~patient,~~ registered agent~~, parent, or legal guardian~~ *if applicable*. Thereafter, an initial dispensing may be delivered to the patient, registered agent, parent, legal guardian, or designated caregiver facility. Prior to any subsequent dispensing of cannabis ~~oil~~ *products* pursuant to each written certification, an employee or delivery agent shall view a current photo identification of the patient, registered agent, *parent*, or legal guardian and the current board registration issued to the ~~patient,~~ registered agent~~, parent, or legal guardian~~ *if applicable*. No pharmaceutical processor or cannabis dispensing facility shall dispense more than a 90-day supply of a cannabis product, as determined by the dispensing pharmacist or certifying practitioner, for any patient during any 90-day period; however, a pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. No more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. A pharmaceutical processor or cannabis dispensing facility may dispense less than a 90-day supply. In determining the appropriate amount of a cannabis product to be dispensed to a patient, a pharmaceutical processor or cannabis dispensing facility shall consider all cannabis products dispensed to the patient and adjust the amount dispensed accordingly.

B. A pharmaceutical processor or cannabis dispensing facility shall dispense only cannabis products produced on the premises of a pharmaceutical processor permitted by the Board or cannabis ~~oil~~ *products* that ~~has~~ *have* been formulated with ~~oil~~ *extracts* from industrial hemp acquired by a pharmaceutical processor from a registered industrial hemp dealer or processor pursuant to § 54.1-3442.6. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House Committee for Health, Welfare and Institutions and the Senate Committee on Education and Health on the operation of pharmaceutical processors and cannabis dispensing facilities issued a permit by the Board~~, including the number of practitioners, patients, registered agents, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3~~.

D. The concentration of delta-9-tetrahydrocannabinol in any cannabis product on site may be up to 10 percent greater than or less than the level of delta-9-tetrahydrocannabinol measured for labeling. A pharmaceutical processor and cannabis dispensing facility shall ensure that such concentration in any cannabis product on site is within such range. A pharmaceutical processor producing cannabis products shall establish a stability testing schedule of cannabis products.

2. That the Board of Pharmacy shall amend its regulations, including subsection A of 18VAC110-60-280 of the Virginia Administrative Code, to permit the use of hydrocarbon-based solvents, and any other generally accepted technology, in the cultivation, extraction, production, or manufacturing process of cannabis products.

3. That the Board of Pharmacy shall amend its regulations, including subsection B of 18VAC110-60-330 of the Virginia Administrative Code, to (i) require only the presence of a pharmacist or the responsible party to witness destruction and disposal of green waste, extracts, and cannabis oil, as applicable; (ii) allow for disposal of green waste by incineration, inert composting, or any other means of disposal or destruction; and (iii) allow a pharmaceutical processor to sell or otherwise distribute inert composted green waste.

4. That the Board of Pharmacy shall permit pharmaceutical processors to engage in wholesale transactions of bulk cannabis oil, botanical cannabis, and usable cannabis and amend its regulations, including subsection A of 18VAC110-60-251 of the Virginia Administrative Code, to remove the requirements that wholesale transactions of bulk cannabis oil, botanical cannabis, and usable cannabis from any lot or batch (i) must have passed the tests required in subsections G and H of 18VAC110-60-300 of the Virginia Administrative Code and (ii) are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 of the Virginia Administrative Code. The regulations shall state that wholesale cannabis oil, botanical cannabis, and usable cannabis shall be packaged in a tamper-evident container and labeled with (a) the

seller's name and address; (b) the buyer's name and address; (c) the quantity or weight of the cannabis oil, botanical cannabis, or usable cannabis in each container; (d) identification of the contents of the container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate; (e) a unique serial number that will match a cannabis product with the cultivator and manufacturer and lot or batch number to facilitate any warnings or recalls that the Board of Pharmacy or any successor governmental or quasi-governmental body authorized to regulate cannabis or the original pharmaceutical processor deems appropriate; (f) the date of laboratory testing and the name and address of the testing laboratory; (g) the dates of harvest and packaging; and (h) an expiration date.

5. That the Board of Pharmacy shall amend the pharmaceutical processor permit application to include designation of a corporate point of contact who shall receive copies of all investigative and disciplinary communications sent to the pharmacist in charge or responsible party.

6. That the Board of Pharmacy shall amend its regulations to allow pharmaceutical processors to engage in marketing activity, inclusive of product, program, company, and related communications other than those marketing activities that (i) include false or misleading statements; (ii) promote excessive consumption; (iii) depict a person younger than 21 years of age consuming cannabis; (iv) include any image designed or likely to appeal to minors, specifically including cartoons, toys, animals, children, or any other likeness to images, characters, or phrases that are popularly used to advertise to children; (v) depict products or product packaging or labeling that bears reasonable resemblance to any product legally available for consumption as a candy or that promotes cannabis consumption; or (vi) contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead registered patients or the general public to believe that the cannabis product has been endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except where specifically authorized.

7. That the Board of Pharmacy shall amend its regulations, including subsection B of 18VAC110-60-285 of the Virginia Administrative Code, to include the following exceptions: (i) where the total tetrahydrocannabinol (THC) concentration is less than 5 milligrams per dose, the concentration of THC shall be within 0.5 milligrams per dose and (ii) where the total cannabidiol (CBD) concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose.

8. That the Board of Pharmacy shall amend its regulations, including 18VAC110-60-285 and 18VAC110-60-290 of the Virginia Administrative Code, in addition to its product registration form, to permit labeling of cannabis products with an expiration date assigned by the pharmaceutical processor of six months or less from the date of the cannabis product registration approval.

9. That the Board of Pharmacy (the Board) shall maintain an electronic database of certified patients as reported to the Board by pharmaceutical processors and cannabis dispensing facilities. The Board may utilize the information in this database, in conjunction with information reported to the prescription monitoring program, to investigate any fraudulent or aberrant certifications.

10. That the Board of Pharmacy (the Board) shall issue a registration card to any patient who (i) is in possession of an active written certification and (ii) has voluntarily requested such registration card on a form approved by the Board. No registration card shall be required for dispensing of cannabis products to a patient in possession of a written certification by a pharmaceutical processor or cannabis dispensing facility.

11. That the Board of Pharmacy may assess and collect regulatory fees from each pharmaceutical processor in an amount sufficient to implement the provisions of this act.

12. That the Board of Pharmacy's initial adoption of regulations necessary to implement the provisions of this act shall be exempt from the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia), except that the Board of Pharmacy shall provide an opportunity for public comment on the regulations prior to adoption of such regulations.

13. That the Board of Pharmacy shall amend and promulgate regulations in accordance with this act by September 15, 2022.

Commonwealth of Virginia

REGULATIONS

GOVERNING PHARMACEUTICAL PROCESSORS

Title of Regulations: 18 VAC 110-60-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34

of Title 54.1 of the *Code of Virginia*

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Part I
General Provisions

18VAC110-60-10. Definitions.

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

"90-day supply" means the amount of cannabis products reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for ~~registered~~ patients with a valid, unexpired written certification issued by a practitioner for the use of cannabis products.

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation of visual, oral, or written communication through any means to directly induce any person to patronize a particular pharmaceutical processor or cannabis dispensing facility or to purchase particular approved cannabis products. Advertising includes marketing.

"Batch" means a quantity of (i) cannabis oil from a production lot or (ii) harvested botanical cannabis product that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

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

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

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

   a. Incorrect product;

   b. Incorrect product strength;

   c. Incorrect dosage form;

   d. Incorrect patient; or

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

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

   a. Known therapeutic duplication;

   b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

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

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

3. Delivery of a cannabis product to the incorrect patient.

4. An act or omission relating to the dispensing of cannabis product that results in, or may reasonably be expected to result in, injury to or death of a ~~registered~~ patient or results in any detrimental change to the medical treatment for the patient.

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

"ISO/IEC" means the joint technical committee of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories.

"On duty" means that a pharmacist, the responsible party, or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 is on the premises at the address of the permitted pharmaceutical processor and is available as needed.

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

"PIC" means the pharmacist-in-charge whose name is on the pharmaceutical processor or cannabis dispensing facility application for a permit that has been issued and who shall have oversight of the processor's dispensing area or cannabis dispensing facility.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana for the creation of usable cannabis, botanical cannabis, or a cannabis product derived thereof, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a combination

of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

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

~~"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabis products to such patient.~~

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

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

"Responsible party" means the person designated on the pharmaceutical processor application who shall have oversight of the cultivation and production areas of the pharmaceutical processor.

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

Room or Phase	Temperature	Humidity
Mother room	65 - 85° F	50% - 75%
Nursery phase	65 - 85° F	50% - 75%
Vegetation phase	65 - 85° F	50% - 75%
Flower/harvest phase	65 - 85° F	40% - 75%
Drying/extraction rooms	< 75° F	40% - 75%

"Temporarily resides" means a person that does not maintain a principal place of residence within Virginia but resides in Virginia on a temporary basis as evidenced by documentation substantiating such temporary residence.

18VAC110-60-20. Fees.

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

B. Registration of practitioner.

1. Initial registration.	$50

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

C. ~~Registration~~ Voluntary registration by a qualifying patient, parent, legal guardian, or registered agent.

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

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000
4. Change of name of processor.	$100
5. Change of PIC or responsible party or any other information provided on the permit application.	$100
6. Change of ownership not requiring a criminal background check.	$100
7. Change of ownership requiring a criminal background check.	$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
9. Reinspection fee.	$1,000
10. Registration of each cannabis oil product.	$25

E. Cannabis dispensing facility permit.

1. Initial permit.	$5,000

2. Annual renewal of permit.	$1,500
3. Change of name of dispensing facility.	$100
4. Change of PIC or any other information provided on the permit application.	$100
5. Change of ownership not requiring a criminal background check.	$100
6. Change of ownership requiring a criminal background check.	$250
7. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
8. Reinspection fee.	$1,000

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

Part II
Requirements for Practitioners and Patients

18VAC110-60-30. Requirements for practitioner issuing a certification.

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

B. A practitioner issuing a certification shall:

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

2. Diagnose the patient;

3. Be of the opinion that the potential benefits of cannabis products would likely outweigh the health risks of such use to the qualifying patient;

4. Authorize on the written certification the use of botanical cannabis for a minor patient if the practitioner determines such use is consistent with the standard of care to dispense botanical cannabis to a minor. If not specifically included on the initial written certification, authorization for botanical cannabis may be communicated verbally or in writing to the pharmacist at the time of dispensing;

5. Explain proper administration and the potential risks and benefits of the cannabis product to the qualifying patient and, if the qualifying patient lacks legal capacity, to a parent or legal guardian prior to issuing the written certification;

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

7. Comply with generally accepted standards of medical practice, except to the extent such standards would counsel against certifying a qualifying patient for cannabis products;

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

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

C. The practitioner shall use his professional judgment to determine the manner and frequency of patient care and evaluation, which may include the use of telemedicine, provided that the use of telemedicine:

1. Includes the delivery of patient care through real-time interactive audio-visual technology;

2. Conforms to the standard of care expected for in-person care; and

3. Transmits information in a manner that protects patient confidentiality.

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

E. The practitioner shall provide instructions for the use of cannabis products to the patient, parent, or guardian, as applicable, and shall also securely transmit such instructions to the permitted pharmaceutical processor.

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

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

A. A practitioner who issues certifications shall not:

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

2. Offer a discount or any other thing of value to a qualifying patient, parent, guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabis product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabis products are dispensed or produced; or

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

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor, a cannabis dispensing facility, or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabis products, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabis product.

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

D. A practitioner shall not provide product samples containing cannabis other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. ~~Registration~~ Voluntary registration of a patient, parent, legal guardian, or registered agent.

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

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

2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt or proof of temporary residency, if applicable, such as a current academic identification card from a Virginia institution of higher learning, rental agreement, utility bill, or attestation on a form prescribed by the board that contains information sufficient to document temporary residency in Virginia;

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

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

5. Payment of the appropriate fees; and

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

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabis products on behalf of the patient. An individual may serve as a registered agent for no more than two ~~registered~~ patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, and birthdate~~, and registration number~~ of each ~~registered~~ patient for whom the individual intends to act as a registered agent;

2. A copy of the written certification, issued to the patient, for the use of cannabis products for treatment of or to alleviate the symptoms of any diagnosed condition or disease;

~~2~~3. Proof of identity in the form of a copy of a government-issued identification card;

~~3~~4. Payment of the applicable fee; and

~~4~~5. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

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

~~D. Patients, parents, legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabis products.~~

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

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

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

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

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

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

5. Has presented a certification issued by a practitioner who is not authorized to certify patients for cannabis products; or

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

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

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

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

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

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

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

E. If a patient, parent, legal guardian, or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, legal guardian, or registered agent, the registrant shall notify the

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

18VAC110-60-80. Proper storage and disposal of cannabis products by patients, parents, legal guardians, or registered agents.

A. A ~~registered~~ patient, parent, legal guardian, or registered agent shall exercise reasonable caution to transport and store cannabis products in a manner to prevent theft, loss, or access by unauthorized persons.

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

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

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

18VAC110-60-90. Revocation or suspension of a ~~qualifying patient, parent, legal guardian, or~~ registered agent registration or invalidation of the voluntary registration of a patient, parent, or legal guardian.

The board may revoke or suspend the registration of a ~~registrant (i.e., a patient, parent, legal guardian, or registered agent)~~ registered agent or invalidate the voluntary registration of a patient, parent, or legal guardian under the following circumstances:

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

2. The ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian provided false, misleading, or incorrect information to the board;

3. The ~~registrant~~ patient on whose behalf the registered agent is receiving cannabis products or the voluntarily registered patient, parent, or legal guardian is no longer a resident of Virginia or is no longer temporarily residing in Virginia;

4. The ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian obtained more than a 90-day supply of cannabis products in a 90-day period;

5. The ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian ~~provided or~~ sold or improperly provided cannabis products to any person, including another ~~registrant~~ registered agent;

6. The ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian permitted another person to use the registration of the ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian, except as required for a registered agent to act on behalf of a patient;

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

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

9. The ~~registrant~~ registered agent or voluntarily registered patient, parent, or legal guardian failed to notify the board of a change in registration information or notified the board of such change more than 15 days after the change; or

10. The ~~patient, parent, or legal guardian~~ registered agent or voluntarily registered patient, parent, or legal guardian violated any federal or state law or regulation.

Part III
Application and Approval Process for Pharmaceutical Processors and Cannabis Dispensing Facilities

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

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

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

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

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

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

B. Submission of initial application.

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

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

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

c. Detailed information regarding the applicant's financial position indicating all assets, liabilities, income, and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis products pursuant to §§ 54.1-3442.6 and 54.1-3442.7 of the Code of Virginia, which may include evidence of an escrow account, letter of credit, or performance surety bond;

d. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis products;

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

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

g. Information about any previous or current involvement in the medical cannabis industry;

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

i. Any business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis products;

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

k. A blueprint of the proposed pharmaceutical processor that shall show and identify (i) the square footage of each area of the facility; (ii) the location of all safes or vaults used to store the Cannabis plants and products; (iii) the location of all areas that may contain Cannabis plants or cannabis products; (iv) the placement of walls, partitions, and counters; and (v) all areas of ingress and egress;

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

m. Information about the applicant's expertise in agriculture and other production techniques required to produce cannabis products and to safely dispense such products; and

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

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

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

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

D. No person who has been convicted of a felony under the Code of Virginia or another jurisdiction within the last five years shall have a 5.0% or greater ownership, be employed by, or act as an agent of a pharmaceutical processor.

18VAC110-60-120. Conditional approval.

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

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

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

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

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

4. The applicant's ability to maintain the knowledge, understanding, judgment, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing and sale of cannabis products;

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

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

C. The board may disqualify any applicant who:

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

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

3. Fails to pay all applicable fees; or

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

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

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

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

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

1. Designation of a PIC and responsible party;

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

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

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

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

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

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

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

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

G. Once the permit is issued, a processor may begin cultivation of Cannabis, and the responsible party or a person who is qualified to provide supervision in accordance with 18VAC110-60-170 shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. Once Cannabis has been placed in the dispensing area of the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. The responsible party shall ensure security measures are adequate to protect the cannabis in the cultivation and production area from diversion at all times, and the PIC shall have concurrent responsibility for preventing diversion from the dispensing area. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist or the responsible party shall continue to be on site on a daily basis.

18VAC110-60-135. Application for and granting of a permit for a cannabis dispensing facility.

A. Pursuant to § 54.1-3442.6 of the Code of Virginia, the board may issue up to five cannabis dispensing facility permits for each health service area. A permit may be issued to a facility that is owned, at least in part, by the pharmaceutical processor located in that health service area for the dispensing of cannabis products that has been cultivated and produced on the premises of a pharmaceutical processor. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

B. A separate application and fee for each cannabis dispensing facility permit shall be submitted to the board, along with the following information and documentation:

1. The name and address of the facility, which shall not be within 1,000 feet of a school or daycare;

2. The name and address of the facility's owners with 5.0% or greater ownership;

3. Name and signature of pharmacist-in-charge practicing at the facility;

4. Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of cannabis products; and

5. Information necessary for the board to conduct a criminal background check on the facilities' owners with 5.0% or greater ownership.

C. Prior to issuing the permit, an inspection of the facility shall be performed by an agent of the board. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

D. A cannabis dispensing facility shall comply with all state and local laws and ordinances.

E. A cannabis dispensing facility permit shall not be issued to any person to operate from a private dwelling or residence.

F. No person who has been convicted of a felony under the laws of the Commonwealth or another jurisdiction within the last five years shall be employed by or act as an agent of a cannabis dispensing facility.

G. If the cannabis dispensing facility is not operational within 90 days from the date the permit is issued, the board shall rescind the permit unless an extension is granted for good cause shown.

H. A cannabis dispensing facility shall be deemed to have commenced operation if it is in receipt of cannabis products from a pharmaceutical processor.

I. Once the facility is in possession of cannabis products, a pharmacist shall be on site at all times during the declared hours of operation.

18VAC110-60-136. Denial of a cannabis dispensing facility permit application.

A. The board may deny an application for a cannabis dispensing facility permit if the applicant:

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

2. Fails to pay all applicable fees; or

3. Fails to comply with all requirements for a cannabis dispensing facility.

B. If the board denies an application of cannabis dispensing facility permit, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-140. Notification of changes by pharmaceutical processor or cannabis dispensing facility.

A. Unless otherwise provided in law or regulation, the PIC or the responsible party designated on the application of the pharmaceutical processor or a cannabis dispensing facility shall provide any notification or information that is required from a pharmaceutical processor or a cannabis dispensing facility with respect to their designated areas of oversight.

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

C. Any person wishing to engage in the acquisition of an existing pharmaceutical processor or cannabis dispensing facility, change the location of an existing pharmaceutical processor or cannabis dispensing facility, make structural changes to an existing pharmaceutical processor or cannabis dispensing facility, or make changes to a previously approved security system shall submit an application to the board and pay the required fee.

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

2. Cannabis, ~~oil acquired from~~ industrial hemp ~~extract~~ extracts, or cannabis products shall not be moved to a new location until approval is granted by the inspector or board staff.

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

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

1. Notify the board;

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

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

B. The proposed disposition of all Cannabis, ~~oil from~~ industrial hemp extracts, cannabis products, dispensing records, patient information records, and other required records, as applicable, shall be reported to the board. If the Cannabis, cannabis products, and records are to be transferred to another processor located in Virginia or to another cannabis dispensing facility in the same health service area, the owner shall inform the board and the patients and include on the public notice the name and address of the processor or cannabis dispensing facility to whom the Cannabis, cannabis products, and records are being transferred and the date of transfer.

C. Exceptions to the public notice shall be approved by the board and may include sudden closing due to fire, destruction, natural disaster, death, property seizure, eviction, bankruptcy, or other emergency circumstances. If the pharmaceutical processor or cannabis dispensing facility is not able to meet the notification requirements, the owner shall ensure that the board and public are properly notified as soon as the owner knows of the closure and shall disclose the emergency circumstances preventing the notification within the required deadlines.

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

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

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

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

3. If a new owner's share constitutes 5.0% or greater of the total ownership, the new owner shall submit to fingerprinting and the criminal history record search required of § 54.1-3442.6 of the Code of Virginia.

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

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

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

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabis products, or other controlled substances;

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

5. Permitting another person to use the permit of a permit holder, ~~or registration~~ the written certification of a qualifying patient, parent, or legal guardian, the registration of a qualifying patient, parent, legal guardian that has voluntarily registered with the board or a registered agent, except as required for a registered agent to act on behalf of a patient;

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

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

Part IV
Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor or cannabis dispensing facility employee licenses and registrations.

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

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the dispensing area of the pharmaceutical processor or of a cannabis dispensing facility at all times during its hours of operation.

C. The person who is designated as the responsible party for a pharmaceutical processor shall practice at the location of the address on the pharmaceutical processor application, shall have oversight of the cultivation and production areas, and shall possess:

1. A current, unrestricted license as a pharmacist issued by the board;

2. A degree in chemistry, pharmacology, or a field related to the cultivation of plants;

3. A certification recognized by the board; or

4. At least two years of verifiable experience cultivating plants or extracting chemicals from plants.

D. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia a may perform the following duties under supervision of a pharmacist:

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

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

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

4. The measuring of the cannabis product to be dispensed;

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

6. The packaging and labeling of bulk cannabis oil, botanical cannabis, and usable cannabis intended to be wholesale distributed pursuant to 18VAC110-60-251;

~~6~~7. The stocking or loading of devices used in the dispensing process;

~~7~~8. The selling of the cannabis product to the ~~registered~~ patient, parent, legal guardian or registered agent; and

~~8~~9. The performance of any other task restricted to pharmacy technicians by the board's regulations.

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

F. A pharmaceutical processor may employ individuals with less than two years of experience to perform cultivation-related duties under the supervision of an individual who has received a degree in a

field related to the cultivation of plants or a certification recognized by the board or who has at least two years of experience cultivating plants.

G. A pharmaceutical processor may employ individuals with less than two years of experience to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

H. At no time shall the dispensing area of a pharmaceutical processor operate or be accessed without a pharmacist on duty. At no time shall the cultivation and production area operate or be accessed without an employee on duty who satisfies the requirements for providing direct supervision for the activities in the respective areas.

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

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

18VAC110-60-180. Employee training.

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

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

2. Procedures and instructions for responding to an emergency;

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

4. Developments in the field of the medical use of cannabis products.

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

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

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

1. The name of the person receiving the training;

2. The dates of the training;

3. A general description of the topics covered;

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

5. The signatures of the person receiving the training and the PIC or the responsible party.

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

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

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

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

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

1. Is on duty where the pharmacy technician is performing routine cannabis product production or dispensing functions; and

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

C. Pharmacy technicians shall not:

1. Counsel a ~~registered~~ patient or the patient's parent legal guardian, or registered agent regarding (i) cannabis products or other drugs either before or after cannabis products have been dispensed or (ii) any medical information contained in a patient medication record;

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

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

4. Determine whether a different formulation of cannabis product should be substituted for the cannabis product or formulation recommended by the practitioner or requested by the ~~registered~~ patient or parent or legal guardian; or

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

18VAC110-60-195. Responsibilities of the responsible party.

A. A person may only serve as the responsible party for one pharmaceutical processor at any one time. The responsible party shall be employed full time in a managerial position at the location of the processor and shall be actively engaged in daily operations of the processor during normal hours of operation.

B. The responsible party shall be aware of and knowledgeable about all policies and procedures pertaining to the operations of the pharmaceutical processor.

C. The responsible party shall ensure compliance with all security measures to protect the Cannabis within the cultivation and production areas from diversion at all times and ensure that cultivation and production is performed in a safe and compliant manner and free of adulteration and misbranding.

D. The responsible party shall be responsible for ensuring that:

1. All employees practicing in the cultivation and production areas are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants and the cannabis products, within the cultivation and production area are met; and

4. Any other required filings or notifications regarding the cultivation and production areas are made on behalf of the processor as set forth in regulation.

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

F. The outgoing responsible party shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, or cannabis products on hand in the cultivation and production areas, on the date he ceases to be the responsible party unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

G. A responsible party who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the responsible party. If the responsible party knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences

by the responsible party that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new responsible party.

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

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

A. The PIC of a pharmaceutical processor shall not serve as PIC of any other facility at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board. A person may serve simultaneously as the PIC for no more than two cannabis dispensing facilities located within the same health service area at any one time.

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

C. The PIC of a pharmaceutical processor or cannabis dispensing facility shall be responsible for ensuring that:

1. Pharmacy technicians are registered and properly trained;

2. All record retention requirements pertaining to the dispensing area met;

3. All requirements for the physical security of the cannabis products are met;

4. The pharmaceutical processor or cannabis dispensing facility has appropriate pharmaceutical reference materials to ensure that cannabis products can be properly dispensed;

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

a. Pharmaceutical processor permit or cannabis dispensing facility permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility; and

c. The price of all cannabis products offered by the pharmaceutical processor or cannabis dispensing facility; and

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

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

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all cannabis products on hand in the dispensing area of the pharmaceutical processor or the dispensing facility on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

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

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

Part V
Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

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

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

C. The PIC, pharmacist, responsible party, or person who is qualified to provide supervision in accordance with 18VAC110-60-170 on duty shall restrict access to the pharmaceutical processor or cannabis dispensing facility to:

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

2. A person who is a ~~registered~~ patient, parent, legal guardian, registered agent, or a companion of the patient, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, or cannabis products are stored

D. A pharmacist, pharmacy technician, or an employee of the pharmaceutical processor or cannabis dispensing facility who has routine access to confidential patient data and who has signed a patient data confidentiality agreement with the processor or dispensing facility may determine eligibility for access to the processor or facility by verifying through a verification source recognized by the board that the registration of the patient, parent, legal guardian, or registered agent is current.

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

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

G. A pharmaceutical processor or cannabis dispensing facility shall be open for ~~registered~~ patients, parents, legal guardians, or registered agents to purchase cannabis products for a minimum of 35 hours a week, except as otherwise authorized by the board.

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

I. A pharmacist shall counsel ~~registered~~ patients, parents, legal guardians, and registered agents, if applicable, regarding the use of cannabis products. Such counseling shall include information related to safe techniques for proper use and storage of cannabis products and for disposal of the products in a manner that renders them nonrecoverable.

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

18VAC110-60-215. ~~Advertising~~ Marketing and advertising.

A. A pharmaceutical processor may engage in marketing activities related to products, the medical cannabis program, the pharmaceutical processor company, and related communications, except those marketing activities that (i) include false or misleading statements; (ii) promote excessive consumption; (iii) depict a person younger than 21 years of age consuming cannabis; (iv) include any image designed or likely to appeal to minors, specifically including cartoons, toys, animals, children, or any other likeness to images, character, or phrases that are popularly used to advertise to children; (v) depict products or product packaging or labeling that bears reasonable resemblance to any product legally available for consumption as a candy or that promotes cannabis consumption; (vi) contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead patients or the general public to believe that the cannabis product has been endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except where specifically authorized.

~~A~~B. A pharmaceutical processor or cannabis dispensing facility shall not advertise (i) through any means unless at least 85% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.

~~B~~C. Advertising must accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and include a statement that cannabis products are for use by ~~registered~~ patients only. Any advertisement for cannabis products that is related to the benefits, safety, or efficacy, including therapeutic or medical claims, shall:

1. Be supported by substantial, current clinical evidence or data; and

2. Include information on side effects or risks associated with the use of cannabis.

~~C~~D. Advertising shall not:

1. Be misleading, deceptive, or false or contain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

2. Contain a statement, design, illustration, picture, or representation that:

a. Encourages or represents the recreational use of cannabis;

b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;

c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;

d. Encourages or promotes cannabis for use as an intoxicant; or

e. Is obscene or indecent.

3. Display cannabis or cannabis product pricing except as allowed in 18VAC110-60-215 F.

4. Display cannabis products or images of products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

5. Include coupons, giveaways of free cannabis products, or distribution of merchandise that displays anything other than the facility name and contact information.

~~D~~E. A pharmaceutical processor or cannabis dispensing facility may list its business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence and a description of the nature of the business. A pharmaceutical processor or cannabis dispensing facility shall not engage in the use of pop-up digital advertisements.

~~E~~F. Any website or social media site owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism.

~~F~~G. A pharmaceutical processor or cannabis dispensing facility may display the following information on its website or social media site:

1. Name and location of the processor or facility;

2. Contact information for the processor or facility;

3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;

4. Laboratory results;

5. Product information and pricing;

6. Directions to the processor or facility; and

7. Educational materials regarding the use of cannabis products that are supported by substantial, current clinical evidence or data.

~~G~~H. Communication and engagement for educational purposes with registered practitioners, ~~registered~~ patients, parents, legal guardians, registered agents, other health care practitioners, and the general public, including the dissemination of information permitted by 18VAC110-60-215 F and educational materials

regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility, is allowed.

~~H~~I. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

~~I~~J. Signs placed on the property of a pharmaceutical processor or cannabis dispensing facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;

2. Draw undue attention to the facility but may be designed to assist ~~registered~~ patients, parents, legal guardians, and registered agents to find the pharmaceutical processor or cannabis dispensing facility; or

3. Be illuminated during non-business hours.

~~J~~K. All outdoor signage must be in compliance with local or state requirements.

~~K~~L. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements.

~~L~~M. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location.

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

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabis products in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

2. Sell, deliver, transport, or distribute Cannabis, including cannabis products, to any other facility except for wholesale distribution ~~between pharmaceutical processors and to a cannabis dispensing facility~~ pursuant to 18VAC110-60-251;

3. Produce or manufacture cannabis products for use outside of Virginia; or

4. Provide cannabis products samples.

B. No cannabis dispensing facility shall:

1. Dispense cannabis products in any place except the approved facility at the address of record on the application for the cannabis dispensing facility permit;

2. Sell, deliver, transport, or distribute cannabis products to any other facility, except for wholesale distribution pursuant to 18VAC110-60-251 *that it may distribute cannabis products back to the pharmaceutical processor from which it obtained the products or distribute cannabis oil products between cannabis dispensing facilities (strike italics)*; or

3. Provide cannabis product samples.

C. Except for certain employee access to secured areas designated for cultivation and production and authorized by the responsible party pursuant to § 54.1-3442.6 of the Code of Virginia, no pharmaceutical processor or cannabis dispensing facility shall be open or in operation, and no person shall be in the dispensing area of a pharmaceutical processor or in a cannabis dispensing facility, unless a pharmacist is on the premises and directly supervising the activity within the dispensing area of the pharmaceutical processor or a cannabis dispensing facility. At all other times, the dispensing area of the pharmaceutical processor or the cannabis dispensing facility shall be closed and properly secured.

D. No pharmaceutical processor or cannabis dispensing facility shall sell anything other than cannabis products except for devices for administration of dispensed products or hemp-based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and D 3.

E. No cannabis products shall be consumed on the premises of a pharmaceutical processor or cannabis dispensing facility, except for emergency administration to a registered patient. Such administration shall be recorded and a file maintained for a period of two years.

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

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

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

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

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

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

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

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

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor or cannabis dispensing facility prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, and cannabis products, at the facility. The responsible party shall ensure all required inventories are performed in the cultivation and production areas, and the PIC shall ensure all required inventories are performed in the dispensing area. The inventories shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory. If a facility commences business with no Cannabis or cannabis products on hand, the pharmacist or responsible party shall record this fact as the initial inventory; and

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

B. Upon commencing business, each pharmaceutical processor shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, and cannabis products in stock, that shall include, at a

minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist, pharmacy technician, responsible party, or person authorized by the responsible party who provides supervision of cultivation or production-related activities who conducted the inventory.

C. Upon commencing business, each cannabis dispensing facility shall maintain a perpetual inventory of all cannabis products received and dispensed that accurately indicates the physical count of each cannabis product on hand at the time of performing the inventory. The perpetual inventory shall include a reconciliation of each cannabis product at least monthly with a written explanation for any difference between the physical count and the theoretical count.

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

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

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

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

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

18VAC110-60-240. Security requirements.

A. A pharmaceutical processor shall initially cultivate only the number of Cannabis plants necessary to produce cannabis products for the number of patients anticipated within the first nine months of operation. Thereafter, the processor shall not maintain cannabis product in excess of the quantity required for normal, efficient operation.

B. At no time shall a cannabis dispensing facility maintain cannabis products in excess of the quantity required for normal, efficient operation.

C. Items a pharmaceutical processor shall properly secure include Cannabis plants, seeds, parts of plants, extracts, and cannabis products. A cannabis dispensing facility shall properly secure cannabis products. To secure these items a pharmaceutical processor and a cannabis dispensing facility shall:

1. Maintain all Cannabis plants, seeds, parts of plants, extracts, and cannabis products in a secure area or location accessible only by the minimum number of authorized employees essential for efficient operation;

2. Store all cut parts of Cannabis plants, extracts, or cannabis products in an approved safe or approved vault within the pharmaceutical processor or cannabis dispensing facility and not sell cannabis products when the pharmaceutical processor or cannabis dispensing facility is closed;

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

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

5. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the dispensing area to pharmacists practicing at the pharmaceutical processor or cannabis dispensing facility;

6. Restrict access to keys or codes to all safes, approved vaults, or other approved equipment or areas in the cultivation and production areas to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing in the processor or persons supervising cultivation-related or production-related activities at the processor; and

7. Not allow keys to be left in the locks or accessible to persons not authorized by the PIC or responsible party.

D. Employees, other than a pharmacist or person supervising cultivation-related or production-related activities at the processor, but so designated by the PIC or responsible party, may have the ability to unlock a secured area to gain entrance to perform required job duties, but only during hours of operation of the processor or dispensing facility. At no time shall these employees have access to the security system.

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

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

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

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

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

5. Access to the alarm system for the dispensing area of the processor or cannabis dispensing facility shall be restricted to the pharmacists working at the pharmaceutical processor or cannabis dispensing facility, and the system shall be activated whenever the processor or facility is closed for business. Access to the alarm system in areas of a pharmaceutical processor that are designated for cultivation and production shall be restricted to the responsible party and to those authorized by the responsible party who shall be the pharmacists practicing at the pharmaceutical processor or person supervising cultivation-related or production-related activities at the processor.

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

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

2. The video system shall have:

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

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

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

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

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

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

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

H. A pharmaceutical processor or cannabis dispensing facility shall limit access to surveillance areas to persons who are essential to surveillance operations, law-enforcement agencies, security system service employees, the board or the board's agent, and others when approved by the board. A processor or facility shall make available a current list of authorized employees and security system service employees who have access to the surveillance room to the processor or facility. The pharmaceutical processor or cannabis dispensing facility shall keep all onsite surveillance rooms locked and shall not use such rooms for any other function.

I. If diversion, theft, or loss of Cannabis plants, seeds, parts of plants, extracts, or cannabis products has occurred from a pharmaceutical processor, the board may require additional safeguards to ensure the security of the products.

18VAC110-60-250. Requirements for the storage and handling of Cannabis or cannabis products.

A. A pharmaceutical processor or cannabis dispensing facility shall:

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

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

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

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

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

1. Restrict movement between compartments;

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

3. Require pocketless clothing for all employees working in an area containing Cannabis plants, seeds, and extracts, including cannabis oil and cannabis products; and

4. Document the chain of custody of all Cannabis plants, parts of plants, seeds, extracts, and cannabis products.

C. A cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures regarding best practices for the secure and proper dispensing of cannabis products, including a requirement for pocketless clothing for all facility employees working in an area containing cannabis products.

D. The PIC and responsible party of a pharmaceutical processor or the PIC of a cannabis dispensing facility shall establish, maintain, and comply with written policies and procedures for the cultivation, production, security, storage, and inventory of Cannabis, including the seeds, parts of plants, extracts, and the cannabis products, as applicable. Such policies and procedures shall include methods for identifying, recording, and reporting diversion, theft, or loss, and for correcting all errors and inaccuracies in inventories. Pharmaceutical processors and cannabis dispensing facilities shall include in their written policies and procedures a process for the following:

1. Handling mandatory and voluntary recalls of cannabis products and bulk cannabis oil, botanical cannabis, and usable cannabis distributed or received via wholesale distribution. The process shall be adequate to deal with recalls due to any action initiated at the request of the board and any voluntary action by the pharmaceutical processor or cannabis dispensing facility to (i) remove

defective or potentially defective cannabis products from the market or (ii) promote public health and safety by replacing existing cannabis products with improved products or packaging;

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

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

4. Ensuring the oldest stock of Cannabis, including seeds, parts of plants, extracts, and cannabis products are used first. The procedure may permit deviation from this requirement if such deviation is temporary and appropriate.

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

F. The cannabis dispensing facility shall store all cannabis products in such a manner as to prevent diversion, theft, or loss; shall make cannabis products accessible only to the minimum number of specifically authorized employees essential for efficient operation; and shall return the cannabis products to their secure location at the completion of the dispensing or at end of the scheduled business day.

18VAC110-60-251. Wholesale distribution of cannabis ~~oil~~ products, bulk cannabis oil, botanical cannabis, and usable cannabis.

A. Cannabis oil, cannabis products, botanical cannabis, and usable cannabis from a batch that have passed the tests required in 18VAC110-60-300 G and H and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors, ~~and~~ between a pharmaceutical processor and a cannabis dispensing facility, and between cannabis dispensing facilities.

B. ~~Cannabis oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue tests and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between cannabis dispensing facilities.~~ Bulk cannabis oil, botanical cannabis, and usable cannabis that has not been packaged for sale and has not passed the tests required in 18VAC110-60-300(G) and (H) and does not bear an appropriate expiration date may be wholesale distributed between pharmaceutical processors. Prior to distribution, the bulk cannabis oil, botanical cannabis and usable cannabis shall be labeled in compliance with 18VAC110-60-295.

C. A pharmaceutical processor or cannabis dispensing facility wholesale distributing the products shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor or cannabis dispensing facility distributing the product and the processor or cannabis dispensing facility receiving the product, (iii) the kind and quantity of product being distributed, and (iv) the batch and lot identifying information to include harvest date, testing date, processing or manufacturing date, and expiration date. The record of the transaction shall be maintained by the distributing pharmaceutical processor or cannabis dispensing facility with its records of distribution, and a copy of the record shall be provided to and maintained by the processor or facility receiving the product in its records of receipt. Such records shall be maintained by each processor or facility for three years in compliance with 18VAC110-60-260.

D. A pharmaceutical processor wholesale distributing bulk cannabis oil, botanical cannabis, and usable cannabis shall create a record of the transaction that shows (i) the date of distribution, (ii) the names and addresses of the processor distributing the bulk cannabis oil, botanical cannabis, and usable cannabis and the processor receiving the bulk cannabis oil, botanical cannabis, and usable cannabis, (iii) the quantity or weight of the cannabis oil, botanical cannabis, or usable cannabis in each container; (iv) the quantity of each type of container being distributed; (v) the identification of the contents of each container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate; (vi) the lot or batch number or unique identifier so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate, and; (vii) the dates of harvest and packaging. The record of the transaction shall be maintained by the distributing pharmaceutical processor with its records of distribution, and a copy of the record shall be provided to and maintained by the processor receiving the product in its records of receipt. Such records shall be maintained by each processor for three years in compliance with 18VAC110-60-260.

~~D~~E. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products shall provide the receiving processor or cannabis dispensing facility with a copy of the lab results for the distributed product or electronic access to the information that can be shared upon request to ~~registered~~ patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, or an agent of the board.

~~E~~F. A pharmaceutical processor or cannabis dispensing facility wholesale distributing cannabis products and pharmaceutical processors wholesale distributing bulk cannabis oil, botanical cannabis, and usable cannabis shall store and handle ~~products~~ the items and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

~~F~~G. If a pharmaceutical processor or cannabis dispensing facility participating in wholesale ~~distributing products~~ distribution uses an electronic system for the storage and retrieval of records related to distributing ~~products~~, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

18VAC110-60-260. Recordkeeping requirements.

A. If a pharmaceutical processor or cannabis dispensing facility uses an electronic system for the storage and retrieval of patient information or other records related to cultivating, producing, and dispensing cannabis products, as applicable, the pharmaceutical processor or cannabis dispensing facility shall use a system that:

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

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

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

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

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

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

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

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

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

2. A breach of security;

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

4. Corrective measures taken if any.

D. A pharmacist, responsible party, pharmaceutical processor, or cannabis dispensing facility shall immediately notify the board of an employee convicted of a felony.

Part VI
Cultivation, Production, and Dispensing of Cannabis Products

18VAC110-60-280. Cultivation and production of cannabis products.

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

B. Cultivation methods for Cannabis plants, ~~and~~ extraction methods used to produce the cannabis products, and the manufacturing of cannabis products shall be performed in a manner deemed safe and effective based on current standards or scientific literature.

1. The cultivation, extraction, production, and manufacturing of cannabis products may include the use of hydrocarbon-based solvents as described in 18VAC110-60-281.

2. The cultivation, extraction, production, and manufacturing of cannabis products may include any other generally accepted technology, provided that:

    a. The pharmaceutical processor complies with any applicable requirements contained in 18VAC110-60-281 regarding flammable solvents as defined in that section;

    b. The pharmaceutical processor complies with any licensing, permitting, and general safety laws or regulations of any state or federal agency which governs the technology and the use of such technology; and

    c. The pharmaceutical processor maintains sole responsibility for any adverse outcomes or violations of state or federal laws or regulations ~~arising from~~ caused by such use.

C. Any Cannabis plant, seed, parts of plant, extract, or cannabis products not in compliance with this section shall be deemed adulterated.

D. A pharmaceutical processor may acquire ~~oil from~~ industrial hemp extract, including isolates and distillates, for the purpose of formulating such ~~oil extract~~ extracts ~~with cannabis plant extract~~ into allowable dosages of cannabis ~~oil~~ products provided:

1. The pharmaceutical processor acquires the ~~oil~~ extracts from industrial hemp extract processed in Virginia and in compliance with state or federal law from a registered industrial hemp dealer or processor;

2. The ~~oil~~ extracts from industrial hemp acquired by a pharmaceutical processor is subject to the same third-party testing requirements applicable to cannabis plant extract as verified by testing performed by a laboratory located in Virginia and in compliance with state law; and

3. The industrial hemp dealer or processor provides such third-party testing results to the pharmaceutical processor before ~~oil~~ extracts from industrial hemp ~~is~~ are acquired.

E. A pharmaceutical processor acquiring oil from industrial hemp extract shall ensure receipt of a record of the transaction that shows the date of distribution, the names and addresses of the registered industrial hemp dealer or processor distributing the product and the pharmaceutical processor receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the pharmaceutical processor with its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years.

F. A pharmaceutical processor shall maintain policies and procedures for the proper storage and handling of ~~oil from~~ industrial hemp ~~extract~~ extracts, to include a process for executing or responding to mandatory and voluntary recalls in a manner that complies with 18VAC110-60-250.

G. No cannabis oil intended to be vaporized or inhaled shall contain vitamin E acetate.

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 shall comply with all regulations regarding use of 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 promulgated.
5. A pharmaceutical processor using hydrocarbon-based solvents maintains sole responsibility for any adverse outcomes or violations of state or federal laws or regulations ~~arising from~~ 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 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 more flammable solvents onsite 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.

18VAC110-60-285. Registration of products.

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

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THC-A);

3. Cannabidiols (CBD); and

4. Cannabidiolic acid (CBDA).

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

B. A pharmaceutical processor shall not label two products with the same brand name unless the laboratory test results for each product indicate that they contain the same level of each active ingredient listed in subsection A of this section within a range of 90% to 110%, except (i) where the total tetrahydrocannabinol (THC) concentration is less than 5 milligrams per dose, the concentration of THC shall be within 0.5 milligrams per dose and (ii) where the total cannabidiol (CBD) concentration is less than 5 milligrams per dose, the concentration of total CBD shall be within 0.5 milligrams per dose.

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

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

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

3. Is confusingly similar to the name of a previously approved cannabis oil product brand name;

4. Is obscene or indecent;

5. May encourage the use of marijuana or cannabis products for recreational purposes;

6. May encourage the use of cannabis products for a disease or condition other than the disease or condition the practitioner intended to treat;

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

8. Is related to the benefits, safety, or efficacy of the cannabis product unless supported by substantial evidence or substantial clinical data.

18VAC110-60-290. Labeling of batch of cannabis products.

A. Cannabis products produced as a batch shall not be adulterated.

B. Cannabis products produced as a batch shall be:

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

2. Labeled with:

a. The name and address of the pharmaceutical processor;

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

c. A unique serial number that matches the product with the pharmaceutical processor batch and lot number, including the cultivator and manufacturer if produced from bulk cannabis oil, botanical cannabis, or usable cannabis obtained through distribution from another pharmaceutical processor, so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate;

d. The date of testing and packaging;

e. For products produced from bulk cannabis oil, botanical cannabis, or usable cannabis obtained through distribution from another pharmaceutical processor, the name and address of the testing laboratory;

~~e~~f. The expiration date, which shall be six months or less from the date of ~~packaging~~ the cannabis product registration approval, unless supported by stability testing;

~~f~~g. The quantity of cannabis products contained in the batch;

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

(1) Tetrahydrocannabinol (THC);

(2) Tetrahydrocannabinol acid (THC-A);

(3) Cannabidiol (CBD); and

(4) Cannabidiolic acid (CBDA).

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

h. For cannabis oil products, pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis; and

i. For botanical cannabis products, a pass or fail rating based on the laboratory's microbiological, mycotoxins, heavy metals, pesticide chemical residue analysis, water activity, and moisture content, and the potency.

18VAC110-60-295 Labeling of Bulk Cannabis Oil, Botanical Cannabis, and Usable Cannabis

A. Bulk cannabis oil, botanical cannabis, and usable cannabis shall not be adulterated.

B. Bulk cannabis oil, botanical cannabis, and usable cannabis produced for wholesale distribution shall be:

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

2. Packaged in a tamper-evident container, and;

3. Labeled with:

a. the name and addresses of the pharmaceutical processor distributing the product and the pharmaceutical processor receiving the product;

b. the quantity or weight of the cannabis oil, botanical cannabis, or usable cannabis in the container;

c. identification of the contents of the container, including a brief description of the type or form of cannabis oil, botanical cannabis, or usable cannabis and the strain name, as appropriate;

d. the prominent statement "Not Packaged for Final Sale";

e. a unique serial number that will match a cannabis product with the cultivator and manufacturer and lot or batch number so as to facilitate any warnings or recalls the board or pharmaceutical processor deem appropriate; and

f. the dates of harvest and packaging.

C. Cannabis products produced from bulk cannabis oil, botanical cannabis, and usable cannabis shall comply with all laboratory testing and labeling requirements prior to dispensing.

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

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabis products unless such laboratory:

1. Is independent from all other persons involved in the cannabis industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, cannabis dispensing facility, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabis products; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at

least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

3. Has obtained a controlled substances registration certificate pursuant to § 54.1-3423 of the Code of Virginia authorizing the testing of cannabis products.

4. Has provided proof to the board of accreditation in testing and calibration in accordance with the most current version of the International Standard for Organization and the ISO/IEC 17025 or proof that the laboratory has applied for accreditation in testing and calibration in the most current version of ISO/IEC 17025. Any testing and calibration method utilized to perform a cannabis-related analysis for pharmaceutical processors shall be in accordance with the laboratory's ISO/IEC 17025 accreditation. The accrediting body shall be recognized by International Laboratory Accreditation Cooperation.

a. A laboratory applying for authorization to provide cannabis-related analytical tests for pharmaceutical processors shall receive ISO/IEC 17025 accreditation within two years from the date the laboratory applied for ISO/IEC 17025 accreditation. A laboratory may request, and the board may grant for good cause shown, additional time for the laboratory to receive ISO/IEC 17025 accreditation.

b. A laboratory shall send proof of ISO/IEC 17025 accreditation to the board for cannabis-related analytical test methods for pharmaceutical processors for which it has received ISO/IEC 17025 accreditation no later than five business days after the date in which the accreditation was received.

c. A laboratory may use nonaccredited analytical test methods so long as the laboratory has commenced an application for ISO/IEC 17025 accreditation for analytical test methods for cannabis-related analysis for pharmaceutical processors. No laboratory shall use nonaccredited analytical test methods for cannabis-related analysis for pharmaceutical processors if it has applied for and has not received ISO/IEC 17025 accreditation within two years. The laboratory may request and the board may grant for good cause shown additional time for the laboratory to utilize nonaccredited analytical test methods for cannabis-related analysis.

d. At such time that a laboratory loses its ISO/IEC 17025 accreditation for any cannabis-related analytical test methods for pharmaceutical processors, it shall inform the board within 24 hours. The laboratory shall immediately stop handling, testing, or analyzing Cannabis for pharmaceutical processors.

5. Complies with a transportation protocol for transporting Cannabis or cannabis products to or from itself or to or from pharmaceutical processors.

B. After processing and before dispensing the cannabis oil product, a pharmaceutical processor shall make a sample available from each homogenized batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue; and (ii) conduct an active ingredient analysis and terpenes profile. Each laboratory shall determine a valid sample size for testing, which may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5% of individual units for dispensing or distribution from each homogenized batch of cannabis oil is required to achieve a representative sample for analysis.

C. A pharmaceutical processor shall make a sample available from each harvest batch of botanical cannabis product to (i) test for microbiological contaminants, mycotoxins, heavy metals, pesticide chemical reside, water activity, and moisture content and (ii) conduct an active ingredient analysis and terpenes profile. In determining the minimum sample size for testing from each batch of botanical cannabis, the certified testing laboratory may determine the minimum sample size. The sample must be representative of the entire batch to include selection from various points in the batch lot and be of sufficient sample size to allow for analysis of all required tests.

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

E. Under no circumstances shall a pharmaceutical processor or cannabis dispensing facility sell a cannabis product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

F. The processor shall require the laboratory to immediately return or properly dispose of any cannabis products and materials upon the completion of any testing, use, or research.

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

1. For purposes of the microbiological test, a cannabis oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabis oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabis oil product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabis oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence.

H. If a sample of botanical cannabis product does not pass the microbiological, mycotoxin, heavy metal, ~~pesticide chemical residue,~~ water activity, or moisture content test based on the standards set forth in this

subsection, the batch may be remediated. A botanical cannabis product that does not pass the pesticide chemical residue test cannot be remediated. Once remediated, the batch shall be retested for microbiological, mycotoxin, heavy metal, pesticide chemical residue, water activity, and moisture content, and an active ingredient analysis and terpenes profile shall be conducted. If the botanical cannabis batch fails retesting, it shall be considered usable cannabis and may be processed into cannabis oil, unless the failure is related to pesticide requirements, in which case the batch shall not be considered usable cannabis and shall not be processed into cannabis oil. Any batch processed into cannabis oil shall comply with all testing standards set forth in subsection G of this section.

1. For purposes of the microbiological test, a botanical cannabis product sample shall be deemed to have passed if it satisfies the standards set forth in the most current American Herbal Pharmacopoeia Cannabis Inflorescence Standards of Identity, Analysis, and Quality Control.

2. For purposes of the mycotoxin test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of botanical cannabis product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of botanical cannabis product shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR Part 180).

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

a. Total tetrahydrocannabinol (THC); and

b. Total cannabidiol (CBD).

6. For the purposes of water activity and moisture content for botanical cannabis, the product shall be deemed to have passed if the water activity rate does not exceed 0.65Aw and the moisture content does not exceed 15%.

I. If a sample of cannabis product passes the required tests listed in subsections G and H of this section, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products, except stability testing shall not be required for cannabis products if ~~the pharmaceutical processor assigns~~ an expiration date of six months or less from the date of ~~packaging~~ the cannabis product registration approval is signed.

J. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the required tests listed in subsections G and H of this section at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

K. Each pharmaceutical processor or cannabis dispensing facility shall have such laboratory results available upon request to ~~registered~~ patients, parents, legal guardians, registered agents, registered practitioners who have certified qualifying patients, the board, or an agent of the board.

18VAC110-60-310. Dispensing of cannabis products.

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

1. Prior to the initial dispensing of cannabis products pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor or cannabis dispensing facility shall view in person or by audiovisual means a current photo identification of the patient, parent, legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that ~~the~~ any registrations, if applicable, are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabis products to the ~~registered~~ patient.

2. A pharmacist or pharmacy technician employed by the processor or cannabis dispensing facility shall make a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible and shall maintain it on site or by electronic means

for two years. The pharmaceutical processor and cannabis dispensing facility shall also provide an electronic copy of the written certification to the Board of Pharmacy.

3. Prior to any subsequent dispensing, the pharmacist or pharmacy technician shall verify that the written certification on file has not expired. An employee or delivery agent shall view a current photo identification and current registration of the patient, parent, legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the pharmaceutical processor or cannabis dispensing facility.

B. A pharmacist may dispense a portion of a ~~registered~~ patient's 90-day supply of cannabis product. The pharmacist may dispense the remaining portion of the 90-day supply of cannabis products at any time except that no ~~registered~~ patient, parent, legal guardian, or registered agent shall receive more than a 90-day supply of cannabis products for a patient in a 90-day period from any pharmaceutical processor or cannabis dispensing facility. A pharmaceutical processor or cannabis dispensing facility may dispense more than one cannabis product to a patient at one time. However, no more than four ounces of botanical cannabis shall be dispensed for each 30-day period for which botanical cannabis is dispensed. In determining the appropriate amount of cannabis product to be dispensed to a patient, a pharmacist shall consider all cannabis products dispensed and adjust the amount dispensed accordingly.

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

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

2. The brand name of cannabis product that was registered with the board pursuant to 18VAC110-60-285 and its strength;

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

4. The date of dispensing the cannabis product;

5. The quantity of cannabis products dispensed;

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

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

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

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, pesticide chemical residue analysis, and for botanical cannabis, the water activity and moisture content analysis;

8. The name ~~and registration number~~ of the ~~registered~~ patient;

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

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

11. For botanical cannabis, the amount recommended by the practitioner or dispensing pharmacist;

12. The name or initials of the dispensing pharmacist;

13. Name, address, and telephone number of the pharmaceutical processor or cannabis dispensing facility;

14. Any necessary cautionary statement;

15. A prominently printed expiration date based on stability testing; and

16. The pharmaceutical processor’s or cannabis dispensing facility’s recommended conditions of use and storage that can be read and understood by the ordinary individual.

D. The label shall be exempt from containing the items listed in subdivisions C 6, C 7, and C 15 if the items are included on the batch label as required in 18VAC110-60-290 and are clearly visible to the patient.

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

F. The cannabis products shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

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

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

I. A pharmacist shall document a ~~registered~~ patient's self-assessment of the effects of cannabis products in treating the ~~registered~~ patient's diagnosed condition or disease or the symptoms thereof. If the authorization for botanical cannabis for a minor is communicated verbally or in writing to the pharmacist at the time of dispensing, the pharmacist shall also document such authorization. A pharmaceutical processor or cannabis dispensing facility shall maintain such documentation in writing or electronically for

three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

J. A pharmacist shall exercise professional judgment to determine whether to dispense cannabis products to a ~~registered~~ patient, parent, legal guardian, or registered agent if the pharmacist suspects that dispensing cannabis products to the ~~registered~~ patient, parent, legal guardian, or registered agent may have negative health or safety consequences for the ~~registered~~ patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor or cannabis dispensing facility shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor or cannabis dispensing facility shall distribute the written policies and procedures to all pharmaceutical processor or cannabis dispensing facility employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor or cannabis dispensing facility. The policies and procedures shall include:

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

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

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

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

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

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

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

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

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

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

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

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

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

18VAC110-60-321. Devices, hemp-based CBD products, and inert product samples.

A. A pharmaceutical processor or cannabis dispensing facility may have for sale on-site devices intended for the administration of dispensed cannabis products and hemp based CBD products that meet the applicable standards set forth in state and federal law and that meet testing requirements of 18VAC110-60-280 D 2 and D 3.

B. The pharmaceutical processor or cannabis dispensing facility may use and distribute inert product samples that do not contain any active cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility without the need for a written certification. Such inert product samples may not be sold or further distributed.

18VAC110-60-330. Disposal of cannabis products.

A. To mitigate the risk of diversion, a pharmaceutical processor shall routinely and promptly dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated green waste, chemical, dangerous, and hazardous waste, extracts, and cannabis products, as applicable. Green waste includes Cannabis plants seeds and parts of plants. Green waste shall be weighed, ground, and combined with a minimum of 51% non-cannabis waste to render the mixture inactive and unrecognizable. Once rendered unrecognizable, green waste shall be considered agricultural waste and may be disposed of accordingly.

B. The destruction and disposal of green waste, extracts, and cannabis oil, as applicable, shall be witnessed by a pharmacist ~~and at least one other employee~~ or the responsible party of the pharmaceutical processor or cannabis dispensing facility, respectively, and shall be conducted under video surveillance.

The persons destroying and disposing of the green waste, extracts, or cannabis products shall maintain and make available a separate record of each occurrence of destruction and disposal indicating:

1. The date and time of destruction and disposal;

2. The manner of destruction and disposal;

3. The name and quantity of cannabis product and green waste destroyed and disposed of; and

4. The signatures of the persons destroying and disposing of the green waste, extracts, or cannabis products.

C. Disposal of green waste may be by incineration, inert composting, or any other means of disposal or destruction.

D. A pharmaceutical processor may sell or otherwise distribute inert composted green waste.

E. The record of destruction and disposal shall be maintained at the pharmaceutical processor or cannabis dispensing facility for three years from the date of destruction and disposal.

F. Disposal of chemical, dangerous, and hazardous waste must be conducted in a manner consistent with federal, state, and local statutes and regulations. This may include, but is not limited to, any waste product soaked in a flammable solvent.

1. Any waste that may be hazardous must be treated as hazardous waste in regard to storage, labeling, and disposal.

2. The pharmaceutical processor can, alternatively, test waste that may be hazardous for elemental impurities content.

    a. When tested for elemental impurities content, materials that meet the definition of hazardous waste, as defined by the Resource Conservation and Recovery Act ("RCRA") or other applicable federal, state, or local statutes and regulations, must be treated as hazardous waste. Such materials must be properly labeled, contained, stored, and disposed of in accordance with the Environmental Protection Agency, RCRA, and other applicable regulations for hazardous waste.

    b. Materials that contain elemental impurities concentrations less than the allowable concentration limits specified in RCRA and are not designated hazardous waste by other applicable federal, state, or local statutes and regulations, may be disposed of in accordance with this section.

DHARMA
PHARMACEUTICALS

August 12, 2022

via Electronic transmission
Erin L. Barrett
Agency Regulatory Coordinator
9960 Mayland Drive; Suite 300
Henrico, VA 23233

Dear Ms Barrett:

Thank you for the opportunity to submit public comment on the proposed changes to the Regulations Governing Pharmaceutical Processors, Title of Regulations: 18 VAC 110-60-10 et seq.

We appreciate the diligent efforts of the Board of Pharmacy in drafting proposed regulations to conform to the legislation passed by the 2022 Virginia General Assembly which eliminated mandatory patient registration and made changes in allowable manufacturing and extraction of cannabis products, wholesale transactions of bulk cannabis, and marketing of cannabis products, as well as other changes.

Thanks to these program improvements, thousands of qualified patients in Virginia now have improved access to the medical cannabis program.

In reviewing the proposed regulation changes, we noted a discrepancy in 18VAC110-60-220 (B)(2) and 18VAC110-60-251(A) pertaining to language regarding pharmaceutical processors' inter-dispensary transfers of cannabis, specifically cannabis oils. Section 18VAC110-60-220 (B)(2) includes permissive language to "Sell, deliver, transport, or distribute cannabis products to any other facility, except that it may distribute cannabis products back to the pharmaceutical processor from which it obtained the products or distribute cannabis oil products between cannabis dispensing facilities". This Section 18VAC110-60-220 (B)(2) omits the ability to send the other product forms (beyond cannabis oil) between dispensing facilities.

> Our recommendation is to revise Section 18VAC110-60-220 (B)(2) to allow for inter-dispensary transfers of all cannabis products. We believe this meets the intent.

We appreciate the opportunity to provide this public comment and look forward to our continued work together.

Kindest regards,

Dharma Pharmaceuticals, llc

Jack L. Page, Market Leader – Virginia

MACAULAY & JAMERSON & SESSA ATTORNEYS AT LAW

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August 12, 2022

VIA ELECTRONIC MAIL
Department of Health Professions
Attn: Erin Barrett, Esq.
Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233

RE: Dalitso, LLC
Public Comment re: Pharmaceutical Processor Proposed Regulations

Dear Ms. Barrett:

Macaulay, Jamerson & Sessa, P.C. represents Dalitso LLC ("Dalitso") and its parent, Jushi Inc. On behalf of Dalitso, please find enclosed requested changes to the draft Regulations Governing Pharmaceutical Processors.

Dalitso sincerely appreciates the time and attention the Board of Pharmacy ("Board") has given to drafting the regulations now open for public comment (the "Regulations").

Without waiving its previous public comment, and while reiterating those associated request for changes, Daliso respectfully seeks specific clarifications and recommends minor revisions as set forth herein.

1. 18VAC110-65-50. Voluntary registration of a patient, parent, legal guardian, or registered agent.

- This regulation appears in conflict with the statutory changes set forth in HB 933 as it amended Va. Code 54.1-3408.3(F), which eliminated mandatory registration for patients, parents and legal guardians.
- The second sentence of section A is now proposed to read: "If the qualifying patient is a minor or a vulnerable adult, the qualifying patient's parent or legal guardian *shall* register with the board in accordance with this section."
- Retaining "shall" in this subsection does not reflect that registration for parents and guardians is now voluntary. The section should be clarified that the regulation will now only apply to those parents and legal guardians who voluntarily register.

Recommended Revision:

"If the qualifying patient is a minor or vulnerable adult, the qualifying patient's parent or guardian may voluntarily request registration ~~shall register~~ with the board [ ]."

2. 18VAC110-60-215. Advertising.

- Dalitso understood the legislative intent of HB 933's sixth enactment clause, which gave rise to proposed changes in this section, as a direction to replace the existing language with the language set forth in enactment clause six.
- Simply inserting proposed Section A as a prologue to the existing rule creates redundances and compromise clarity.

Recommended Revisions:

(i) Strike subsection (B) and allow HB 933's language to stand on its own.

(ii) If the existing regulatory language is not removed entirely, then the proposed Section A should be blended with existing regulation to avoid confusing overlap.

A. A pharmaceutical processor may engage in marketing activities related to products, the medical cannabis program, the pharmaceutical processor company, and related communications, except those marketing activities that (i) include false, ~~or~~ misleading *or deceptive* statements; (ii) promote excessive consumption; (iii) depict a person younger than 21 years of age consuming cannabis; (iv) include any image designed or likely to appeal to minors, specifically including cartoons ~~s~~ *characters*, *mascots,* toys, animals, children, or any other likeness to images, character, or phrases that are popularly used to advertise to children; (v) depict products or product packaging or labeling that bears reasonable resemblance to any product legally available for consumption as a candy or that promotes cannabis consumption; (vi) contain any seal, flag, crest, coat of arms, or other insignia that is likely to mislead patients or the general public to believe that the cannabis product has been endorsed, made, or used by the Commonwealth of Virginia or any of its representatives except where specifically authorized.

B. ~~A pharmaceutical processor or cannabis dispensing facility shall not advertise (i) through any means unless at least 85% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience composition data or (ii) on television or the radio at any time outside of regular school hours for elementary and secondary schools.~~

Grounds for revision: Restricting advertising to adults 18 years of age or older is captured in section (A).

C. Advertising must accurately and legibly identify the pharmaceutical processor or cannabis dispensing facility responsible for its content and include a statement that cannabis products are for use by registered patients only. Any advertisement for cannabis products that is related to the benefits, safety, or efficacy, including therapeutic or medical claims, shall:

1. Be supported by substantial, current clinical evidence or data; and
2. Include information on side effects or risks associated with the use of cannabis.

D. Advertising shall not:

1. ~~Be misleading, deceptive, or false or~~ *C*ontain any health-related statement that is untrue in any particular manner or tends to create a misleading impression as to the effects on health of cannabis consumption;

Grounds for revision: Prohibiting false and misleading advertising is captured in section (A), which is further amended as shown above to incorporate "deceptive" advertising.

2. Contain a statement, design, illustration, picture, or representation that:

   a. Encourages or represents the recreational use of cannabis;

   ~~b. Targets or is attractive to persons younger than 18 years of age, including a cartoon character, a mascot, or any other depiction or image that is commonly used to market products to minors;~~

   c. Displays the use of cannabis, including the consumption, smoking, or vaping of cannabis;

   d. Encourages or promotes cannabis for use as an intoxicant; or

   e. Is obscene or indecent.

Grounds for revision – 2(b): Prohibiting use of material attractive to children in advertisements or advertisements that target children is addressed in section (A).

3. Display cannabis or cannabis product pricing except as allowed in 18VAC110-60-215 F.

4. Display cannabis products or images of products where the advertisement is visible to members of the public from any street, sidewalk, park, or other public place; and

5. Include coupons, giveaways of free cannabis products, or distribution of merchandise that displays anything other than the facility name and contact information.

E. ~~A pharmaceutical processor or cannabis dispensing facility may list its business in public phone books, business directories, search engines, or other places where it is reasonable for a business to maintain an informational presence of its existence and a description of the nature of the business. A pharmaceutical processor or cannabis dispensing facility shall not engage in the use of pop-up digital advertisements.~~

Grounds for revision – E: Existing language is inconsistent with HB 933, enactment clause 6. Acceptable media and scope of advertising is captured in section (A).

F. Any website ~~or social media site~~ owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility shall employ a neutral age-screening mechanism that verifies that the user is at least 18 years of age, including by using an age-gate, age-screen, or age verification mechanism. *This provision shall apply to any social media site owned, managed, or operated by a pharmaceutical processor or cannabis dispensing facility to the extent an age screening tool is available.*

Grounds for revision – F: This proposed revision addresses technical differences between websites and social media platforms as applied to age gates.

G. A pharmaceutical processor or cannabis dispensing facility may display the following information on its website or social media site:

1. Name and location of the processor or facility;
2. Contact information for the processor or facility;
3. Hours and days the pharmaceutical processor or cannabis dispensing facility is open for dispensing cannabis products;
4. Laboratory results;
5. Product information and pricing;
6. Directions to the processor or facility; ~~and~~
7. *Materials* regarding the use of cannabis products that are supported by substantial, current clinical evidence or data*; and*
8. Educational materials ~~regarding the use of cannabis products that are supported by substantial, current clinical evidence or data~~.

H. Communication and engagement for educational purposes with registered practitioners, registered patients, parents, legal guardians, registered agents, other health care practitioners, and the general public, including the dissemination of information permitted by 18VAC110-60-215 F and educational materials regarding the use of cannabis products available from the pharmaceutical processor or cannabis dispensing facility, is allowed.

I. No outdoor cannabis product advertising shall be placed within 1,000 feet of (i) a school or daycare; (ii) a public or private playground or similar recreational or child-centered facility; or (iii) a substance use disorder treatment facility.

J. Signs placed on the property of a pharmaceutical processor or cannabis dispensing facility shall not:

1. Display imagery of cannabis or the use of cannabis or utilize long luminous gas-discharge tubes that contain rarefied neon or other gases;
2. Draw undue attention to the facility but may be designed to assist registered patients, parents, legal guardians, and registered agents to find the pharmaceutical processor or cannabis dispensing facility; or
3. Be illuminated during non-business hours.

K. All outdoor signage must be in compliance with local or state requirements.

L. A pharmaceutical processor or cannabis dispensing facility shall not advertise at any sporting event or use any billboard advertisements.

M. No cannabis product advertising shall be on or in a public transit vehicle, public transit shelter, bus stop, taxi stand, transportation waiting area, train station, airport, or any similar transit-related location.

3. 18VAC110-60-280. Cultivation, Production, and Dispensing.

- **In section A**, there appears to be a legacy reference to petroleum-based solvents in the top line that should be removed.

  Recommended Revision:

  "A. No cannabis products shall have had pesticide chemicals ~~or petroleum-based solvents~~ used during the cultivation, extraction, production, or manufacturing process [ ]."

  Grounds for revision: Internal consistency and alignment with HB 933, enactment clause 6.

- **In subsection B(2)(b):**
  - The reference to "regulations of any state" is concerningly broad and should be revised.
  - Reference to any agency other than the Board of Pharmacy should be carefully considered.
    - Application of another body of law or otherwise unrelated regulations could have serious implications in ensuring a stable supply chain and patient access to cannabis products.
    - Neither a federal agency nor any other Virginia agency regulates cannabis and therefore such bodies would not have cause to contemplate cannabis product production in regulations.
    - In short, the absence of rules governing technology or use of technology that specifically address cannabis product production or application to cannabis generally should not work to prevent implementation of HB 933, enactment clause 2.

  Recommended Revision:

  "b. The pharmaceutical processor complies with any licensing, permitting, and general safety laws or regulations of any ~~state or~~ federal or Virginia state agency which governs the technology and the use of such technology, except that any such regulations shall not prohibit or restrict a pharmaceutical processor from using a particular technology where regulations governing the technology and its use do not contemplate cannabis product production;"

  Grounds for revision: Necessary clarification limiting applicable state-level authority to the laws and regulations of Virginia and ensuring enactment clause 2 of HB 933 can be effectively implemented.

- **In subsection B(2)(c)**, creating a strict liability standard for any "adverse event" is overly broad, punitive and could foreclose the processor from raising appropriate legal defenses or bringing cross

claim actions in the event of a product defect in the extraction device. Further, producing cannabis products *per se* violates federal law notwithstanding the type of extraction technology used.

Recommended Revision:

- Strike subsection (c). Processors are already liable for adverse outcomes by virtue of their licenses.
- In the alternative, if the Board believes imposing a higher liability standard is necessary with respect to non-CO2 extraction, revise subsection (c) to provide clarity and specificity as follows:
    - *"adverse outcome"* should be limited to manufacturing-type accidents resulting in serious bodily injury causally linked to improper use of non-CO2 extraction equipment installed, used and maintained as recommended or otherwise endorsed by the equipment manufacturer.
    - To the extent the Board construes this liability provision to also apply to adverse patient outcomes:
        - Here, *"adverse outcomes"* triggering a heightened liability standard must be limited to those events resulting in serious bodily injury causally linked to either (i) a substance used in non-CO2 extraction, or (ii) improper use of non-CO2 extraction equipment or processes, and (iii) the processor's failure to test, package and label, and register the product in question as required by 18VAC110-60-300, 18VAC110-60-290 and 18VAC110-60-285, respectively.
        - Such language should be added to this subsection if the Board does construe an "adverse outcome" as applicable to patient outcomes as opposed to manufacturing operations.
    - The pharmaceutical processor maintains sole responsibility for any adverse outcomes or violations of state or federal laws or regulations governing non-CO2 extraction equipment *and* arising from such use *that results in serious bodily injury causally linked to improper use of technology installed, used and maintained as recommended or otherwise endorsed by the equipment manufacturer*.

Grounds for revision: Provide the regulated community with clarity and specificity respecting liability.

4. **18VAC110-60-281. Use of Hydrocarbon-based solvents**.

Generally:

- The proposed reference to OSHA standards should be reconsidered as OSHA is not a cannabis-specific authority and nationally recognized cannabis-specific authorities are available.
- Regulations governing cannabis extraction and manufacturing are spelled out in the international codes and fire codes.

- Dalitso consulted third-party experts who noted using OSHA standards for extraction-related issues would be inconsistent with how other jurisdictions are currently handling safety standards and recommended reviewing and considering the requirements set forth in the following authorities:
    - National Fire Protection Association, Chapter 38 (Marijuana Growing, Processing or Extraction Facilities)
        - https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=1
    - National Fire Protection Association, Chapter 33 (Spray Application Using Flammable or Combustible Materials)
        - https://www.nfpa.org/codes-and-standards/all-codes-and-standards/list-of-codes-and-standards/detail?code=33
    - International Fire Code, Chapter 39 (Processing and Extraction Facilities)
        - https://codes.iccsafe.org/content/IFC2018P6/chapter-39-processing-and-extraction-facilities
    - International Building Code
        - https://codes.iccsafe.org/content/IBC2021P2
    - International Mechanical Code, Section 510 (Hazardous Exhaust Systems)
        - https://codes.iccsafe.org/content/IMC2018/chapter-5-exhaust-systems#IMC2018_Ch05_Sec510

Relating to section (B)(5):

- Creating a strict liability standard for any "adverse event" is overly broad, punitive and could foreclose the processor from raising appropriate legal defenses or bringing cross claim actions in the event of a product defect in the extraction device.
- *See generally* comments to section 18VAC110-60-280(B)(2)(b) above.

Relating to section (B)(8)(b):

- Hydrocarbon extraction systems cannot be "listed" at this point in time. The systems are reviewed by a registered design professional and an Engineering Peer Reviewed technical report (EPR) is issued for the system.
- The EPR is submitted to the authority having jurisdiction for review and approval.
- Following installation and prior to operation, the designer/engineer of record performs a field verification of the extraction unit and produces a technical report to confirm the equipment installed is the same model and type as was identified in the technical report. This report is also shared with the authority having jurisdiction for review and approval.

Finally, it is Dalitso's understanding that the following transportation is authorized under the proposed regulations:

- A pharmaceutical processor may transport bulk cannabis oil, botanical cannabis, usable cannabis and cannabis products between processor facilities, and
- Cannabis products may be transported between cannabis dispensing facilities, between a processor facility and one or more dispensing facilities, and from a dispensing facility to a certified patients subject to delivery requirements.

Thank you for your consideration of Dalitso's requested clarifications and changes.

Sincerely,

Hunter W. Jamerson
Counsel to Dalitso, LLC

cc: Caroline Juran, Executive Director
Annette Kelley, Deputy Executive Director
Sara Payne, Esq., Jushi Inc.

Agenda Item: Adoption of Emergency Regulations/NOIRA for Pharmacy Working Conditions

Included in Agenda Packet:

- Copy of HB 1324
- Draft emergency regulations

Staff Note: Emergency regulations are effective for only 18 months. A one-time extension for an additional 6 months may be requested of the Governor. In addition to adopting emergency regulations, the Board will need to adopt a Notice of Intended Regulatory Action (NOIRA) to promulgate permanent regulations to become effective when the emergency regulations expire.

Action Needed:

- Motion to adopt the emergency regulations as presented or amended and a NOIRA for replacement regulations.

CHAPTER 628

An Act to direct the Board of Pharmacy to adopt regulations related to work environment requirements for pharmacy personnel.

[H 1324]

Approved April 11, 2022

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy shall adopt regulations related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients. Such regulations shall include provisions (i) addressing sufficient pharmacy staffing to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competence and safety; (ii) stating standards for uninterrupted rest periods and meal breaks for pharmacy personnel; (iii) stating standards that ensure adequate time for pharmacists to complete professional duties and responsibilities, including drug utilization reviews, immunization administration, patient counseling, and verification of prescription accuracy; and (iv) limiting external factors such as productivity or production quotas to the extent that such factors interfere with the ability to provide appropriate professional services to the public.*

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

Project 7342 - Emergency/NOIRA

Board of Pharmacy

Pharmacy working conditions

18VAC110-20-113. Pharmacy working conditions.

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

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

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions which interfere with a pharmacist's ability to practice with reasonable competence and safety, recognizing that vaccine administration shall be more heavily weighed compared to total prescription volume;

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

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

3. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensuring staff demonstrate competency, and that pharmacy technician trainees

work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the pharmacist-in-charge;

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

a. A permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, however, a pharmacist may volunteer to work longer than 12 continuous hours.

b. A pharmacy may, but is not required to, close when a pharmacist is on break. A pharmacist on duty may use professional judgment about whether to close the pharmacy provided notice has been posted at least 14 days in advance of the closure;

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

d. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;

e. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided; and

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

a. drug utilization review;

b. immunization;

c. counseling;

d. verification of prescriptions;

e. patient testing; and

f. all other duties required by §§ 54.1-3300 *et seq.* and 54.1-3400 *et seq.* of the Code of Virginia and 18VAC110-20-10 *et seq.*

6. Not override the on duty pharmacist's control of all aspects of the practice of pharmacy, including a pharmacist's decision to not administer vaccines when only a single pharmacist is on duty and in the pharmacist's professional judgement the vaccine cannot be administered safely.

C. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, produced for inspection by the board.

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

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

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

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

2. Document any corrective action taken or justification for inaction which shall be produced for inspection by the Board.

Agenda Item: Consider Ability for Pharmacy Technicians Trainees to Administer Vaccines

Staff Note: Staff recently received an inquiry as to whether a pharmacy technician trainee may administer vaccines to persons 3 years of age and older since HB 1323 became effective July 1, 2022. Currently, the Federal PREP Act prohibits a pharmacy technician trainee from administering vaccines. The qualifying person must hold registration as a pharmacy technician.

Included in Agenda Packet:

- Copy of HB 1323
- Draft amendments of Guidance Document 110-33

Actions Needed:

- Motion to adopt the amendments of Guidance Document 110-33 as presented or amended;
- Motion to adopt NOIRA if determined that act should be prohibited.

VIRGINIA ACTS OF ASSEMBLY -- CHAPTER

An Act to amend and reenact §§ 32.1-325, 54.1-3303.1, and 54.1-3321 of the Code of Virginia, relating to pharmacists; initiation of treatment with and dispensing and administration of vaccines.

[H 1323]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ **32.1-325**, **54.1-3303.1**, and **54.1-3321** of the Code of Virginia are amended and reenacted as follows:

§ **32.1-325**. Board to submit plan for medical assistance services to U.S. Secretary of Health and Human Services pursuant to federal law; administration of plan; contracts with health care providers.

A. The Board, subject to the approval of the Governor, is authorized to prepare, amend from time to time, and submit to the U.S. Secretary of Health and Human Services a state plan for medical assistance services pursuant to Title XIX of the United States Social Security Act and any amendments thereto. The Board shall include in such plan:

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;

2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of $3,500 for the individual and an amount not in excess of $3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;

3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed $5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;

4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;

5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;

6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of

Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

7. A provision for the payment for family planning services on behalf of women who were Medicaid-eligible for prenatal care and delivery as provided in this section at the time of delivery. Such family planning services shall begin with delivery and continue for a period of 24 months, if the woman continues to meet the financial eligibility requirements for a pregnant woman under Medicaid. For the purposes of this section, family planning services shall not cover payment for abortion services and no funds shall be used to perform, assist, encourage or make direct referrals for abortions;

8. A provision for payment of medical assistance for high-dose chemotherapy and bone marrow transplants on behalf of individuals over the age of 21 who have been diagnosed with lymphoma, breast cancer, myeloma, or leukemia and have been determined by the treating health care provider to have a performance status sufficient to proceed with such high-dose chemotherapy and bone marrow transplant. Appeals of these cases shall be handled in accordance with the Department's expedited appeals process;

9. A provision identifying entities approved by the Board to receive applications and to determine eligibility for medical assistance, which shall include a requirement that such entities (i) obtain accurate contact information, including the best available address and telephone number, from each applicant for medical assistance, to the extent required by federal law and regulations, and (ii) provide each applicant for medical assistance with information about advance directives pursuant to Article 8 (§ **54.1-2981** et seq.) of Chapter 29 of Title 54.1, including information about the purpose and benefits of advance directives and how the applicant may make an advance directive;

10. A provision for breast reconstructive surgery following the medically necessary removal of a breast for any medical reason. Breast reductions shall be covered, if prior authorization has been obtained, for all medically necessary indications. Such procedures shall be considered noncosmetic;

11. A provision for payment of medical assistance for annual pap smears;

12. A provision for payment of medical assistance services for prostheses following the medically necessary complete or partial removal of a breast for any medical reason;

13. A provision for payment of medical assistance which provides for payment for 48 hours of inpatient treatment for a patient following a radical or modified radical mastectomy and 24 hours of inpatient care following a total mastectomy or a partial mastectomy with lymph node dissection for treatment of disease or trauma of the breast. Nothing in this subdivision shall be construed as requiring the provision of inpatient coverage where the attending physician in consultation with the patient determines that a shorter period of hospital stay is appropriate;

14. A requirement that certificates of medical necessity for durable medical equipment and any supporting verifiable documentation shall be signed, dated, and returned by the physician, physician assistant, or nurse practitioner and in the durable medical equipment provider's possession within 60 days from the time the ordered durable medical equipment and supplies are first furnished by the durable medical equipment provider;

15. A provision for payment of medical assistance to (i) persons age 50 and over and (ii) persons age 40 and over who are at high risk for prostate cancer, according to the most recent published guidelines of the American Cancer Society, for one PSA test in a 12-month period and digital rectal examinations, all in accordance with American Cancer Society guidelines. For the purpose of this subdivision, "PSA testing" means the analysis of a blood sample to determine the level of prostate specific antigen;

16. A provision for payment of medical assistance for low-dose screening mammograms for determining the presence of occult breast cancer. Such coverage shall make available one screening mammogram to persons age 35 through 39, one such mammogram biennially to persons age 40 through 49, and one such mammogram annually to persons age 50 and over. The term "mammogram" means an X-ray examination of the breast using equipment dedicated specifically for mammography, including but not limited to the X-ray tube, filter, compression device, screens, film and cassettes, with an average radiation exposure of less than one rad mid-breast, two views of each breast;

17. A provision, when in compliance with federal law and regulation and approved by the Centers for Medicare & Medicaid Services (CMS), for payment of medical assistance services delivered to Medicaid-eligible students when such services qualify for reimbursement by the Virginia Medicaid program and may be provided by school divisions, regardless of whether the student receiving care has an individualized education program or whether the health care service is included in a student's individualized education program. Such services shall include those covered under the state plan for medical assistance services or by the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit as specified in § 1905(r) of the federal Social Security Act, and shall include a provision for payment of medical assistance for health care services provided through telemedicine services, as defined in § **38.2-3418.16**. No health care provider who provides health care services through telemedicine shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services;

18. A provision for payment of medical assistance services for liver, heart and lung transplantation procedures for individuals over the age of 21 years when (i) there is no effective alternative medical or surgical therapy available with outcomes that are at least comparable; (ii) the transplant procedure and application of the procedure in treatment of the specific condition have been clearly demonstrated to be medically effective and not experimental or investigational; (iii) prior authorization by the Department of Medical Assistance Services has been obtained; (iv) the patient selection criteria of the specific transplant center where the surgery is proposed to be performed have been used by the transplant team or program to determine the appropriateness of the patient for the procedure; (v) current medical therapy has failed and the patient has failed to respond to appropriate therapeutic management; (vi) the patient is not in an irreversible terminal state; and (vii) the transplant is likely to prolong the patient's life and restore a range of physical and social functioning in the activities of daily living;

19. A provision for payment of medical assistance for colorectal cancer screening, specifically screening with an annual fecal occult blood test, flexible sigmoidoscopy or colonoscopy, or in appropriate circumstances radiologic imaging, in accordance with the most recently published recommendations established by the American College of Gastroenterology, in consultation with the American Cancer Society, for the ages, family histories, and frequencies referenced in such recommendations;

20. A provision for payment of medical assistance for custom ocular prostheses;

21. A provision for payment for medical assistance for infant hearing screenings and all necessary audiological examinations provided pursuant to § **32.1-64.1** using any technology approved by the United States Food and Drug Administration, and as recommended by the national Joint Committee on Infant Hearing in its most current position statement addressing early hearing detection and intervention programs. Such provision shall include payment for

medical assistance for follow-up audiological examinations as recommended by a physician, physician assistant, nurse practitioner, or audiologist and performed by a licensed audiologist to confirm the existence or absence of hearing loss;

22. A provision for payment of medical assistance, pursuant to the Breast and Cervical Cancer Prevention and Treatment Act of 2000 (P.L. **106-354**), for certain women with breast or cervical cancer when such women (i) have been screened for breast or cervical cancer under the Centers for Disease Control and Prevention (CDC) Breast and Cervical Cancer Early Detection Program established under Title XV of the Public Health Service Act; (ii) need treatment for breast or cervical cancer, including treatment for a precancerous condition of the breast or cervix; (iii) are not otherwise covered under creditable coverage, as defined in § 2701 (c) of the Public Health Service Act; (iv) are not otherwise eligible for medical assistance services under any mandatory categorically needy eligibility group; and (v) have not attained age 65. This provision shall include an expedited eligibility determination for such women;

23. A provision for the coordinated administration, including outreach, enrollment, re-enrollment and services delivery, of medical assistance services provided to medically indigent children pursuant to this chapter, which shall be called Family Access to Medical Insurance Security (FAMIS) Plus and the FAMIS Plan program in § **32.1-351**. A single application form shall be used to determine eligibility for both programs;

24. A provision, when authorized by and in compliance with federal law, to establish a public-private long-term care partnership program between the Commonwealth of Virginia and private insurance companies that shall be established through the filing of an amendment to the state plan for medical assistance services by the Department of Medical Assistance Services. The purpose of the program shall be to reduce Medicaid costs for long-term care by delaying or eliminating dependence on Medicaid for such services through encouraging the purchase of private long-term care insurance policies that have been designated as qualified state long-term care insurance partnerships and may be used as the first source of benefits for the participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

25. A provision for the payment of medical assistance for otherwise eligible pregnant women during the first five years of lawful residence in the United States, pursuant to § 214 of the Children's Health Insurance Program Reauthorization Act of 2009 (P.L. **111-3**);

26. A provision for the payment of medical assistance for medically necessary health care services provided through telemedicine services, as defined in § **38.2-3418.16**, regardless of the originating site or whether the patient is accompanied by a health care provider at the time such services are provided. No health care provider who provides health care services through telemedicine services shall be required to use proprietary technology or applications in order to be reimbursed for providing telemedicine services.

For the purposes of this subdivision, "originating site" means any location where the patient is located, including any medical care facility or office of a health care provider, the home of the patient, the patient's place of employment, or any public or private primary or secondary school or postsecondary institution of higher education at which the person to whom telemedicine services are provided is located;

27. A provision for the payment of medical assistance for the dispensing or furnishing of up to a 12-month supply of hormonal contraceptives at one time. Absent clinical contraindications, the Department shall not impose any utilization controls or other forms of medical management limiting the supply of hormonal contraceptives that may be dispensed or furnished to an amount less than a 12-month supply. Nothing in this subdivision shall be construed to (i) require a provider to prescribe, dispense, or furnish a 12-month supply of self-administered hormonal contraceptives at one time

or (ii) exclude coverage for hormonal contraceptives as prescribed by a prescriber, acting within his scope of practice, for reasons other than contraceptive purposes. As used in this subdivision, "hormonal contraceptive" means a medication taken to prevent pregnancy by means of ingestion of hormones, including medications containing estrogen or progesterone, that is self-administered, requires a prescription, and is approved by the U.S. Food and Drug Administration for such purpose; and

28. A provision for payment of medical assistance for remote patient monitoring services provided via telemedicine, as defined in § **38.2-3418.16**, for (i) high-risk pregnant persons; (ii) medically complex infants and children; (iii) transplant patients; (iv) patients who have undergone surgery, for up to three months following the date of such surgery; and (v) patients with a chronic health condition who have had two or more hospitalizations or emergency department visits related to such chronic health condition in the previous 12 months. For the purposes of this subdivision, "remote patient monitoring services" means the use of digital technologies to collect medical and other forms of health data from patients in one location and electronically transmit that information securely to health care providers in a different location for analysis, interpretation, and recommendations, and management of the patient. "Remote patient monitoring services" includes monitoring of clinical patient data such as weight, blood pressure, pulse, pulse oximetry, blood glucose, and other patient physiological data, treatment adherence monitoring, and interactive videoconferencing with or without digital image upload.

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.

2. Initiate such cost containment or other measures as are set forth in the appropriation act.

3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.

4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § **2.2-4007.05**, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.

5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

6. On and after July 1, 2002, require that a prescription benefit card, health insurance benefit card, or other technology that complies with the requirements set forth in § **38.2-3407.4:2** be issued to each recipient of medical assistance services, and shall upon any changes in the required data elements set forth in subsection A of § **38.2-3407.4:2**, either reissue the card or provide recipients such corrective information as may be required to electronically process a prescription claim.

C. In order to enable the Commonwealth to continue to receive federal grants or reimbursement for medical assistance or related services, the Board, subject to the approval of the Governor, may adopt, regardless of any other provision of this chapter, such amendments to the state plan for medical assistance services as may be necessary to conform such

plan with amendments to the United States Social Security Act or other relevant federal law and their implementing regulations or constructions of these laws and regulations by courts of competent jurisdiction or the United States Secretary of Health and Human Services.

In the event conforming amendments to the state plan for medical assistance services are adopted, the Board shall not be required to comply with the requirements of Article 2 (§ **2.2-4006** et seq.) of Chapter 40 of Title 2.2. However, the Board shall, pursuant to the requirements of § **2.2-4002**, (i) notify the Registrar of Regulations that such amendment is necessary to meet the requirements of federal law or regulations or because of the order of any state or federal court, or (ii) certify to the Governor that the regulations are necessitated by an emergency situation. Any such amendments that are in conflict with the Code of Virginia shall only remain in effect until July 1 following adjournment of the next regular session of the General Assembly unless enacted into law.

D. The Director of Medical Assistance Services is authorized to:

1. Administer such state plan and receive and expend federal funds therefor in accordance with applicable federal and state laws and regulations; and enter into all contracts necessary or incidental to the performance of the Department's duties and the execution of its powers as provided by law.

2. Enter into agreements and contracts with medical care facilities, physicians, dentists and other health care providers where necessary to carry out the provisions of such state plan. Any such agreement or contract shall terminate upon conviction of the provider of a felony. In the event such conviction is reversed upon appeal, the provider may apply to the Director of Medical Assistance Services for a new agreement or contract. Such provider may also apply to the Director for reconsideration of the agreement or contract termination if the conviction is not appealed, or if it is not reversed upon appeal.

3. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with any provider who has been convicted of or otherwise pled guilty to a felony, or pursuant to Subparts A, B, and C of 42 C.F.R. Part 1002, and upon notice of such action to the provider as required by 42 C.F.R. § 1002.212.

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when such corporation has been convicted of or otherwise pled guilty to any violation of § **32.1-314**, **32.1-315**, **32.1-316**, or **32.1-317**, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

5. Terminate or suspend a provider agreement with a home care organization pursuant to subsection E of § **32.1-162.13**.

For the purposes of this subsection, "provider" may refer to an individual or an entity.

E. In any case in which a Medicaid agreement or contract is terminated or denied to a provider pursuant to subsection D, the provider shall be entitled to appeal the decision pursuant to 42 C.F.R. § 1002.213 and to a post-determination or post-denial hearing in accordance with the Administrative Process Act (§ **2.2-4000** et seq.). All such requests shall be in writing and be received within 15 days of the date of receipt of the notice.

The Director may consider aggravating and mitigating factors including the nature and extent of any adverse impact the agreement or contract denial or termination may have on the medical care provided to Virginia Medicaid recipients. In cases in which an agreement or contract is terminated pursuant to subsection D, the Director may determine the

period of exclusion and may consider aggravating and mitigating factors to lengthen or shorten the period of exclusion, and may reinstate the provider pursuant to 42 C.F.R. § 1002.215.

F. When the services provided for by such plan are services which a marriage and family therapist, clinical psychologist, clinical social worker, professional counselor, or clinical nurse specialist is licensed to render in Virginia, the Director shall contract with any duly licensed marriage and family therapist, duly licensed clinical psychologist, licensed clinical social worker, licensed professional counselor or licensed clinical nurse specialist who makes application to be a provider of such services, and thereafter shall pay for covered services as provided in the state plan. The Board shall promulgate regulations which reimburse licensed marriage and family therapists, licensed clinical psychologists, licensed clinical social workers, licensed professional counselors and licensed clinical nurse specialists at rates based upon reasonable criteria, including the professional credentials required for licensure.

G. The Board shall prepare and submit to the Secretary of the United States Department of Health and Human Services such amendments to the state plan for medical assistance services as may be permitted by federal law to establish a program of family assistance whereby children over the age of 18 years shall make reasonable contributions, as determined by regulations of the Board, toward the cost of providing medical assistance under the plan to their parents.

H. The Department of Medical Assistance Services shall:

1. Include in its provider networks and all of its health maintenance organization contracts a provision for the payment of medical assistance on behalf of individuals up to the age of 21 who have special needs and who are Medicaid eligible, including individuals who have been victims of child abuse and neglect, for medically necessary assessment and treatment services, when such services are delivered by a provider which specializes solely in the diagnosis and treatment of child abuse and neglect, or a provider with comparable expertise, as determined by the Director.

2. Amend the Medallion II waiver and its implementing regulations to develop and implement an exception, with procedural requirements, to mandatory enrollment for certain children between birth and age three certified by the Department of Behavioral Health and Developmental Services as eligible for services pursuant to Part C of the Individuals with Disabilities Education Act (20 U.S.C. § 1471 et seq.).

3. Utilize, to the extent practicable, electronic funds transfer technology for reimbursement to contractors and enrolled providers for the provision of health care services under Medicaid and the Family Access to Medical Insurance Security Plan established under § **32.1-351**.

4. Require any managed care organization with which the Department enters into an agreement for the provision of medical assistance services to include in any contract between the managed care organization and a pharmacy benefits manager provisions prohibiting the pharmacy benefits manager or a representative of the pharmacy benefits manager from conducting spread pricing with regards to the managed care organization's managed care plans. For the purposes of this subdivision:

"Pharmacy benefits management" means the administration or management of prescription drug benefits provided by a managed care organization for the benefit of covered individuals.

"Pharmacy benefits manager" means a person that performs pharmacy benefits management.

"Spread pricing" means the model of prescription drug pricing in which the pharmacy benefits manager charges a managed care plan a contracted price for prescription drugs, and the contracted price for the prescription drugs differs

from the amount the pharmacy benefits manager directly or indirectly pays the pharmacist or pharmacy for pharmacist services.

I. The Director is authorized to negotiate and enter into agreements for services rendered to eligible recipients with special needs. The Board shall promulgate regulations regarding these special needs patients, to include persons with AIDS, ventilator-dependent patients, and other recipients with special needs as defined by the Board.

J. Except as provided in subdivision A 1 of § **2.2-4345**, the provisions of the Virginia Public Procurement Act (§ **2.2-4300** et seq.) shall not apply to the activities of the Director authorized by subsection I of this section. Agreements made pursuant to this subsection shall comply with federal law and regulation.

*K. When the services provided for by such plan are services related to initiation of treatment with or dispensing or administration of a vaccination by a pharmacist, pharmacy technician, or pharmacy intern in accordance with § **54.1-3303.1**, the Department shall provide reimbursement for such service.*

§ **54.1-3303.1**. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § **54.1-3303**, a pharmacist may initiate treatment with, dispense, or administer the following drugs, devices, controlled paraphernalia, and other supplies and equipment to persons 18 years of age or older *with whom the pharmacist has a bona fide pharmacist-patient relationship and* in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § **54.1-3466**, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;

6. Drugs as defined in § **54.1-3401**, devices as defined in § **54.1-3401**, controlled paraphernalia as defined in § **54.1-3466**, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ *and vaccines for COVID-19*;

8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention*;*

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ ***54.1-3400*** *et seq.), together with providing appropriate patient counseling; and*

11. Tests for COVID-19 and other coronaviruses.

B. *Notwithstanding the provisions of §* ***54.1-3303****, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:*

1. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.).* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and~~, upon request,~~ provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

~~C.~~ *D.* A pharmacist who administers a vaccination pursuant to ~~subdivision~~ *subdivisions* A 7 *and B 1* shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § **32.1-46.01**.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § ***38.2-3418.16****, in compliance with all requirements of §* ***54.1-3303*** *and consistent with the applicable standard of care.*

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

§ **54.1-3321**. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § **54.1-3303.1**, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*

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

B. To be registered as a pharmacy technician, a person shall submit:

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

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

2. That the Board of Medicine, in collaboration with the Board of Pharmacy and the Department of Health, shall establish a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § **54.1-3303.1** of the Code of Virginia, as amended by this act, by November 1, 2022, and the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq., as amended.

3. That the provisions of subdivisions B 1 and 2 of § **54.1-3303.1** of the Code of Virginia, as amended by this act, shall become effective upon the expiration of the provisions of the federal Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 related to the vaccination and COVID-19 testing of minors.

Virginia Board of Pharmacy

Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio, and Pharmacy Technician Trainees

For the purpose of gaining practical experience to meet requirements for becoming a pharmacist, a registered pharmacy intern is by law allowed to perform tasks restricted to pharmacists provided they are directly monitored by a pharmacist. When a pharmacy intern is engaged in obtaining required practical experience hours, to be used either by the college of pharmacy or submitted to the Board on an affidavit, the pharmacy intern is not counted in the pharmacist to pharmacy technician ratio. For example, one pharmacist could be supervising a pharmacy intern for experience and up to four pharmacy technicians at the same time.

The Board has determined that properly registered pharmacy interns may also act as pharmacy technicians without being registered as such during times when they are not gaining practical experience. Pharmacy interns when acting as pharmacy technicians, shall be considered part of the 1:4 pharmacist to technician ratio.

Pharmacy technician trainees performing technician tasks in a pharmacy, are considered to be acting as pharmacy technicians and as such, are included in the 1:4 pharmacist to technician ratio. Except for the administration of drugs or devices, a pharmacy technician trainee enrolled in a training program for pharmacy technicians may engage in acts pursuant to § 54.1-3321 (A) for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

Agenda Item: Amendment of Guidance Document 110-25

Included in your agenda package are:

- Suggested amendments to Guidance Document 110-25 in redline.
- Suggested amendments to Guidance Document 110-25.

Action needed:

- Motion to amend Guidance Document 110-25.

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Virginia Board of Pharmacy

Life of a Prescription or Written Certification When the Prescriber Is No Longer In Practice

Whenever a prescriber is no longer in practice due to death, extended illness, retirement, relocation, suspension or revocation of the license by the relevant licensing board, or other reason, pharmacists question whether they can ~~fill~~ dispense or continue to ~~refill~~ dispense pursuant to prescriptions or written certifications that were ~~written~~ issued prior to the cessation of practice. There will be prescriptions which have been filled, but for which there are still valid refills remaining, or written certifications for medical cannabis that are unexpired. There will probably also be prescriptions or written certifications ~~written~~ issued prior to the ceasing of practice, but not yet presented to a pharmacy or cannabis dispensary for filling by the patient for any number of reasons. This could include Schedule II prescriptions written with "do not fill until <*future date*>" instructions.

While there is nothing in law that specifically addresses this issue, §54.1-3303 does state that no prescription shall be filled which does not result from a bona fide practitioner-patient-pharmacist relationship. At the point in time when the prescription was written and refills authorized, it is assumed that a bona fide relationship existed and that the prescriber envisioned that the patient could safely receive the authorized refills without further intervention on his part. However, while still in practice, the prescriber would be available for consultation should questions or problems arise. Once the prescriber retires, is suspended, moves from the area, etc., the prescriber ~~he~~ is no longer available for consultation, and there is no longer a relationship if a problem occurs.

The Board believes that, in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the decision to ~~fill or refill~~dispense or continue to dispense pursuant to these prescriptions or written certifications should be left to the professional judgment of the pharmacist. Each prescription or written certification should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. At the same time, each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write a new prescription~~s~~ or written certification for any required drugs. In cases where a license is denied, suspended, revoked, or restricted, in whole or part, because of illegal or inappropriate prescribing practices, the pharmacist must carefully evaluate if the written certification was appropriately issued or if the prescription and any remaining refills ~~to determine if~~

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~~the prescription~~ actually resulted from a bona fide practitioner-patient relationship at the time written, and if it was written for a legitimate medical purpose.

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Virginia Board of Pharmacy

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Whenever a prescriber is no longer in practice due to death, extended illness, retirement, relocation, suspension or revocation of the license by the relevant licensing board, or other reason, pharmacists question whether they can dispense or continue to dispense pursuant to prescriptions or written certifications that were issued prior to the cessation of practice. There will be prescriptions which have been filled, but for which there are still valid refills remaining, or written certifications for medical cannabis that are unexpired. There will probably also be prescriptions or written certifications issued prior to the ceasing of practice, but not yet presented to a pharmacy or cannabis dispensary for filling by the patient for any number of reasons. This could include Schedule II prescriptions written with "do not fill until <*future date*>" instructions.

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The Board believes that, in the absence of any specific instructions from the original prescriber or a subsequent practitioner assuming medical care of the patient, the decision to dispense or continue to dispense pursuant to these prescriptions or written certifications should be left to the professional judgment of the pharmacist. Each prescription or written certification should be evaluated on an individual basis to determine which course of action would be in the best interest of the patient. At the same time, each patient should be encouraged to establish a relationship with a new medical practitioner as soon as possible and have that practitioner write a new prescription or written certification for any required drugs. In cases where a license is denied, suspended, revoked, or restricted, in whole or part, because of illegal or inappropriate prescribing practices, the pharmacist must carefully evaluate if the written certification was appropriately issued or if the prescription and any remaining refills actually resulted from a bona fide practitioner-patient relationship at the time written, and if it was written for a legitimate medical purpose.

Agenda Item: Amendment of Guidance Document 110-6

Included in your agenda package are:

- SB511
- Draft Amendments to Guidance Document 110-6 redlined and clean copy.

Action needed:

- Motion to amend Guidance Document 110-6.

CHAPTER 138

An Act to amend and reenact § 54.1-3321 of the Code of Virginia, relating to opioid treatment program pharmacy; medication dispensing; registered nurses and licensed practical nurses.

[S 511]

Approved April 7, 2022

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3321 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

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

B. To be registered as a pharmacy technician, a person shall submit:

1. An application and fee specified in regulations of the Board;

2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and

3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

D. The Board shall waive the initial registration fee for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program

described in subsection B.

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

I. A registered nurse or licensed practical nurse practicing at an opioid treatment program pharmacy may perform the duties set forth for pharmacy technicians in subsection A, provided that all take-home medication doses are verified for accuracy by a pharmacist prior to dispensing.

Guidance Document 110-6

~~Adopted~~Amended: September ~~25~~6, ~~2019~~2022
Effective: ~~November 28, 2019~~October 27, 2022

Virginia Board of Pharmacy
Guidance for Pharmacies within Opioid Treatment Programs

Opioid treatment programs ("OTP") that do not have a need for a full service pharmacy may apply for a special or limited-use permit as described in section 18-VAC-10-20-120 of the Virginia Board of Pharmacy Regulations and must submit the required information with the application and fee. Pursuant to Virginia Code § 54.1-3321(I), a registered nurse ("RN") or licensed practical nurse ("LPN") practicing at an OTP may perform duties otherwise limited to a pharmacy technician under § 54.1-3321(A), provided that all take-home medication doses are verified for accuracy by a pharmacist. Additionally, ~~W~~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 18VAC110-20-190 to allow nurses access to an OTP pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone doses for administration and retrieving pharmacist-verified take home doses of methadone and buprenorphine.

Pharmacies located within an OTP should comply with the following guidance to ensure drug security and protect against diversion:

Preparation of drugs for administration and dispensing

- A pharmacist, ~~or a~~ registered pharmacy technician under the supervision of a pharmacist, or an RN or LPN under the supervision of a pharmacist must prepare the methadone take-home doses or the dispensing of other drugs, to include performing the data entry of information into a computer system, if applicable, and the repackaging and labeling of the drugs. ~~There is no authority for nurses to prepare or pre-label bottles for methadone take-home doses or other drugs for dispensing, as they may not perform duties restricted to a pharmacy technician in § 54.1-3321 unless they are registered as a pharmacy technician.~~
- If certain provisions of 18VAC110-20-190, such as the requirement that the pharmacy enclosure be locked and alarmed at all times when a pharmacist is not on duty, are waived by the Board to allow nurses access to the pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone or buprenorphine doses for administration or retrieving pharmacist-verified take home doses of methadone and buprenorphine, then the nurse may access the key and alarm code for this specific purpose only. The pharmacy must remain locked and alarmed at all other times. ~~The nurse must ensure a valid order for administration exists prior to preparing the drug for administration and must properly maintain a record of administration that contains minimally, the name of the patient, name of ordering physician, drug name, drug strength, quantity of drug administered, and date of administration. The pharmacy's inventory records must also accurately reflect the drug name, drug strength, quantity of drug removed from stock, date, and identification of person removing drug from inventory for patient administration.~~
- Only one drug and strength, as ordered for the patient, may be placed in the container, i.e., do not combine multiple strengths of a single drug or multiple types of drugs in one labeled container. Additionally, caution should be taken to not mix the same drug from multiple manufacturers in the same container.
- The National Drug Code (NDC) for the actual drug dispensed or administered should be accurately captured in the computer system, if applicable, and on all applicable records. If the

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computer defaults to a particular drug strength that is not consistent with the actual drug being dispensed, this must be corrected prior to dispensing or administering to accurately reflect the drug administered or dispensed.

- Per 2008 guidance from the Substance Abuse and Mental Health Services Administration, the label for a methadone take-home dose should include the opioid treatment program's name, address, telephone number, patient's name, medication name, physician's name, and dispensing date. ~~-~~In addition, labels for liquid methadone should include the dose and the directions of use such as "single dose."~~.~~
- The label for dispensed drugs, other than methadone, shall include all required elements for a dispensed prescription drug. ~~-~~For example, the labels for Suboxone® or Subutex® should also include the strength, quantity dispensed, and the appropriate directions of use such as "Take [#] tablet(s) under the tongue once a day" or "Take [#] tablet(s) once a day," respectively.
- Appropriate cautionary statements should also appear on the take-home bottle. ~~-~~According to 21 C.F.R. § 290.5:

  [t]he label of any drug listed as a 'controlled substance' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

  ~~, "[t]he label of any drug listed as a 'controlled substance' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: 'Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.'"~~
- A pharmacist must verify the accuracy of take-home doses and other dispensed drugs in all aspects, including verification that a valid order exists, prior to the patient receiving the drug.

Records

- The pharmacist must ensure records are properly maintained, to include all invoices, orders, and inventories, and should ensure that nurses are properly trained in recordkeeping requirements.
- Drug that is returned to stock must be inventoried. The pharmacist must print a reconciliation report and should routinely review the reconciliation report for accuracy and patterns of possible diversion.
- Overfill in manufacturer packages must be reconciled in the inventory record. The pharmacist may request a letter from the manufacturer regarding the amount of overfill in a bottle.
- The total amount, including overfill, may be accounted for when the bottle is initially added to inventory or the amount of overfill can be added as a separate entry.
- Spillage of drugs must be accurately documented.

Expired drugs

- Expired drugs must be segregated from the working stock and stored within the pharmacy.
- Expired drugs must be included in the inventory record until returned to a reverse distributor. Some software programs offer a "quarantine" feature to identify drugs removed from the working stock.
- Expired drugs should not be "stockpiled", but should be returned to a reverse distributor as soon as possible.

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Guidance Document 110-6

~~Adopted~~Amended: September ~~25~~6, ~~2019~~2022
Effective: ~~November 28, 2019~~October 27, 2022

Naloxone

- Naloxone stored in the pharmacy may be dispensed by the pharmacist pursuant to Virginia Code §54.1-3408. Naloxone dispensed by persons other than a pharmacist should be stored outside of the pharmacy and may be dispensed in accordance with Virginia Code § 54.1-3408.

Relevant statutes and regulations:

Va. Code § 54.1-3321
Va. Code § 54.1-3408
18VAC110-20-190
- 21 CFR § 290.5

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~~***18VAC110-20-190. Prescription department enclosures; access to prescription department.***~~

~~*A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:*~~

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~~*1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.*~~

~~*2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.*~~

~~*3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.*~~

~~*B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:*~~

~~*1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.*~~

~~*2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.*~~

~~*C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.*~~

~~*D. A PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.*~~

~~*E. Upon a request by a patient to obtain an already dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:*~~

~~*1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;*~~

~~*2. Alternate pharmacist coverage cannot immediately be obtained;*~~

~~*3. The technician is accompanied by a member of the pharmacy's management or administration; and*~~

~~*4. All requirements of subsection F of this section are met.*~~

~~*F. Requirements for entry into the prescription department in the absence of a pharmacist.*~~

~~*1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.*~~

~~*2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.*~~

~~*3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.*~~

~~*4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.*~~

~~*5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.*~~

DRAFT
Virginia Board of Pharmacy
Guidance for Pharmacies within Opioid Treatment Programs

Opioid treatment programs ("OTP") that do not have a need for a full service pharmacy may apply for a special or limited-use permit as described in section 18VAC10-20-120 of the Virginia Board of Pharmacy Regulations and must submit the required information with the application and fee. Pursuant to Virginia Code § 54.1-3321(I), a registered nurse ("RN") or licensed practical nurse ("LPN") practicing at an OTP may perform duties otherwise limited to a pharmacy technician under § 54.1-3321(A), provided that all take-home medication doses are verified for accuracy by a pharmacist. Additionally, 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 18VAC110-20-190 to allow nurses access to an OTP pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone doses for administration and retrieving pharmacist-verified take home doses of methadone and buprenorphine.

Pharmacies located within an OTP should comply with the following guidance to ensure drug security and protect against diversion:

Preparation of drugs for administration and dispensing

- A pharmacist, registered pharmacy technician under the supervision of a pharmacist, or an RN or LPN under the supervision of a pharmacist must prepare the methadone take-home doses or the dispensing of other drugs, to include performing the data entry of information into a computer system, if applicable, and the repackaging and labeling of the drugs.
- If certain provisions of 18VAC110-20-190, such as the requirement that the pharmacy enclosure be locked and alarmed at all times when a pharmacist is not on duty, are waived by the Board to allow nurses access to the pharmacy at a time when the pharmacist is not on-duty for the purpose of obtaining methadone or buprenorphine doses for administration or retrieving pharmacist-verified take home doses of methadone and buprenorphine, then the nurse may access the key and alarm code for this specific purpose only. The pharmacy must remain locked and alarmed at all other times.
- Only one drug and strength, as ordered for the patient, may be placed in the container, i.e., do not combine multiple strengths of a single drug or multiple types of drugs in one labeled container. Additionally, caution should be taken to not mix the same drug from multiple manufacturers in the same container.
- The National Drug Code (NDC) for the actual drug dispensed or administered should be accurately captured in the computer system, if applicable, and on all applicable records. If the computer defaults to a particular drug strength that is not consistent with the actual drug being dispensed, this must be corrected prior to dispensing or administering to accurately reflect the drug administered or dispensed.
- Per 2008 guidance from the Substance Abuse and Mental Health Services Administration, the label for a methadone take-home dose should include the opioid treatment program's name, address, telephone number, patient's name, medication name, physician's name, and dispensing date. In addition, labels for liquid methadone should include the dose and the directions of use such as "single dose."

- The label for dispensed drugs, other than methadone, shall include all required elements for a dispensed prescription drug. For example, the labels for Suboxone® or Subutex® should also include the strength, quantity dispensed, and the appropriate directions of use such as "Take [#] tablet(s) under the tongue once a day" or "Take [#] tablet(s) once a day," respectively.
- Appropriate cautionary statements should also appear on the take-home bottle. According to 21 C.F.R. § 290.5:

  > [t]he label of any drug listed as a 'controlled substance' in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

- A pharmacist must verify the accuracy of take-home doses and other dispensed drugs in all aspects, including verification that a valid order exists, prior to the patient receiving the drug.

Records

- The pharmacist must ensure records are properly maintained, to include all invoices, orders, and inventories, and should ensure that nurses are properly trained in recordkeeping requirements.
- Drug that is returned to stock must be inventoried. The pharmacist must print a reconciliation report and should routinely review the reconciliation report for accuracy and patterns of possible diversion.
- Overfill in manufacturer packages must be reconciled in the inventory record. The pharmacist may request a letter from the manufacturer regarding the amount of overfill in a bottle.
- The total amount, including overfill, may be accounted for when the bottle is initially added to inventory or the amount of overfill can be added as a separate entry.
- Spillage of drugs must be accurately documented.

Expired drugs

- Expired drugs must be segregated from the working stock and stored within the pharmacy.
- Expired drugs must be included in the inventory record until returned to a reverse distributor. Some software programs offer a "quarantine" feature to identify drugs removed from the working stock.
- Expired drugs should not be "stockpiled", but should be returned to a reverse distributor as soon as possible.

Naloxone

- Naloxone stored in the pharmacy may be dispensed by the pharmacist pursuant to Virginia Code §54.1-3408. Naloxone dispensed by persons other than a pharmacist should be stored outside of the pharmacy and may be dispensed in accordance with Virginia Code § 54.1-3408.

Relevant statutes and regulations:

Va. Code § 54.1-3321
Va. Code § 54.1-3408
18VAC110-20-190
21 CFR § 290.5

Agenda Item: Amendment of Guidance Document 110-35

Included in your agenda package are:

- Va. Code § 54.1-3408.01.
- Draft Amendments to Guidance Document 110-35.

Action needed:

- Motion to amend Guidance Document 110-35.

8/6/2022

Code of Virginia
Title 54.1. Professions and Occupations
Chapter 34. Drug Control Act

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If the prescriber is providing expedited partner therapy pursuant to § 54.1-3303 and the contact patient's name and address are unavailable, then "Expedited Partner Therapy" or "EPT" shall be affixed on the written prescription, in lieu of the contact patient's name and address. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term-care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

2000, cc. 135, 861; 2002, c. 411; 2003, c. 639; 2006, c. 195; 2009, cc. 813, 840; 2020, c. 464.

VIRGINIA BOARD OF PHARMACY

GUIDANCE ON
VIRGINIA PRESCRIPTION REQUIREMENTS

Written Prescriptions:

- Written prescriptions shall include the patient's first and last name except for expedited partner therapy pursuant to Virginia Code § 54.1-3303. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.

- For prescriptions which provide expedited partner therapy pursuant to Virginia Code § 54.1-3303, "Expedited Partner Therapy" or "EPT" may be entered for the patient's name and address if otherwise unknown. *See* Va. Code § 54.1-3408.01(A).

- The prescription shall contain the prescriber's name, address, and telephone number, and DEA number if for a Schedule II-V prescriptions. Prescriber information shall be either preprinted on the blank, electronically printed, typed, stamped, or printed by hand in a legible manner. Interns and residents in a residency program may use the hospital DEA number and an assigned suffix.

- Prescriptions issued by physician assistants for drugs in Schedule II-V shall also include the name of their collaborating physician or podiatrist. Note: the physician is not required to *co-sign* a physician assistant's prescription for a Schedule II-VI drug.

- As of March 4, 2020, nurse practitioners are no longer issued a separate license for prescriptive authority. Nurse practitioners who have been granted prescriptive authority will have an additional designation of "RX Authority" clearly displayed on their license to practice nursing which begins with the numbers 0024. Nurse practitioners who are authorized for autonomous practice or who are authorized by a practice agreement with a collaborating physician to prescribe Schedule II-VI drugs are not required to include the prescriptive authority number issued to them by the Boards of Nursing and Medicine, if their DEA registration number is included on the prescription. Nurse practitioners who are authorized by a practice agreement to only prescribe Schedule VI drugs and who do not have a DEA number must include the prescriptive authority number issued to them by the Boards of Nursing and Medicine.

- Written prescriptions shall be legibly written with ink or individually typed or printed.

- Written prescriptions may be prepared by an agent for the prescriber's signature, but shall be manually signed by the prescriber.

- Computer-generated prescriptions that are printed out shall be manually signed by the prescriber.

- Written prescriptions shall be dated with the date the prescription is written.

- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

- Prescriptions for Schedule VI drugs may be preprinted with the drug name, directions for use, quantity, but must still meet all other requirements of individually written prescriptions for patient name, signatures, issue date, and any other required information. Preprinted prescriptions may contain a list of drugs with a checkbox beside the drug name to be selected by the prescriber, but only one drug may be selected for each prescription.

- Schedule II prescriptions shall be written and may not be refilled.

- There is no longer a specific format required for written prescriptions. A pharmacist may substitute an Orange-Book rated "therapeutically equivalent drug product" for a brand name drug unless the prescriber prohibits substitution by indicating "brand medically necessary."

- A prescription blank may only contain one prescription. There are a few limited exceptions to this law such as multiple blanks for the Department of Corrections and chart orders for hospital, nursing home, home infusion, and hospice patients.

- A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

    - The chart order was written for a patient while in a hospital or long term care facility.
    - The pharmacist has all information necessary to constitute a valid outpatient prescription.
    - The pharmacist in an outpatient setting must have direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.
    - The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

Requirements of the Virginia Department of Medical Assistance Services for written prescriptions for Medicaid and FAMIS fee-for-service patients:

- Tamper-resistant prescriptions are required for all prescriptions used for Medicaid and FAMIS fee-for-service recipients. Tamper resistant pads are defined as having at least one feature in all three of the following categories:

1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form,
2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, or
3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Oral Prescriptions:

- Oral prescriptions shall contain all the same information as written prescriptions except for the prescriber's signature, and shall be reduced to writing by the pharmacist receiving the prescription.

- The prescriber or his authorized agent may transmit the prescription. If transmitted by an authorized agent, the pharmacist shall record the full name of the agent. According to Virginia law, an authorized agent may only be an employee of the prescriber under his immediate and personal supervision, or if not an employee may only be someone who holds a license to administer drugs, such as a nurse, physician assistant, or another pharmacist. For Schedule II-V oral prescriptions, DEA may interpret the authority of an agent differently, as well as who can be an authorized agent.

Faxed Prescriptions:

- A faxed prescription that starts out as a written prescription and is placed onto a fax machine in the physician's office and sent via phone to a pharmacy's fax machine where a facsimile image is printed for the pharmacy records must meet all requirements for a written prescription, to include the manual signature of the prescriber.

- Computer-generated prescriptions that are faxed must be manually signed by the prescriber.

- Schedule III-VI prescriptions may be faxed to a pharmacy.

- Schedule II prescriptions (or chart orders) may **only** be faxed to a pharmacy for long term care facility patients, home infusion patients, and hospice patients.

- Pharmacies may not begin the dispensing process when a prescription is faxed directly from the patient, even if the patient brings in the hard copy when they come to pick up the medication. Prescriptions may only be faxed from the prescriber's practice location

Electronically transmitted prescriptions:

- An electronically transmitted prescription is one that is generated from the prescriber's office electronically, sent out as an electronic transmission, is normally routed through a switch to the appropriate pharmacy, and is received by the pharmacy in the form of an electronic transmission or is converted by the switch to a fax, and is printed out on the pharmacy's fax machine. "Electronic prescription" means a written prescription that is generated on an

electronic application and transmitted to a pharmacy as an electronic data file. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber that identifies him as the source of the message and indicates his approval of the information contained in the message. If the prescription is generated electronically, but then is printed out in the office and given to the patient, it is no longer an electronic prescription and must follow the guidelines of a written prescription to include bearing the prescriber's manual signature.

- Schedule II - VI prescriptions may be transmitted electronically. Schedule II – V prescriptions must meet all federal requirements including required security and authenticity features, as well as required recordkeeping for the prescriber and pharmacy.

- The application provider used by a prescriber or a pharmacy for electronic prescriptions of Schedules II-V drugs must be reviewed and certified by an approved certification body for compliance with DEA's standards. The application provider must provide a copy of this report to the pharmacy or prescriber using its services. A pharmacy or prescriber shall not dispense or issue an electronic prescription for Schedules II-V drugs until a report is received from the application provider indicating full compliance with DEA's standards. A pharmacy or prescriber may continue dispensing or issuing electronic prescriptions for Schedule VI drugs in compliance with Board regulations prior to receiving a report from the application provider regarding its status of compliance with federal law.

- Individual prescribers authorized to prescribe Schedules II-V drugs who choose to issue electronic prescriptions for Schedules II-V drugs shall first apply to certain federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates.

- An electronic prescription for a Schedule VI drug may either directly populate the pharmacy's automated dispensing system or may be converted by the switch to a fax, and printed out on the pharmacy's fax machine. Federal law does not permit an electronic prescription for a Schedule II-V drug to be converted to the pharmacy's fax machine. It must directly populate the pharmacy's automated dispensing system in conformity with federal law.

- Please refer to the federal regulations for additional guidance.

Agenda Item: Adoption of Guidance Document 110-45 and 110-20

Included in your agenda package are:

- Draft Guidance Document 110-45.
- Draft Guidance Document 110-20

Action needed:

- Motion to adopt Guidance Document 110-45 and 110-20.

DRAFT
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.

Adopted: September 24, 2021
Revised: September 6, 2022
Effective: ~~November 25, 2021~~

VIRGINA BOARD OF PHARMACY

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

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

Notwithstanding 18VAC110-60-135, the Board interprets the requirement for material owners of a pharmaceutical processor or cannabis dispensing facility permit as referenced in § 54.1-3442.6 to mean those owners with 5.0% or greater ownership. For facilities that do not have owners with 5.0% or greater ownership, a criminal background check should be performed on the facility's executive leadership with ownership such as the chief executive officer and chief financial officer.

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

~~***. Permit to operate pharmaceutical processor or cannabis dispensing facility.***~~

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

Virginia Board of Pharmacy
September 06, 2022
Licenses Issued

	2/1/21-4/30/21	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	License Count 8/18/2022
Business CSR	25	44	25	28	35	30	1,496
Cannabis Dispensing Facility			1	2	2	1	5
CE Courses	1	1	1	0	1	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	5	1	6	0	0	4	221
Non-restricted Manufacturer	1	0	1	2	0	2	33
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	1	0	1
Pharmaceutical Processor	0	0	0	0	0	0	4
Pharmacist	175	275	279	157	187	265	16,276
Pharmacist Volunteer Registration	0	0	1	0	1	0	0
Pharmacy	11	10	9	16	9	11	1,768
Pharmacy Intern	107	59	179	87	88	56	1,242
Pharmacy Technician	424	460	353	360	360	531	13,279
Pharmacy Technician Trainee	1256	1414	1280	1385	1042	777	6,487
Physician Selling Controlled Substances	7	19	39	14	17	33	590
Limited Use Practitioner Dispensing	0	0	0	0	0	1	2
Physician Selling Drugs Location	4	4	1	4	2	6	161
Pilot Programs	0	0	0	0	2	1	22
Registered Practitioner For Medical Cannabis	122	162	66	81	106	56	1,007
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	1	0	0	0	0	0	36
Third Party Logistics Provider	1	0	0	0	1	1	7
Warehouser	5	0	1	1	1	1	121
Wholesale Distributor	1	1	1	0	0	0	63
Total	**2,146**	**2,450**	**2,243**	**2,137**	**1,855**	**1,776**	**42,839**

Virginia Board of Pharmacy
September 6, 2022
Nonresident Licenses Issued

	2/1/21-4/30/21	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	License Count 8/11/2022
Nonresident Manufacturer	6	6	10	1	12	4	215
Nonresident Medical Equipment Supplier	8	6	10	5	5	7	356
Nonresident Outsourcing Facility	1	1	1	1	0	2	31
Nonresident Pharmacy	37	17	17	22	25	27	903
Nonresident Third Party Logistics Provider	10	9	4	7	1	8	189
Nonresident Warehouser	12	5	4	5	6	0	99
Nonresident Wholesale Distributor	20	18	14	14	6	7	638
Total	**94**	**62**	**60**	**55**	**55**	**55**	**2,431**

Enforcement Division Inspections Report:

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

Quarterly Review – Date Range 04/01/2022 ending 06/30/2022

Numbers of Inspections Completed by License Type

Count of Insp ID		Insp Type							
Insp Status	License Type	Change of Location	Compliance	Focus	New	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	4			32		5	102	143
	Cannabis Dispensing Facility				1				1
	Medical Equipment Supplier	2			4			15	21
	Non-restricted Manufacturer				3	1		1	5
	Pharmaceutical Processor Permit					1	2	3	6
	Pharmacy	2	1	2	9	4	47	180	245
	Physician Selling Drugs Location	2			7	1		23	33
	Third Party Logistics Provider							2	2
	Warehouser	1			2	1	1	7	12
	Wholesale Distributor							6	6
Completed Total		11	1	2	58	8	55	339	474
Completed	Business CSR	1			2		1		4
	Non-restricted Manufacturer					1			1
	Pharmacy					4	5		9
Completed Virtual Total		1			2	5	6		14
Grand Total		12	1	2	60	13	61	339	488

Enforcement Division Inspections Report:

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

Date Range: 04/01/2022 ending 06/30/2022

Routine Inspections, Deficiencies by License Type

Count of Insp ID	Result			
License Type	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	41		61	102
Medical Equipment Supplier	3		12	15
Non-restricted Manufacturer			1	1
Pharmaceutical Processor Permit	3			3
Pharmacy	40	97	43	180
Physician Selling Drugs Location	20		3	23
Third Party Logistics Provider			2	2
Warehouser	3		4	7
Wholesale Distributor			6	6
Grand Total	110	97	132	339

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

Enforcement Division Inspections Report:

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

Date Range: 04/01/2022 ending 06/30/2022

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

Description	Number of times for occurrence
110-20-180	24

Deficiency 9a. The alarm system does not include a feature by which any breach shall be communicated to the PIC
Deficiency 9a: Alarm is operational but does not fully protect the prescription department
Deficiency 9: The Alarm is not separation. The enclosure is not locked at all times.
Deficiency 10: Unauthorized access to alarm and locking device to the prescription department

110-20-190	21

Deficiency 12: Storage of prescription drugs not in the prescription department
Deficiency 12: Storage of prescription devices not in the prescription department
Deficiency 108: Emergency access alarm code/key not maintained in compliance
Deficiency 11: Insufficient enclosures or locking devices
A hard copy prescription is not placed on file for every new prescription dispensed and is not being maintained for two years from date of last refill

110-20-240	49

Deficiency 14: The PIC inventory was taken 2 days prior to the effective date of change. The application for the change of the prior PIC was sent into the BOP without an effective date
Deficiency 15: Perpetual inventory not being maintained as required
Deficiency 17: Hard copy prescriptions not maintained or retrievable as required
Deficiency 113: Inventory taken on time, but not in compliance
Deficiency 114: Records of receipt (e.g. invoices) not maintained as required
Deficiency 14: The Pharmacist-in-Charge inventory was taken 3 days prior to the effective date of change
The video camera system did not remain operational during a power outage on 06/03/2022

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

110-20-270	28

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	22

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 policy for alternate delivery does not included a provision for informing patient sand obtaining consent
There is no written contract or agreement between two parties describing the procedures for such delivery
There is a policy and procedure manual in place but not being followed.

110-20-276	20

Deficiency 123: Engaging in remote processing not in compliance

110-20-418	26

Deficiency 142: No record maintained and available for 12 months from date of analysis of dispensing errors/ patient safety
Deficiency 142: Continuous Quality Improvement records were reviewed from 06/21 thru 06/22. The month of Jan 2022 had not record indicated the evolution of incidents or zero reports for the month
Deficiency 142: Incomplete records maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization

110-20-700	27

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 clinic
Access to the controlled substances is not limited to the supervision practioners or to those who are authored
The list of drugs was not signed by the new supervising practitioner

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

54.1-3404	30

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
Current biennial of all stocks on hand of Schedules 1 through V drugs was not available at the time of the inspection
Distribution record does not include the strength of drug
The distribution record does not include the quantity of the drug dispensed
Records of receipt of Vii-V drugs are missing signatures and dates

54.1-3410.2	122

800: Assessment of Risk has not been performed (Inspections Manager Note: Highest number of deficiencies for this category)
Deficiency 20: Pharmacists not checking and documenting repackaging or bulk packaging
Deficiency 20b: Pharmacist not documenting verification of accuracy of sterile compounding
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 26a: Documentation that a person who failed a media-fill test or gloved finertip test has performed low or medial risk level compouding of sterile preporaitons after reciept of failed tes result
Deficiency 28: Compounding copies of commercially available products
Deficiency 29: Unlawful compounding for futher distribution by other entities
Deficiency 32: Have clean room, but not all physical standards in compliance
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 September 6, 2022 - Board of Pharmacy Meeting

54.1-3434	28

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

Enforcement Division Inspections Report:

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

Two Year Review - Date Range: 06/30/2020 ending 06/30/2022

Number of Inspections Completed by License Type

Count of Insp ID		Insp Type								
Insp Status	License Type	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	52			141		8	20	501	722
	Cannabis Dispensing Facility				7		2			9
	Medical Equipment Supplier	15			18				92	125
	Non-restricted Manufacturer	1			7		4	1	3	16
	Pharmaceutical Processor Permit	1					3	10	16	30
	Pharmacy	28	8	7	73	1	29	231	1217	1594
	Physician Selling Drugs Location	5		1	19		5	2	101	133
	Pilot Programs					8				8
	Restricted Manufacturer	1			1				1	3
	Third Party Logistics Provider				2				5	7
	Warehouser	9			10		3	3	60	85
	Wholesale Distributor	3		1	3			3	34	44
Completed Total		115	8	9	281	9	54	270	2030	2776
Completed Virtual	Business CSR	21			77	1	6	12	306	423
	Medical Equipment Supplier	4			6			2	21	33
	Non-restricted Manufacturer						1			1
	Pharmacy	7		1	10		19	63	1	101
	Physician Selling Drugs Location	1			6		5	1	8	21
	Pilot Programs					5				5
	Third Party Logistics Provider				1					1
	Warehouser	1			3		1	1	14	20
	Wholesale Distributor				1		2	2	8	13
Completed Virtual Total		34		1	104	6	34	81	358	618
Grand Total		149	8	10	385	15	88	351	2388	3394

Enforcement Division Inspections Report:

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

Date Range: 06/30/2020 ending 06/30/2022

Routine Inspections, Deficiencies by License Type

Count of Insp ID	Result			
License Type	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	378		429	807
Medical Equipment Supplier	44		69	113
Non-restricted Manufacturer			3	3
Pharmaceutical Processor Permit	15		1	16
Pharmacy	398	525	295	1218
Physician Selling Drugs Location	90		19	109
Restricted Manufacturer	1			1
Third Party Logistics Provider	3		2	5
Warehouser	16		58	74
Wholesale Distributor	17		25	42
Grand Total	962	525	901	2388

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

General Announcement-

- Our Enforcement Division has fully transitioned into BOX. All cases and inspections are now completed utilizing this tool.
- Enf. Staff are continuing to assist and support Boards and other DHP staff during the transitions.

Two Staffing Announcements -

- Pharmacy Inspector, Amy Branson, Pharm.D, successfully completed the Critical Point Sterile Compound Training course.
- Interviews for the Senior Inspector position in Central Virginia will take place on August 16, 2022. We had excellent candidates and by the time of the Board meeting, I may be able to announce the selected candidate.

Reports Extracted on 08/11/2022 -

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

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

Pharmaceutical Processors Report-September 6, 2022

- One additional cannabis dispensing facility has been permitted during the last quarter, for a total of seven cannabis dispensing facilities.
- The RFA for a pharmaceutical processor permit in Health Service Area I that was posted from September 25, 2020 to December 4, 2020 resulted in 26 applications being received. Currently the application review process continues to be on hold due to a court order.
- With the change to the requirement for patients/parents/legal guardians to register with the Board, the number of applications received has decreased significantly. For the month of July, just under 1,000 total applications were received.
- The Board of Pharmacy/DHP successfully completed contract negotiations for a new patient and product registration portal with Bio Track. Board and agency staff continue work to develop specific components of the new registration platform.
- The Board has been developing regulations and procedures to address the 2022 legislative changes impacting the program.
- The Board successfully initiated the receipt of new patient written certifications required to be submitted by each dispensary utilizing Box. This was a requirement of the July 1 patient registration legislative changes.
- The pharmaceutical processor program has implemented its own, distinct call center to address the volume of medical cannabis related phone inquiries.

Pharmaceutical Processors Program-By the Numbers
As of 8/11/2022

Registered Practitioners	1,001
Registered Patients	48,297
Registered Parents/Guardians	229
Registered Agents	176
Registered Cannabis Oil Products (cumulative)	1,691

Discipline Program Report

Open Cases as of 8/19/22:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	TOTALS
Patient Care Cases	81	13	85	8	8	1	0	5	201
Non-Patient Care Cases	130	15	40	3	3	1	27	0	219
						TOTAL:			**420**

- The Board has two cases currently being appealed in circuit court. In August, the appeals court ruled in favor of the Board in the matter of the Board vs. Pharmacy Services of America, LLC.
- APD has hired a fourth employee to assist with Board of Pharmacy cases.

Pharmacy Monthly Snapshot for June 2022

Pharmacy closed more cases in June than received. Pharmacy closed 31 patient care cases and 35 non-patient care cases for a total of 66 cases.

Cases Closed	
Patient Care	31
Non-Patient Care	35
Total	**66**

Pharmacy has received 19 patient care cases and 35 non-patient care cases for a total of 54 cases.

Cases Received	
Patient Care	19
Non-Patient Care	35
Total	**54**

As of June 30, 2022 there were 212 patient care cases open and 201 non-patient care cases open for a total of 413 cases.

Cases Open	
Patient Care	212
Non-Patient Care	201
Total	**413**

Upcoming Disciplinary Proceedings:

September 27, 2022	Richards-Spruill/Yuan	Informal Conference
October 12, 2022	St. Clair/Garvin	Innovative Pilot Committee
October 18, 2022 (Ratliff recused)	Full Board	Formal Hearings
October 19, 2022	Garvin/Nash	Informal Conference
October 26, 2022 (St.Clair recused x1)	Full Board	Formal Hearings
November 2, 2022	Ratliff/Lee	Informal Conference
November 15, 2022	Full Board	Formal Hearings
November 17, 2022	Garvin/Nash	Informal Conference
December 6, 2022	Full Board	Formal Hearings
December 7, 2022	Richards-Spruill/Yuan	Informal Conference
January 3, 2023	Ratliff/Lee	Informal Conference
January 4, 2023	Full Board	Formal Hearings
January 11, 2023	Garvin/Nash	Informal Conference

Executive Director's Report – September 6, 2022

Staffing:

- Staff is currently teleworking one or two days/week.
- Recently hired licensing administrative assistant.
- Recruiting for vacant records administrative assistant.
- Executive Assistant on extended leave until mid-October.
- Planning teambuilding activity.

Projects:

- Entered contract for new licensing software for cannabis program; planning implementation.
- Transition to digital disciplinary evidence packets and meeting agendas; Use of Box, SharePoint, and DocuSign.
- Researching development of BOTs to assist with licensing activities.
- Continued participation with SAMHSA regarding buprenorphine access.
- Eliminating paper Board orders
- Developing additional online licensure applications; recent MLO upgrade
- Pharmacy technician training high school initiative

Recent Meetings Attended:

- Virginia Alliance for Animal Shelters
- New Board Member Orientation
- Industrial Hemp Taskforce
- E-prescribing Opioids Workgroup
- Statewide Protocol Workgroup
- Drug Donation Workgroup
- Virginia Pharmacists Association
- NABP Executive Committee

Upcoming Meetings:

- Tri-Regulator Meeting
- Tri-Regulator Symposium
- FDA 50-State Intergovernmental Meeting
- International Pharmaceutical Federation
- NABP Executive Officer Interactive Forum and Leadership Academy
- NABP/AACP Districts 1 & 2 Meeting