



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Third Floor
Henrico, Virginia 23233

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

Tentative Agenda of Full Board Meeting

May 19, 2025

9AM

TOPIC

PAGES

Call to Order of Public Hearing: Cheri Garvin, RPh, Chairman

- Welcome & Introductions
- Scheduling of Drugs in Schedule I

106-111

Adjournment of Public Hearing

Call to Order of Full Board Meeting:

- Approval of Agenda

Approval of Previous Board Meeting Minutes:

- Full Board Meeting, March 25, 2025
- Formal Hearing, March 25, 2025
- March 27, 2025, Innovative Pilot Program
- Formal Hearing, April 15, 2025
- Educational Forum, April 25, 2025

3-10

11-13

14-15

16-22

23-27

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

DHP Director's Report: Arne Owens

New Business:

- Review Current Revenue and Expenditures
- Election of Chairman and Vice Chairman

28-29

Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh

- Chart of Regulatory Actions
- Adopt Fast-track and Exempt Regulatory Amendments to Chapter 20 regarding Other Opioid Antagonists
- Amend Guidance Document 110-44, *Naloxone or Other Opioid Antagonist Protocols*
- Adoption of Guidance Document 110-20 to address HB2378
- Amend Guidance Document 110-6, *Guidance for Pharmacies within Opioid Treatment Programs*
- Adoption of exempt regulatory action to conform to General Assembly scheduling legislation
- Adoption of exempt regulatory action – addition of chemicals to Schedule I
- Adopt Exempt Regulatory Amendments 18VAC110-21-141
- Amend Guidance Document 110-34, *Manufacturer, Third-party Logistics Provider, Warehouser, and Wholesale Distributor Licensure Guidance*
- Amend Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*

30-33

34-49

50-70

71-73

74-86

87-105

106-111

112-117

118-120

121-138

- Review 2026 Legislative proposals regarding finances and fees of the agency

139-142

Reports:

- Chairman's Report - Cheri Garvin, RPh
- Report on NABP Annual Meeting, Derek Webb, PharmD
- Report on Licensure Program – Ryan Logan, RPh
- Report on Inspection Program – Beth O'Halloran, RPh
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD
- Executive Director's Report – Caroline D. Juran, RPh

143-146

147-150

151-162

163

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

Adjourn

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

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING**

Tuesday, March 25, 2025

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

CALL TO ORDER: A full board meeting was called to order at 9:05AM.

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

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

MEMBERS ABSENT: **Cheri Garvin**, RPh, Chairman
Patricia Richards-Spruill, RPh

STAFF PRESENT: **Caroline Juran**, RPh, Executive Director, Virginia Board of Pharmacy
Arne Owens, Director, DHP (left at 10AM)
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP (left at 11:05AM)
James Rutkowski, JD, Senior Assistant Attorney General
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy

**PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING:** Michael Elkin (CT License Number: PCT.0006418)
Natalie Nguyen (VA License Number: 0202213050)

QUORUM: With 8 members present, a quorum was established.

APPROVAL OF AGENDA:

Hearing no comment, Dr. Yuan indicated the meeting agenda packet was approved as presented.

**APPROVAL OF PREVIOUS
BOARD MEETING
MINUTES:**

Hearing no comment, Dr. Yuan indicated the previous meeting minutes for the meetings held between December 17, 2024, and March 10, 2025 and as listed in the agenda packet, were approved as presented.

Dr. Natalie Nguyen provided public comment on behalf of the Virginia Society of Health-System Pharmacists (VSHP). Dr. Nguyen expressed VSHP's gratitude towards the Board for their recent collaboration on legislative matters and challenges resulting from water issues in the City of Richmond. She informed the Board of VSHP's upcoming spring seminar and encouraged attendance as CE credit will be provided.

Jamie Fisher provided public comment on behalf of the Virginia Pharmacy Association (VPhA). Ms. Fisher thanked the Board for their recent engagement during the 2025 General Assembly. Additionally, she thanked the Board for their continued efforts for improvement of pharmacy working conditions. Ms. Juran was identified for her participation at the recent VPhA Annual Meeting held in February 2025.

DHP DIRECTOR'S REPORT:

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

- The General Assembly passed SB1363 which will eliminate the Board of Health Professions.
- The General Assembly will reconvene on April 2, 2025 to consider the Governor's amendments.

**LEGISLATIVE/
REGULATORY/GUIDANCE**

LEGISLATIVE REPORT:

Ms. Barrett reviewed the Legislative Report handout and provided the following updates as of March 24, 2025:

- HB 1724 Prescription Drug Affordability Board established: drug cost affordability review – Not approved by Governor.
- HB 2104 Seizure rescue medications; administration by certain school employees; possession by certain students – Approved by Governor.
- HB 2269 Hospitals; reports of threats or acts of violence against health care providers – Approved by Governor.
- HB 2307 Prescription Monitoring Program; requirements of practitioners; pharmacy technicians; training program – Approved by Governor.
- HB 2319 Drug paraphernalia; controlled paraphernalia; drug checking products; exception – Approved by Governor.
- HB 2378 Therapeutically equivalent drug products; provisions for return of outdates drugs – Approved by Governor.
- HB 2392 Health insurance; pharmacy benefits managers; definition of

- covered entity – Approved by Governor.
- HB 2473 Board of Pharmacy; long-acting injectable or extended-release prescription drugs; correctional facilities – Approved by Governor.
- SB 745 Board of Pharmacy; therapeutic interchange; work group; report – Approved by Governor.
- SB 1257 – Public institutions of higher education; student and campus safety; training in opioid antagonist administration for resident assistants required – Approved by Governor.
- HB 1861 – Department of Health Professions; health regulatory boards; regulations; licensure by endorsement – Approved by Governor.
- HB 2525 – Health insurance; electronic prior authorization; work group; report – Approved by Governor.
- SB 826 – Department of Professional and Occupational Regulation; Department of Health Professions; predetermination for licensing eligibility; prior convictions – Approved by Governor.
- SB 1363 – Elimination of Boards of Health Professions; transfer of powers and duties – Approved by Governor.

CHART OF REGULATORY ACTIONS:

Ms. Barrett briefly reviewed the chart in the agenda packet and provided the following updates:

- 18VAC110-20 Emergency/NOIRA regarding the requirements for use of central fill pharmacy and remote database is now at the Governor's office.
- 18VAC110-20 final regulations regarding the exemption of ADDs stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555 is currently out for publication. It will become effective on 5/21/2025.
- 18VAC110-20 fast-track regulations regarding the replacement of analytic lab regulation for pharmaceutical processors is now at the Department of Planning and Budget
- 18VAC110-20 proposed regulations regarding the allowances for emergency drugs by EMS agencies is now at the Department of Planning and Budget.
- 18VAC110-20 fast-track regulations regarding the removal of chemicals and drugs currently listed in both regulation and the Code is now at the Department of Planning and Budget.
- 18VAC110-20 proposed regulations regarding the crisis stabilization services and use of automated dispensing systems and remote dispensing systems is now at the Department of Planning and Budget.

ADOPTION OF FINAL

**REGULATORY CHANGES
FOR PHARMACY WORKING
CONDITIONS**

The Board reviewed and discussed the adoption of the final regulatory changes for pharmacy working conditions. The review consisted of draft final regulations regarding pharmacy working conditions, Town Hall summary page showing no public comments were received on the subject, and Chapter 628 of the 2022 Acts of Assembly.

MOTION:

The Board voted unanimously to adopt final regulations regarding pharmacy working conditions. (motion by Webb, seconded by Nash)

**ADOPTING FINAL
REGULATORY CHANGES
IMPLEMENTING FEE
INCREASES**

The Board reviewed and discussed the adoption of final regulatory changes for implementing fee increases. Juran and Barrett reported that the agency is researching the possibility of a legislative proposal for receiving general funding for the agency's IT needs. The Board is also researching a possible legislative proposal for recouping investigative costs like the current allowance for the Board of Dentistry. Additional cost-saving measures include the elimination of printing and mailing agenda packets for Full Board Meetings, Regulation Committee Meetings, and IFC Hearings. Such information will be provided electronically as of April 25, 2025. Dr Ratliff suggested changing routine pharmacy inspections to every three years if the previous inspection demonstrated compliance. Ms. Juran indicated that such a change could be considered but it may not yield cost-savings due to inspection needs associated with the other facility categories licensed by the Board.

ACTION ITEMS:

Staff will include the current budget with revenue and expenditures in the next full board meeting agenda packet and then potentially annually thereafter. Staff will also keep the Board informed on any actions taken on the possible cost-saving efficiencies that were discussed.

MOTION:

The Board voted unanimously to adopt the final regulations implementing the fee increases as presented. (motion by Kocot, seconded by Nash)

**ADOPT FINAL
REGULATORY CHANGES
FOR 2023 PHARMACISTS
INITIATING TREATMENT:**

The Board reviewed and discussed the adoption of final regulatory changes for 2023 pharmacists initiating treatment. The review consisted of the draft regulations regarding changes required by 2023 legislation for pharmacists initiating treatment, Chapter 171 of the 2023 Acts of Assembly, and information from Regulatory Town Hall indicating that zero public comments were received during the last public comment opportunity.

MOTION

The Board voted unanimously to adopt final regulations regarding 2023 legislation for pharmacists initiating treatment as presented. (motion by Nash, seconded by Kale)

**ADOPTION OF
AMENDMENTS TO**

Guidance Document 110-38 was last amended at the December 2024 board meeting, but staff noted an inconsistency between the adopted language and

**GUIDANCE DOCUMENT
110-38 *REQUIREMENT FOR
NON-RESIDENT
PHARMACIES AND
OUTSOURCING FACILITIES
TO SUBMIT CURRENT
INSPECTION REPORT:***

MOTION

current practice. The alternative inspection options for a nonresident outsourcing facility should apply to both a new registration and a renewal. However, the alternative inspection options for an outsourcing facility located in Virginia should only apply to renewals since Virginia performs an abbreviated opening inspection of in-state outsourcing facilities.

The Board voted unanimously to adopt the amendments to Guidance Document 110-38 as presented. (motion by Nash, seconded by Dowdy)

NEW BUSINESS

**UPDATE FROM VCU
SCHOOL OF PHARMACY,
KELECHI C. (K.C.)
OGBONNA, PHARM.D.,
MSHA, DEAN & PROFESSOR**

Dean Ogbonna presented a PowerPoint presentation explaining VCU School of Pharmacy's (SOP) mission, curriculum, and contribution to the workforce of the Pharmacy industry. The presentation discussed the school's strategic plan in action. He stated the Bachelor of Science in Pharmaceutical Sciences degree provides a direct entry from high school and that students are able to transfer to the PharmD degree in their fourth year, if desired, which will eliminate one year of study. It is thought that many with this degree will have careers in the pharmaceutical industry. He referenced NextGen, pharmacy technician training program, student success through debt-free education, and research excellence. The SOP averages 80 students but the demographic cliff over the next 5-7 years will result in fewer undergraduate students. Pharmacists can address inadequacies with primary care but challenges with payment, and integration and operability with software must be addressed. Diagnostic evaluations are an ACPE curriculum standard. He stated we must continue to teach students on use of technology and artificial intelligence and continue to embrace a standard of care regulatory structure.

**PRESENTATION AND
ADOPTION OF 2024
PHARMACIST AND
PHARMACY TECHNICIAN
HEALTHCARE
WORKFORCE SURVEY
REPORTS:**

Barbara Hodgdon, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division, presented a PowerPoint presentation reporting the key findings of the 2024 Pharmacist and Pharmacy Technician Workforce Surveys. Highlights of the surveys included:

- There has been a consistent increase in Pharmacist licensees in Virginia's workforce since 2013. There has been a 9% increase in Pharmacist FTEs provided in state between 2013 and 2024.
- Trends in Pharmacist Demographics reveals an increase in female percentage over time. There has been a slight increase in the median age since 2023. However, there has been a slight decrease in pharmacists under the age of 40 since between 2023 and 2024.
- The typical pharmacist earned between \$130,000 and 140,000 in 2024.
- 75% percent have earned a doctorate. 40% carry educational debt with a median debt between \$120,000 and \$140,000.
- 24% of pharmacists are utilizing at least one statewide protocol.

- There has been a decrease in the percentage of pharmacists intending to retire by the age of 65 since 2021.
- There has been a decrease in total number of Pharmacy Technician registrants compared to 2014 but there are 8,016 pharmacy technician trainees that are not included in the report since they do not renew their trainee registration.
- The Pharmacy Technician workforce demographics reveals the workforce consists of 85% women. The median age has risen to 37 years of age.
- The median income for a pharmacy technician has increased to \$35,000 to \$40,000 per year. The median income is higher than the median education debt of a pharmacy technician.
- There has been a decrease in pharmacy technicians intending to retire by the age of 65 since 2021.

MOTION

The Board voted unanimously to adopt the 2024 Pharmacist and Pharmacy Technician Healthcare Workforce Survey Reports as presented. (motion by Dowdy, seconded by Nash)

SELECT DATES FOR 2026 MEETINGS:

The Board requested to receive the possible 2026 dates via a Doodle Poll to allow more time to review their calendars.

CONSIDERATION OF AGENCY SUBORDINATE RECOMMENDATIONS:

The Board agreed to move this discussion to the end of the meeting since it may necessitate going into closed session.

REPORTS

CHAIRMAN'S REPORT:

Dr. Yuan provided the Chairman's report by informing the Board and public of the upcoming Educational Forum scheduled to be held on Friday, April 25th.

TRI-REGULATOR SYMPOSIUM AND OPIOID REGULATORY COLLABORATIVE MEETING:

Dr. Webb provided an overview of his experience at the Tri-Regulator Symposium and Opioid Regulatory Collaborative meeting held earlier in the month.

LICENSURE PROGRAM:

Mr. Logan presented the Licensing Report of Individuals and In-State Facilities which included data from August 2023 through March 2025. As of March 10, 2025, the Virginia Board of Pharmacy consisted of 45,531 total licensees. The Board reviewed graphs documenting the license count of Pharmacists, Pharmacy Technicians, Pharmacy Technician Trainees,

Pharmacy Interns, Resident Pharmacies, and Non-Resident Pharmacies from Q1 2022 through Q2 2025. The Board reviewed graphs documenting the comparison of Resident Pharmacy closures and openings from Q3 2022 through Q2 2025.

INSPECTION PROGRAM:

Ms. O'Halloran presented the Inspections Report including data from October 2024 through December 2024. The reporting period of October 1st through December 31st of 2024 reveals the Inspection Program conducted a total of 488 pharmacy inspections. The 488 pharmacy inspections consisted of 402 in-person inspections and 86 virtual inspections. The top five reported deficiencies are as followed:

- 133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2 (cited 20 times)
- 127. Repackaging records and labeling not kept as required or in compliance (cited 10 times)
- 130A. Compounded products not properly labeled (cited 10 times)
- 15. Perpetual inventory not being maintained as required as it does not include all Schedule II drugs received or dispensed; accurately indicate the physical count of each Schedule II drug "on hand" at the time of the performing inventory; include a reconciliation of each Schedule II drug at least monthly; or include a written explanation of any difference between the physical count and theoretical count. (cited 9 times)
- 148. Theft/unusual loss of drugs reported to the board but report not maintained by pharmacy. (cited 9 times)

DISCIPLINARY PROGRAM:

Dr. Shinaberry presented the Disciplinary Program Report. As of February 27, 2025, the Virginia Board of Pharmacy had a total of 339 open disciplinary cases consisting of 182 patient care cases and 157 non-patient care cases. The Board reviewed graphs documenting the reports of total open or active cases over time, year-to-date composition of cases received for a possible summary suspension, cases at Probable Cause, cases at the Adjudication Process Division, and cases at Investigation. The upcoming disciplinary hearing schedule was reviewed as well.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran reported the recent meetings and presentations she has attended on behalf of the board.

ACTION ITEM:

Dr. Ratliff recommended that Ms. Juran share with the Joint Commission on Healthcare that it should consider surveying pharmacies to assess their willingness to accept commercial insurance, Medicaid, Tri-Care, Workman's Compensation, and Medicare Part D in the future as part of its pharmacy desert study. He stated that while some pharmacy permits may remain current active, patient access issues may be created as pharmacies can no longer agree to accept low reimbursement rates

from insurance companies. Thus, creating challenges similar to a pharmacy desert when pharmacy permits close.

CONSIDERATION OF
AGENCY SUBORDINATE
RECOMMENDATIONS:

The Board reviewed the agency subordinate's recommendations regarding previous IFC Hearings.

MOTION:

The Board voted unanimously to accept the Agency Subordinate's recommendations as presented. (motion by Kale, seconded by Ratliff)

CONSIDERATION OF
CONSENT ORDERS:

Rebecca Ribley, DHP Adjudication Process Specialist presented a consent order for Board consideration regarding Pensacola Apothecary DBA Everwell Specialty Pharmacy (permit # 0214-002167, case #241176).

Upon a motion by Dowdy and duly seconded by Kale, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of Pensacola Apothecary DBA Everwell Specialty Pharmacy. Additionally, she moved that Caroline Juran, Jim Rutkowski, Ellen Shinaberry, and Sorayah Haden attend the closed meeting because their presence is deemed necessary and will aid the Board in its deliberations.

Upon the motion by Dowdy, and duly seconded by Kocot, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board reconvened an open meeting and announced the decision.

Upon a motion by Webb, and duly seconded by Hoffer, the Board voted 7:1 to accept the consent order for Pensacola Apothecary DBA Everwell Specialty Pharmacy (permit # 0214-002167, case #241176). (Kale opposed)

ADJOURNMENT:

Having completed all business, the meeting adjourned at 2:52 PM.

Caroline Juran, RPh
Executive Director

DATE:

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
FORMAL HEARING

Tuesday, March 25, 2025
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER:

A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 3:00 PM for the purpose of consideration of convening a formal hearing.

PRESIDING:

Cheri Garvin, Chairwoman

MEMBERS PRESENT:

Ms. Kelly Hasty Kale
Dr. Wendy Nash
Dr. Shannon Dowdy
Dr. Kris Ratliff

STAFF PRESENT:

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

QUORUM:

With five (5) members of the Board present, a panel of the board was established.

ANDREA MAJOR
Reg. no. 0230-034860

A formal hearing was held in the matter of Andrea Major, pharmacy technician, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as provided in the notice dated January 10, 2025 and continued by notice dated January 27, 2025.

PANEL:

With five (5) members of the Board present, a panel of the board was established.

STAFF PRESENT:

Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Sr. Assistant Attorney General
Sorayah Haden, Executive Assistant

Christine Andreoli, Adjudication Specialist, presented the case for the Commonwealth. Ms. Major was not present at the hearing and was not represented by counsel.

WITNESSES:

Robyn Lorek, Pharmacist-in-Charge, Carilion Roanoke Memorial Hospital, and Daren Jones, Director of Quality, Diversion and Medication Safety for Carilion Roanoke Memorial Hospital, testified in person on behalf of the Commonwealth.

David Cowras, DHP Investigator, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Ratliff, the Board voted 5-0, 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 Andrea Major. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Dowdy/Ratliff)

DECISION:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Nash, the Board voted 5-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth. Upon a motion by Ms. Kale, and duly seconded by Dr. Nash, the Board voted 5-0 to revoke the pharmacy technician registration of Andrea Major.

ADJOURNED:

2:12 PM

Caroline D. Juran, Executive Director

Date

**VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE**

Thursday, March 27, 2025
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 9:05am.

PRESIDING: Cheri Garvin, Committee Chairman

MEMBER PRESENT: Ling Yuan, Committee Member

STAFF PRESENT: Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Rebecca Ribley, Esq., Adjudication Specialist
Christine Andreoli, Esq., Senior Adjudication Specialist
Tim Reilly, Compliance & Innovative Pilot Program Manager

SENTARA RMH MEDICAL CENTER PHARMACY Julia Bynaker, Pharmacy Supervisor, Pharm D, BCPS, Elsbeth Thurston, IT Pharmacy Specialist, Pharm D, MBA, MHA, and Glenn Kozlowski, Pharmacy Resident, Pharm D, MSHSA, appeared in person to discuss the proposed innovative pilot program “Emergency Department Starter Pack Dispensing” as stated in the Notice dated March 4, 2025.

DISCUSSION: Representatives of Sentara RMH Medical Center Pharmacy presented information related to the application for use of an Emergency Department Starter Pack Dispensing.

DECISION: Upon a motion by Ling Yuan, and duly seconded by Cheri Garvin, the Committee decision was unanimous to approve with conditions for the innovative pilot program “Emergency Department Starter Pack Dispensing.”

HAMPTON ROADS CLINIC Lillian Chamberlain, Clinical Services Administrator and Anthony Crisp, Director, Addiction and Recovery Treatment Services, MA, MBA appeared in person to discuss the proposed innovative pilot program “Hampton-Newport News Community Services Board Mobile Outreach” as stated in the Notice dated March 11, 2025.

DISCUSSION: Representatives of HNNCSB-Hampton Roads Clinic presented information related to the application for use of a Hampton-Newport News Community Services Board Mobile Outreach.

DECISION: Upon a motion by Ling Yuan, and duly seconded by Cheri Garvin, the Committee decision was unanimous to deny the innovative pilot program; however, the Committee approved the expansion of current waivers and additional waivers for HNNCSB-Hampton Roads Clinic to include “Hampton-Newport News Community Services Board Mobile Outreach.”

RIVERSIDE SHORE MEMORIAL HOSPITAL Cynthia Williams, BS Pharm, Vice President/Chief Pharmacy Officer and Inga Mintz, BS Pharm, Pharmacy Manager appeared in person to discuss the proposed innovative pilot program “Use of a Technology-Assisted Workflow System for remote validation of sterile compounding” as stated in the Notice dated March 11, 2025.

DISCUSSION: Representatives of Riverside Shore Memorial Hospital presented information related to the application for Use of a Technology-Assisted Workflow System for remote validation of sterile compounding.

DECISION: Upon a motion by Ling Yuan, and duly seconded by Cheri Garvin, the Committee decision was unanimous to approve with conditions for the innovative pilot program “Use of a Technology-Assisted Workflow System for remote validation of sterile compounding.”

With all business concluded, the meeting adjourned at 2:40 pm.

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
POSSIBLE SUMMARY SUSPENSION PRESENTATIONS
CONSIDERATION OF CONSENT ORDERS & FORMAL HEARINGS

Tuesday, April 15, 2025
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 8:34 AM for the purpose of three possible summary suspension presentations.

PRESIDING:

Cheri Garvin, Chairwoman

MEMBERS PRESENT:

Ms. Kelly Hasty Kale
Dr. Wendy Nash
Dr. Shannon Dowdy
Dr. Kris Ratliff
Dr. Derek Webb
Ms. Michelle Hoffer

STAFF PRESENT:

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

QUORUM:

With seven (7) members of the Board present, a quorum of the board was established.

ANGELA KINSER
Reg. no. 0245-011989

A presentation was provided to consider the possible summary suspension of pharmacy technician trainee Angela Kinser.

Sean Murphy, Sr. Asst Attorney General, presented a summary of the evidence in case no. 244355 for the Commonwealth. He was assisted by Jess Weber, DHP Adjudication Specialist.

CLOSED MEETING:

Upon a motion by Dr. Ratliff, and duly seconded by Dr. Nash, 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 case no. 244355. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Ratliff/Hoffer)

DECISION:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Kale, the Board voted 7-0 to summarily suspend the pharmacy technician trainee registration of Angelle Kinser and to offer a pre-hearing consent order in lieu of a formal hearing.

ADDITIONAL BOARD MEMBER

Board member Larry Kocot arrived for the second possible summary suspension presentation.

NATHAN LEE
Reg. no. 0245-015352

A presentation was provided to consider the possible summary suspension of the registration of pharmacy technician trainee Nathan Lee.

David Robinson, Asst. Attorney General, presented a summary of the evidence in case no. 244906 for the Commonwealth. He was assisted by Christine Andreoli, DHP Sr. Adjudication Specialist.

STACY ALLEN
License no. 0202-214581

A presentation was provided to consider the possible summary suspension of the pharmacist license of Stacy Allen.

David Robinson, Asst. Attorney General, presented a summary of the evidence in case no. 245042 for the Commonwealth. He was assisted by Jess Weber, DHP Adjudication Specialist.

CLOSED MEETING:

Upon a motion by Dr. Ratliff, and duly seconded by Dr. Hoffer, 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 in case nos. 244906 and 245042. Additionally, he moved that Ellen Shinaberry, Caroline

Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Ratliff/Hoffer)

DECISION:

Upon a motion by Ms. Hoffer, and duly seconded by Dr. Webb, the Board voted 8-0 to summarily suspend the pharmacy technician trainee registration of Nathan Lee and to offer a pre-hearing consent order in lieu of a formal hearing.

Upon a motion by Ms. Hoffer, and duly seconded by Mr. Kocot, the Board voted 8-0 to summarily suspend the pharmacist license of Stacy Allen and to offer a pre-hearing consent order in lieu of a formal hearing.

CONSIDERATION OF CONSENT ORDERS

DEREK YOUNG
Case no.

Mr. Mykl Egan, Discipline Case Manager, presented a consent order for reinstatement for consideration by the Board.

CLOSED MEETING:

Upon a motion by Dr. Webb, and duly seconded by Dr. Dowdy, 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 regarding the consideration of a consent order. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Webb/Hoffer)

DECISION:

Upon a motion by Dr. Dowdy, and duly seconded by Ms. Kale, the Board voted 8-0 to offer a consent order in lieu of an administrative proceeding.

AKINA PHARMACY
Case no.

Ms. Caroline Juran, Executive Director, presented for consideration the offering of a consent order simultaneously with a mandatory suspension.

CLOSED MEETING:

Upon a motion by Dr. Webb, and duly seconded by Ms. Kale, 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 regarding the consideration of a consent order. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Webb/Kale)

DECISION:

The Board granted the Executive Director authority to offer a consent order for reinstatement simultaneously with the entry of a mandatory suspension.

FORMAL HEARING

CALL TO ORDER:

A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 10:15 AM for a formal hearing.

PRESIDING:

Cheri Garvin, Chairwoman

MEMBERS PRESENT:

Ms. Kelly Hasty Kale
Dr. Wendy Nash
Dr. Shannon Dowdy
Dr. Kris Ratliff
Dr. Derek Webb
Ms. Michelle Hoffer
Mr. Larry Kocot

STAFF PRESENT:

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

PANEL:

With eight (8) members of the Board present, a panel of the board was established.

ANGELLA DEAN
Reg. no.: 0230-038642

A formal hearing was held in the matter of Angella Dean, pharmacy technician, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as provided in the notice dated February 10, 2025.

David Robinson, Asst. Attorney General, presented the case for the Commonwealth. Ms. Dean was not present at the hearing and was not represented by counsel.

WITNESSES:

Shawn Ledger, DHP Investigator, Daniel Perkins, CVS District Asset Protection Leader, and Rick Clary, Director of Pharmacy, and Mary Lou Harris, CVS Pharmacist in Charge testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Ms. Kale, 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 regarding the pharmacy technician registration of Angella Dean. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Dowdy/Kale)

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Ratliff, the Board voted 8-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth, and to revoke the right to renew of the pharmacy technician training registration of Monasha Mitchell.

FORMAL HEARING

CALL TO ORDER:

A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 11:20 AM for a formal hearing.

PRESIDING:

Cheri Garvin, Chairwoman

MEMBERS PRESENT:

Ms. Kelly Hasty Kale
Dr. Wendy Nash
Dr. Shannon Dowdy
Dr. Kris Ratliff
Dr. Derek Webb
Ms. Michelle Hoffer
Mr. Larry Kocot

STAFF PRESENT:

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

PANEL:

With eight (8) members of the Board present, a panel of the board was established.

JESSICA CROSSLEY
Reg. no.: 0245-014624

A formal hearing was held in the matter of Jessica Crossley, pharmacy technician trainee, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia as provided in the notice dated February 10, 2025.

Jess Weber, DHP Adjudication Specialist, presented the case for the Commonwealth. Ms. Crossley was not present at the hearing and was not represented by counsel.

WITNESSES:

Stephen Shirley, DHP Investigator, Matthew Kline, CVS District Asset Protection Leader, and Whitney Brunet, CVS Pharmacist in Charge, testified in person on behalf of the Commonwealth.

Sara Busi, CVS Pharmacist, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Mr. Kocot, and duly seconded by Dr. Dowdy, 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 regarding the pharmacy technician trainee registration of Jessica Crossley. Additionally, he moved that Ellen Shinaberry, Caroline Juran, Jim 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 Board reconvened an open meeting and announced the decision. (Kocot/Hoffer)

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Dowdy, 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, and to revoke the pharmacy technician trainee registration of Jessica Crossley.

ADJOURN:

12:42 PM

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF EDUCATIONAL FORUM**

Friday, April 25, 2025

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

CALL TO ORDER: A board meeting was called to order at 9:06 AM.

PRESIDING: **Cheri Garvin**, RPh, Chairman

MEMBERS PRESENT: **Shannon Dowdy**, PharmD
Kelly Hasty Kale, RPh
Larry Kocot, JD (left at 2:12 PM)
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Derek Webb, PharmD
Ling Yuan, PharmD, Vice-Chairman

MEMBERS ABSENT: **Patricia Richards-Spruill**, RPh
Michelle Hoffer, JD

STAFF PRESENT: **Caroline Juran**, RPh, Executive Director, Virginia Board of Pharmacy
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Ryan Logan, Deputy Executive Director, Virginia Board of Pharmacy
Beth O'Halloran, Deputy Executive Director, Virginia Board of Pharmacy
Ellen Shinaberry, PharmD, Deputy Executive Director, Virginia Board of Pharmacy

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

QUORUM: With 8 members present, a quorum was established.

APPROVAL OF AGENDA:

MOTION **The agenda was adopted as presented.**

PUBLIC COMMENT:

No public comment was provided.

**STATUS OF PHARMACY
WORKING CONDITIONS**

Ms. Juran provided an update on the board's actions regarding pharmacy working conditions. The Board reviewed the draft final regulations, staffing request or concerns forms, excerpts from the National Association of Boards of Pharmacy Model Act, and statistics regarding monetary sanctions of known working condition cases. The Board encourages schools of pharmacy to inform their students of their rights as a participant in the workforce by informing them of their responsibilities, the availability of the staffing request or concern form, the process of filing complaints with the Board, and any other resources of guidance offered by the Board.

ACTION ITEM:

Staff will ask the deans of the four schools of pharmacy in Virginia if information regarding the working condition regulations is being taught in schools. Staff will also offer to provide a presentation to the students to educate students to this topic.

ACTION ITEM:

Staff will send a link to the staffing requests or concerns form to licensees.

ACTION ITEM:

The board will discuss at a future meeting how it wants to be informed of working condition cases that indicate a violation of 18VAC110-20-113.

**OVERVIEW OF
INSPECTION PROGRAM**

Ms. O'Halloran provided an overview of the inspection program. The overview consisted of the number of inspectors, inspection performance statistics, inspection expenses, frequency of inspections, and inspection-related documents available on the Board's website. Interest to potentially shorten the pharmacy inspection report and adjust the inspection frequency of pharmacies was expressed. Board staff stated it will continue to work with DHP's IT staff to collaborate on more efficient ways to collect data from the inspection reports. Ms. Juran reported that the last ad hoc inspection committee was held on 6/20/2018 and that staff routinely updates the inspection report for accuracy with law or regulatory changes.

ACTION ITEM:

The board will discuss at a future meeting if it will convene an ad hoc inspection committee meeting to discuss the inspection reports and frequency of routine inspections.

**OVERVIEW OF
INNOVATIVE PILOT
PROGRAMS**

Dr. Shinaberry provided an overview of the innovative pilot program. The overview consisted of the authorization of innovative programs outlined in §54.1-3307.2, requirements of pilot application submissions, the board approval process, and a brief summary of currently approved innovative pilots. Ms. Juran reported that several pilots will soon expire when pending regulatory actions become final. Some board members commented that

perhaps there should be more than two members on the committee considering innovative pilot program applications. Dr. Shinaberry stated that she will provide a brief update on pilot programs in her report at the quarterly board meetings.

PHARMACIST LICENSURE TRENDS

Mr. Logan presented pharmacist licensure trends. Jasmina Bjegovic, PharmD, National Association of Boards of Pharmacy, Director of Competency Assessment, joined the presentation via phone. The presentation consisted of the statistics regarding the attempt and pass rate of the North America Pharmacist Licensure Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE). The 2024 Virginia Pharmacist Workforce Survey Report was provided as additional supporting documentation. Dr. Bjegovic stated that the first attempt pass rate for NAPLEX is slightly higher than the all attempts pass rate provided in the agenda packet. There was a brief overview of the Uniform Pharmacy Jurisprudence Exam (UPJE) that is scheduled to be released in 2026. States will need to determine if they wish to recognize the UPJE and if their laws and regulations support such a decision.

PHARMACY TECHNICIAN TRAINEE AND PHARMACY TECHNICIAN REGISTRATION TRENDS

Mr. Logan presented pharmacy technician trainee and pharmacy technician registration trends. As of July 1, 2025, the pharmacy technician registration requirements will be updated to also recognize completion of a training program that is recognized by Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA). There are currently 73 online PTCB-recognized training programs, and 55 physical programs located in Virginia. The presentation included graphs documenting the trend within the Pharmacy Technician Trainees and Pharmacy Technician license count from Q1 2022 through Q2 2025. Statistics regarding the completion of the transition process from Pharmacy Technician Trainee to Pharmacy Technician was provided for board review. The 2024 Virginia Pharmacy Technician Workforce Survey Report was provided as additional supporting documentation.

UTILIZATION OF COLLABORATIVE PRACTICE AGREEMENTS AND STATEWIDE PROTOCOLS

Ms. Juran reviewed information from the 2024 Pharmacists Healthcare Workforce Survey report regarding pharmacist participation in collaborative practice agreements and statewide protocols.

OVERVIEW PROCESS OF HANDLING THEFT AND LOSS REPORTS

Mr. Logan provided an overview of the board's process of handling theft and loss reports. Va. Code §54.1-3404 requires the immediate reporting of any theft or any other unusual loss of controlled substances to the Board. Title 21 Code of Federal Regulations (CFR) §1301.74 requires the reporting of theft or significant loss of any controlled substances to the DEA within one business day of discovery. Between January 1, 2025 and April 17, 2025, the Board received approximately 191 theft and loss notifications or DEA 106

forms.

OVERVIEW OF BYLAWS

Ms. Juran provided an overview of the bylaws of the Board as outlined in Guidance Document 110-12.

ACTION ITEM:

The board will discuss at a future meeting if the bylaws should be amended to have more than two members appointed to the innovative pilot committee. Board members will provide staff with potentially other subjects in the bylaws that it may consider amending in advance of such meeting for research purposes.

INCREASE OF STIMULANT PRESCRIPTIONS

Ms. Juran provided an update regarding the increase in stimulant prescriptions. The following documents were reviewed: graph from the Prescription Monitoring Program showing increased dispensing of stimulants, joint FDA-DEA letter regarding shortages, DEA letter regarding quota allocation process, and the DOJ press release regarding investigations involving Cerebral and Done.

FUTURE AGENDA TOPICS

Board members raised additional topics for possible consideration on future meeting agendas and each topic was voted on. Dr. Nash provided a handout of her suggested topics

ACTION ITEM:

The following topic was approved by vote to be added to a future meeting agenda for discussion:

- **Any actions in Virginia that resulted from the 2013 NABP Report of the Task Force on the Regulation of Pharmacy Benefit Managers (Approved with a 5-2 vote).**

The following subjects were not approved by vote to be added to a future meeting agenda for discussion:

- Decline in pharmacy school enrollment, no longer the most respected profession,
- Development of a dashboard to monitor data points to be determined by the board,
- Suicide awareness.

ACTION ITEM:

Prior to leaving, Mr. Kocot had informed the chairman that he would like the board to review its process for accepting a license for surrender. Because he was not there to provide additional information, the subject will be voted on at a future meeting.

ACTION ITEM:

Ms. Juran will email VPhA and VSHP to encourage them to educate members on suicide awareness.

There was a discussion regarding software limitations in running inspection deficiency reports for board meetings. It was determined that the board is

more interested in reviewing a report of the most cited deficiencies rather than a list of all cited deficiencies. Ms. Garvin reminded members to ask themselves at each board meeting if they are getting the data they need from staff's reports.

MEETING ADJOURNED: 4:15 PM

Caroline Juran, RPh
Executive Director

DATE:

DRAFT

FY 2025 Budget / Actual through March 2025

<u>Revenue</u>	<u>% of the Budget Remaining</u>
-----------------------	---

Revenue FY2025 Budget: 4,983,032.00

Revenue Total through March 2025: 4,682,856.25	6%
--	----

<u>Direct Expenditures</u> (consists of Base Budget, Other Budget, Salary/Wage/Benefit Budget)	<u>% of the Budget Remaining</u>
---	---

Base Budget FY2025: 139,083

Largest Base Budget Expenditure through March 2025:

Postal Services: 16,485.82	41%
----------------------------	-----

Base Budget Total Expenditures through March 2025: 60,294.26	57%
--	-----

Other Budget FY2025: 344,857.00	23%
---------------------------------	-----

Largest Other Budget Expenditures through March 2025:

Building Rentals – Non-State Owned Facilities – New: 77,051.42	28%
--	-----

Fiscal Services: 71,515.73	23%
----------------------------	-----

Other Budget Total Expenditures through March 2025: 264,693.63	23%
--	-----

Salary/Wage/Benefit Budget FY2025: 1,918,871.00

Salary/Wage/Benefit Budget Total Expenditures through March 2025: 1,454,746.87	24%
--	-----

Grand Total – Direct Expenditures Budget FY2025: 2,402,811.00

Total Direct Expenditures through March 2025: 1,779,734.76	26%
--	-----

Allocated Expenditures

Largest Allocated Expenditures through February 2025

Enforcement: 1,187,824.22

Data Center: 536,254.57

Administrative Proceedings: 331,569.83

Total Allocated Expenditures through 2/28/25: 2,645,596

Largest Expenditures for the Board of Pharmacy

	FY 25 Budget	FY25 Projection as of April
Direct salaries and benefits: Board of Pharmacy	1,918,871	1,895,789
Enforcement expenditures including ENF salaries and benefits	1,882,154	1,806,065
IT, including IT salaries and benefits	745,046	790,357
All else	1,838,425	1,770,745
Total expenditures for Board	6,384,496	6,262,956

Board of Pharmacy Cash Balance Report

	FY 2025 Budget	FY 2025 Projection in April 2025
Cash Balance as of June 30, 2024	1,714,255	1,714,255
YTD FY 2025 Revenue	4,983,032	5,034,826
Less: YTD FY 2025 Direct and Allocated Expenditures	6,384,496	6,262,956
Cash Balance Projection as of June 30, 2025	312,791	486,125

Board of Pharmacy
Current Regulatory Actions
As of May 1, 2025

In the Governor's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	3/29/2017	2535 days; 8 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-20	Fast-track	Amendment to clarify application of 18VAC110-20-735	6/21/2023	24 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone
18VAC110-20	Emergency/ NOIRA	Requirements for use of central fill pharmacy and remote database	7/8/2024	38 days	Implements requirements of Chapter 407 of the 2024 Acts of Assembly.

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	1124 days 3.1 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy

18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	1124 days 3.1 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	615 days	Implements changes identified during the periodic review process
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	388 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation
18VAC110-20	Final	Centralized warehouse or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	7/8/2024	276 days	Permits centralized warehouse or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-21	Final	2023 pharmacists initiating treatment	4/3/2025	17 days	Implements 2023 legislation and replaces emergency regulations.
18VAC110-20 18VAC110-21 18VAC110-30 18VAC110-50	Final	Increase in fees	3/27/2025	17 days	Increases fees as needed for the Board to maintain operations.

18VAC110-20	Final	Pharmacy working conditions	4/1/2025	13 days	Implements 2022 legislation; replaces emergency regulations.
-------------	-------	-----------------------------	----------	---------	--

In the Department of Planning and Budget

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Fast-track	Replacement of analytic lab regulation for pharmaceutical processors	5/15/2024	30 days	Replaces the former 18VAC110-60-300(A) into Board of Pharmacy regulations as required by Virginia Code § 4.1-1602
18VAC110-20	Proposed	Allowances for emergency drugs by EMS agencies	1/3/2025	34 days	Replaces emergency regulations.
18VAC110-20	Proposed	Crisis stabilization services and use of automated dispensing systems and remote dispensing systems	1/16/2025	21 days	Replaces emergency regulations.
18VAC110-15	Fast-track	Amendment to allow agency subordinates to hear credentials cases	10/1/2024	1 days	Conforms regulatory language to changes in the Virginia Code.

In the Office of the Attorney General

None.

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC110-20	Final/ exempt	September 2024 scheduling of chemicals in Schedule I	4/21/2025	Effective 5/21/2025
18VAC110-20	Final/ exempt	December 2024 scheduling of chemicals in Schedule I	4/21/2025	Effective 5/21/2025
18VAC110-20	Final/ exempt	September 2024 scheduling action to conform to federal scheduling changes December 2023 – September 2024	4/21/2025	Effective 5/21/2025
18VAC110-20	Final/ exempt	Accessible prescription labels	4/21/2025	Effective 5/21/2025
18VAC110-20	Final	Exemption of ADDs stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555	1/3/2025	Effective 5/21/2025
18VAC110-21	Fast-track	Repeal of outdated sections	5/19/2025	Effective 7/3/2025. Repeals old pharmacy technician training regulations which are obsolete.
18VAC110-20	Fast-track	Removal of chemicals and drugs currently listed in both regulation and the Code	6/2/2025	Effective 7/17/2025
18VAC110-20	NOIRA	Exclusion of private dwellings or residences from operating locations of CSRs	6/2/2025	Public comments will be received 6/2 – 7/2.

Agenda Item: Adoption of fast-track regulatory change to include “other opioid antagonists” in references to naloxone

Included in your agenda package:

- Draft fast-track regulatory changes to portions of 18VAC110-20 to include “other opioid antagonists” where naloxone is referenced; and
- SB1035.

Staff notes: SB1035 reflects changes to Virginia Code § 54.1-3408(Y) to include other opioid antagonists where naloxone is referenced. Due to these changes and previous legislative changes to Virginia Code § 54.1-3408(X) to include the same language, board staff propose amending Chapter 20 regulations in a similar way to reflect current terminology.

Action needed:

- Motion to adopt fast-track regulatory changes as presented.

Project 8324 - Fast-Track

Board of Pharmacy

Inclusion of other opioid antagonists in regulations referring to naloxone

18VAC110-20-540. Emergency drug kit.

A. The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.
2. The contents of the kit or an automated drug dispensing system, as provided in subsection B of this section, shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL, diazepam rectal gel, and the intranasal spray formulation of naloxone or other opioid antagonists may be included.
3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.
 - a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken, it cannot be reasonably resealed without the breach being detected.
 - b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication, resealing, or both. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time, and name and quantity of items removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

B. Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.

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

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

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

authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

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

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.
2. Controlled substances registration applications that indicate a requested inspection date or requests that are received after the application is filed shall be honored provided a 14-day notice is allowed prior to the requested inspection date.
3. Requested inspection dates that do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.
4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.
5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

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

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

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.
2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.
3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.
4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

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

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

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and
3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

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

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

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.
2. In an emergency medical services agency, the operational medical director shall supervise.
3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

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

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized

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

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

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

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

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

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

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

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

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

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
2. The installation and device shall be based on accepted alarm industry standards.
3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.
4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.
5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

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

18VAC110-20-735. Requirements for dispensing of naloxone or other opioid antagonist by trained individuals.

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone or other opioid antagonists and dispense naloxone or other opioid antagonists for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone or other opioid antagonist.
2. Invoices or other records showing receipts of naloxone or other opioid antagonists shall be maintained but 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 on site or off site. 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.
3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone or other opioid antagonists transferred to and from the controlled

substances registration location to the off-site training location, along with date of transfer and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of the person receiving naloxone or other opioid antagonists, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of the trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone or other opioid antagonists.

B. The naloxone or other opioid antagonists shall be labeled with directions for use in accordance with the prescriber's standing order, date of dispensing, name of person receiving the drug, drug name and strength, and the name and the telephone number for the entity associated with the controlled substances registration.

C. The naloxone or other opioid antagonists shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect it from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

E. Except for a prescriber's standing order, which shall be maintained on site for a period of not less than two years from the date of the last dispensing, records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 386

An Act to amend and reenact § 54.1-3408 of the Code of Virginia, relating to opioid antagonists; dispensing and administration by person acting on behalf of an organization.

[S 1035]

Approved March 24, 2025

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;
2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;
3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol;
4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility within the scope of such certification, pursuant to an oral or written order or standing protocol to administer drugs and devices at the medical care facility; or
5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, licensed athletic trainer under contract with a local school division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as

administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a place of public accommodation, as defined in subsection A of § 2.2-3904, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by

the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize the possession and administration of undesignated glucagon as set forth in subsection F of § 22.1-274.2.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

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

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services,

Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee

is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

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

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

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone or other opioid antagonist for overdose reversal may dispense naloxone or other opioid antagonist, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone or other opioid antagonist in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone or other opioid antagonist by and proper disposal of a

hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone *or other opioid antagonist* on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone *or other opioid antagonist* that is greater than the cost to the organization of obtaining the naloxone *or other opioid antagonist* dispensed. A person to whom naloxone *or other opioid antagonist* has been dispensed pursuant to this subsection may possess naloxone *or other opioid antagonist* and may administer naloxone *or other opioid antagonist* to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Agenda Item: Adoption of amendments to Guidance Document 110-44 to include “other opioid antagonists”

Included in your agenda package:

- Draft changes to Guidance Document 110-44 to include “other opioid antagonists” where appropriate;
- SB1035; and
- SB1257.

Staff Notes: While SB1035 amended Va. Code § 54.1-3408(Y) as described in conjunction with the fast-track regulatory action to include “other opioid antagonists” in regulations, SB1257 requires resident assistants in university or college student housing to complete training in the administration of opioid antagonists to individuals believed to be experiencing a life-threatening opioid overdose.

Staff present amendments to Guidance Document 110-44 to address both bills.

Action needed:

- Motion to adopt amendments to Guidance Document 110-44 as presented.

Virginia Board of Pharmacy

Naloxone or Other Opioid Antagonist Protocols

Virginia Code § 54.1-3408(X) and (Y) authorize certain persons to dispense prescription-only naloxone or other opioid antagonists used for overdose reversal pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone or other opioid antagonists pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements. **Note: this protocol does not apply to over-the-counter formulations of naloxone or other opioid antagonists that are available for anyone to obtain without a prescription.**

I. Protocol for the Prescribing and Dispensing of Naloxone or Other Opioid Antagonist by Persons Listed in Virginia Code § 54.1-3408(X)

a. Authorized Dispensers

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

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1
- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers,
- Employees of regional jails,
- School nurses,
- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services,
and
emergency medical services personnel, as that term is defined in § 32.1-111.1,
employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers.

- [resident assistants in a student housing facility at a public institution of higher education who have completed training in the administration of an opioid antagonist for overdose reversal pursuant to § 23.1-802.2, and](#)
- Firefighters.

b. **Required Order**

- Prior to dispensing naloxone or other opioid antagonist, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive the drug or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense the drug. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in § 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.
- If the naloxone or other opioid antagonist is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
 - Name of entity or group of entities authorized to dispense the drug pursuant to standing order;
 - Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 - Prescriber’s signature;
 - Date of issuance; and
 - Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	<u>Intranasal</u>
Naloxone 2mg/2ml prefilled syringe, # 2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg #1 twin pack Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg or 8mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Nalmefene nasal spray, #1 twin pack Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 5 minutes until emergency medical assistance arrives.

c. Required Labeling and Recordkeeping

- i. The dispenser shall affix a label to the naloxone or nalmefene container that bears the name and strength of the dispensed drug, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of drug dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.
- iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

d. Instruction

While not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone or nalmefene, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. Such instruction, the instruction may be accomplished by providing the recipient with the current [REVIVE! Pharmacy dispensing brochure](#) available on the Department of Behavioral Health and Developmental Services website or by clicking on the link. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

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

a. Authorized Dispensers

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

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

- ~~Note: Virginia Code § 54.1-3408(Y) does not currently authorize the dispensing of opioid antagonists other than naloxone.~~

b. Training

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

c. Required Order

- i. Prior to dispensing naloxone or other opioid antagonist, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone or other opioid antagonist. The standing order must contain the following information at a minimum:
 1. Name of organization authorized to dispense naloxone or other opioid antagonist pursuant to standing order;
 2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
 3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
 4. Prescriber's signature;
 5. Date of issuance; and
 6. Amount of time, up to two years from date of issuance, for which the order is valid.

Formatted: Strikethrough
Formatted: Strikethrough

Intranasal	Auto-Injector	Intranasal	Injection*	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg, #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg <u>or 8mg</u>, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.	Naloxone nasal spray 8mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. <u>Nalmefene nasal spray, #1 twin pack</u> <u>Directions:</u> <u>Administer a single spray intranasally into one nostril upon signs of opioid overdose.</u> <u>Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds</u>

Formatted: Left

				and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 5 minutes until emergency medical assistance arrives.
--	--	--	--	---

** Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of, hypodermic needles and syringes, who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organization has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes.*

d. **Registration**

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

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

- i. The dispenser shall affix a label to the naloxone [or other opioid antagonist](#) container that bears the name and strength of the dispensed naloxone [or other opioid antagonist](#), directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.
- ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone [or other opioid antagonist](#) dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.
- iii. The standing order must be maintained for two years from the last date of dispensing.
- iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).
- v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. **Instruction**

While it is not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone or other opioid antagonist, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. Such instruction, the instruction may be accomplished by providing the recipient with the current [REVIVE! Pharmacy dispensing brochure](#) available on the Department of Behavioral Health and Developmental Services website or the link above. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone or Other Opioid Antagonists to Entities Authorized to Possess, Administer, and Dispense Such Drugs

- a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone or nalmefene via invoice to:
 - i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1; or
 - ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, ~~and~~ other school board employees or individuals contracted by a school board to provide school health services, and resident assistants in a student housing facility at a public institution of higher education who have successfully completed a training program.
- b. In addition to wholesale distributors, third-party logistics providers, or manufacturers, a pharmacy may distribute naloxone or other opioid antagonist via invoice to persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone or other opioid antagonist pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

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

IV. Resources

Formatted: Strikethrough

Formatted: Strikethrough

- a. [REVIVE! Pharmacy dispensing brochure](#)
- b. Substance Abuse Mental Health Services Administration’s “Opioid Prevention Toolkit” (2014), available at <http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742>
- c. Prescribe to Prevent, <http://prescribetoprevent.org/pharmacists>
- d. Harm Reduction Coalition, <http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials>
- e. Dispensers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 386

An Act to amend and reenact § 54.1-3408 of the Code of Virginia, relating to opioid antagonists; dispensing and administration by person acting on behalf of an organization.

[S 1035]

Approved March 24, 2025

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;
2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;
3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol;
4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility within the scope of such certification, pursuant to an oral or written order or standing protocol to administer drugs and devices at the medical care facility; or
5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, licensed athletic trainer under contract with a local school division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as

administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a place of public accommodation, as defined in subsection A of § 2.2-3904, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by

the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize the possession and administration of undesignated glucagon as set forth in subsection F of § 22.1-274.2.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

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

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services,

Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee

is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

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

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

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone or other opioid antagonist for overdose reversal may dispense naloxone or other opioid antagonist, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone or other opioid antagonist in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone or other opioid antagonist by and proper disposal of a

hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone *or other opioid antagonist* on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone *or other opioid antagonist* that is greater than the cost to the organization of obtaining the naloxone *or other opioid antagonist* dispensed. A person to whom naloxone *or other opioid antagonist* has been dispensed pursuant to this subsection may possess naloxone *or other opioid antagonist* and may administer naloxone *or other opioid antagonist* to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 446

An Act to amend and reenact § 54.1-3408 of the Code of Virginia and to amend the Code of Virginia by adding in Article 1 of Chapter 8 of Title 23.1 a section numbered 23.1-802.2, relating to public institutions of higher education; student and campus safety; training in opioid antagonist administration for resident assistants required.

[S 1257]

Approved March 24, 2025

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 1 of Chapter 8 of Title 23.1 a section numbered 23.1-802.2 as follows:

§ 23.1-802.2. Resident assistant opioid antagonist administration training required.

A. Each resident assistant in a student housing facility at a public institution of higher education shall complete, prior to the commencement of his duties, training in the administration of an opioid antagonist to any student, faculty, or staff member who is believed to be experiencing or about to experience a life-threatening opioid overdose.

B. Each public institution of higher education in the Commonwealth shall, in accordance with the provisions of subsection X of § 54.1-3408, adopt policies and procedures relating to the possession and administration of an opioid antagonist by each resident assistant in a student housing facility at such institution. Such policies and procedures shall:

1. Require each resident assistant in a student housing facility at such institution to be authorized by a prescriber and trained in the administration of an opioid antagonist prior to the commencement of his duties; and

2. Arrange for the provision of such opioid antagonist administration training required pursuant to subdivision 1 by a program administered or approved by the Department of Health.

§ 54.1-3408. Professional use by practitioners.

A. A practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine, a licensed advanced practice registered nurse pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 shall only prescribe, dispense, or administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice. A licensed midwife pursuant to § 54.1-2957.7 shall only obtain, possess, and administer controlled substances in good faith for medicinal or therapeutic purposes within the course of his professional practice.

B. The prescribing practitioner's order may be on a written prescription or pursuant to an oral prescription as authorized by this chapter. The prescriber may administer drugs and devices, or he may cause drugs or devices to be administered by:

1. A nurse, physician assistant, or intern under his direction and supervision;

2. Persons trained to administer drugs and devices to patients in state-owned or state-operated hospitals or facilities licensed as hospitals by the Board of Health or psychiatric hospitals licensed by the Department of Behavioral Health and Developmental Services who administer drugs under the control and supervision of the prescriber or a pharmacist;

3. Emergency medical services personnel certified and authorized to administer drugs and devices pursuant to regulations of the Board of Health who act within the scope of such certification and pursuant to an oral or written order or standing protocol;

4. Persons who are employed or engaged at a medical care facility, as defined in § 32.1-3, who have a valid emergency medical services provider certification issued by the Board of Health as a requirement of being employed or engaged at the medical care facility within the scope of such certification, pursuant to an oral or written order or standing protocol to administer drugs and devices at the medical care facility; or

5. A licensed respiratory therapist as defined in § 54.1-2954 who administers by inhalation controlled substances used in inhalation or respiratory therapy.

C. Pursuant to an oral or written order or standing protocol, the prescriber, who is authorized by state or federal law to possess and administer radiopharmaceuticals in the scope of his practice, may authorize a nuclear medicine technologist to administer, under his supervision, radiopharmaceuticals used in the diagnosis or treatment of disease.

D. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered nurses and licensed practical nurses to possess (i) epinephrine and oxygen for administration in treatment of emergency medical conditions and (ii) heparin and sterile normal saline to use for the maintenance of intravenous access lines.

Pursuant to the regulations of the Board of Health, certain emergency medical services technicians may possess and administer epinephrine in emergency cases of anaphylactic shock.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or standing protocol that shall be issued by the local health director within the course of his professional practice, any school nurse, licensed athletic trainer under contract with a local school division, school board employee, employee of a local governing body, or employee of a local health department who is authorized by the local health director and trained in the administration of albuterol inhalers and valved holding chambers or nebulized albuterol may possess or administer an albuterol inhaler and a valved holding chamber or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education, or any employee of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is authorized by a prescriber and trained in the administration of (a) epinephrine may possess and administer epinephrine and (b) albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any nurse at an early childhood care and education entity, employee at the entity, or employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of a public institution of higher education or a private institution of higher education who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, any employee of an organization providing outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an order or a standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health, such prescriber may authorize any employee of a restaurant licensed pursuant to Chapter 3 (§ 35.1-18 et seq.) of Title 35.1 to possess and administer epinephrine on the premises of the restaurant at which the employee is employed, provided that such person is trained in the administration of epinephrine.

Pursuant to an order issued by the prescriber within the course of his professional practice, an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may possess and administer epinephrine, provided such person is authorized and trained in the administration of epinephrine.

Pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any employee of a place of public accommodation, as defined in subsection A of § 2.2-3904, who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine.

Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize pharmacists to possess epinephrine and oxygen for administration in treatment of emergency medical conditions.

E. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed physical therapists to possess and administer topical corticosteroids, topical lidocaine, and any other Schedule VI topical drug.

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen and IV saline for use in emergency situations; subcutaneous lidocaine for wound closure; epinephrine for use in emergency cases of anaphylactic shock; and naloxone or other opioid antagonist for overdose reversal.

G. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, and in accordance with policies and guidelines established by the Department of Health pursuant to § 32.1-50.2, such prescriber may authorize registered nurses or licensed practical nurses

under the supervision of a registered nurse to possess and administer tuberculin purified protein derivative (PPD) in the absence of a prescriber. The Department of Health's policies and guidelines shall be consistent with applicable guidelines developed by the Centers for Disease Control and Prevention for preventing transmission of mycobacterium tuberculosis and shall be updated to incorporate any subsequently implemented standards of the Occupational Safety and Health Administration and the Department of Labor and Industry to the extent that they are inconsistent with the Department of Health's policies and guidelines. Such standing protocols shall explicitly describe the categories of persons to whom the tuberculin test is to be administered and shall provide for appropriate medical evaluation of those in whom the test is positive. The prescriber shall ensure that the nurse implementing such standing protocols has received adequate training in the practice and principles underlying tuberculin screening.

The Health Commissioner or his designee may authorize registered nurses, acting as agents of the Department of Health, to possess and administer, at the nurse's discretion, tuberculin purified protein derivative (PPD) to those persons in whom tuberculin skin testing is indicated based on protocols and policies established by the Department of Health.

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize the possession and administration of undesignated glucagon as set forth in subsection F of § 22.1-274.2.

Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a public institution of higher education or a private institution of higher education who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administration of glucagon to a student diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Pursuant to a written order issued by the prescriber within the course of his professional practice, such prescriber may authorize an employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services to assist with the administration of insulin or to administer glucagon to a person diagnosed as having diabetes and who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia, provided such employee or person providing services has been trained in the administration of insulin and glucagon.

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

J. A dentist may cause Schedule VI topical drugs to be administered under his direction and supervision by either a dental hygienist or by an authorized agent of the dentist.

Further, pursuant to a written order and in accordance with a standing protocol issued by the dentist in the course of his professional practice, a dentist may authorize a dental hygienist under his general supervision, as defined in § 54.1-2722, or his remote supervision, as defined in subsection E or F of § 54.1-2722, to possess and administer topical oral fluorides, topical oral anesthetics, topical and directly applied antimicrobial agents for treatment of periodontal pocket lesions, and any other Schedule VI topical drug approved by the Board of Dentistry.

In addition, a dentist may authorize a dental hygienist under his direction to administer Schedule VI nitrous oxide and oxygen inhalation analgesia and, to persons 18 years of age or older, Schedule VI local anesthesia.

K. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize registered professional nurses certified as sexual assault nurse examiners-A (SANE-A) under his supervision and when he is not physically present to possess and administer preventive medications for victims of sexual assault as recommended by the Centers for Disease Control and Prevention.

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers such drugs in accordance with a prescriber's instructions pertaining to dosage, frequency, and manner of administration, and in accordance with regulations promulgated by the Board of Pharmacy relating to security and record keeping, when the drugs administered would be normally self-administered by (i) an individual receiving services in a program licensed by the Department of Behavioral Health and Developmental Services; (ii) a resident of the Virginia Rehabilitation Center for the Blind and Vision Impaired; (iii) a resident of a facility approved by the Board or Department of Juvenile Justice for the placement of children in need of services or delinquent or alleged delinquent youth; (iv) a program participant of an adult day center licensed by the Department of Social Services; (v) a resident of any facility authorized or operated by a state or local government whose primary purpose is not to provide health care services; (vi) a resident of a private children's residential facility, as defined in § 63.2-100 and licensed by the Department of Social Services, Department of Education, or Department of Behavioral Health and Developmental Services; or (vii) a student in a school for students with disabilities, as defined in § 22.1-319 and licensed by the Board of Education.

In addition, this section shall not prevent a person who has successfully completed a training program for the administration of drugs via percutaneous gastrostomy tube approved by the Board of Nursing and been evaluated by a registered nurse as having demonstrated competency in administration of drugs via percutaneous gastrostomy tube from administering drugs to a person receiving services from a program licensed by the Department of Behavioral Health and Developmental Services to such person via percutaneous gastrostomy tube. The continued competency of a person to administer drugs via percutaneous gastrostomy tube shall be evaluated semiannually by a registered nurse.

M. Medication aides registered by the Board of Nursing pursuant to Article 7 (§ 54.1-3041 et seq.) of Chapter 30 may administer drugs that would otherwise be self-administered to residents of any assisted living facility licensed by the Department of Social Services. A registered medication aide shall administer drugs pursuant to this section in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; in accordance with regulations promulgated by the Board of Pharmacy relating to security and recordkeeping; in accordance with the assisted living facility's Medication Management Plan; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

N. In addition, this section shall not prevent the administration of drugs by a person who administers such drugs in accordance with a physician's instructions pertaining to dosage, frequency, and manner of administration and with written authorization of a parent, and in accordance with school board regulations relating to training, security and record keeping, when the drugs administered would be normally self-administered by a student of a Virginia public school. Training for such persons shall be accomplished through a program approved by the local school boards, in consultation with the local departments of health.

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 22.1-289.02 and regulated by the Board of Education or a local government pursuant to § 15.2-914, or (ii) a student of a private school that is accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, a licensed practical nurse, an advanced practice registered nurse, a physician assistant, a doctor of medicine or osteopathic medicine, or a pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

P. In addition, this section shall not prevent the administration or dispensing of drugs and devices by persons if they are authorized by the State Health Commissioner in accordance with protocols established by the State Health Commissioner pursuant to § 32.1-42.1 when (i) the Governor has declared a disaster or a state of emergency, the United States Secretary of Health and Human Services has issued a declaration of an actual or potential bioterrorism incident or other actual or potential public health emergency, or the Board of Health has made an emergency order pursuant to § 32.1-13 for the purpose of suppressing nuisances dangerous to the public health and communicable, contagious, and infectious diseases and other dangers to the public life and health and for the limited purpose of administering vaccines as an approved countermeasure for such communicable, contagious, and infectious diseases; (ii) it is necessary to permit the provision of needed drugs or devices; and (iii) such persons have received the training necessary to safely administer or dispense the needed drugs or devices. Such persons shall administer or dispense all drugs or

devices under the direction, control, and supervision of the State Health Commissioner.

Q. Nothing in this title shall prohibit the administration of normally self-administered drugs by unlicensed individuals to a person in his private residence.

R. This section shall not interfere with any prescriber issuing prescriptions in compliance with his authority and scope of practice and the provisions of this section to a Board agent for use pursuant to subsection G of § 18.2-258.1. Such prescriptions issued by such prescriber shall be deemed to be valid prescriptions.

S. Nothing in this title shall prevent or interfere with dialysis care technicians or dialysis patient care technicians who are certified by an organization approved by the Board of Health Professions or persons authorized for provisional practice pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.), in the ordinary course of their duties in a Medicare-certified renal dialysis facility, from administering heparin, topical needle site anesthetics, dialysis solutions, sterile normal saline solution, and blood volumizers, for the purpose of facilitating renal dialysis treatment, when such administration of medications occurs under the orders of a licensed physician, an advanced practice registered nurse, or a physician assistant and under the immediate and direct supervision of a licensed registered nurse. Nothing in this chapter shall be construed to prohibit a patient care dialysis technician trainee from performing dialysis care as part of and within the scope of the clinical skills instruction segment of a supervised dialysis technician training program, provided such trainee is identified as a "trainee" while working in a renal dialysis facility.

The dialysis care technician or dialysis patient care technician administering the medications shall have demonstrated competency as evidenced by holding current valid certification from an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.).

T. Persons who are otherwise authorized to administer controlled substances in hospitals shall be authorized to administer influenza or pneumococcal vaccines pursuant to § 32.1-126.4.

U. Pursuant to a specific order for a patient and under his direct and immediate supervision, a prescriber may authorize the administration of controlled substances by personnel who have been properly trained to assist a doctor of medicine or osteopathic medicine, provided the method does not include intravenous, intrathecal, or epidural administration and the prescriber remains responsible for such administration.

V. A physician assistant, nurse, dental hygienist, or authorized agent of a doctor of medicine, osteopathic medicine, or dentistry may possess and administer topical fluoride varnish pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, or emergency medical services provider who holds an advanced life support certificate issued by the Commissioner of Health when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers, employees of regional jails, employees of any state agency, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, school board employees who have completed training and are certified in the administration of an opioid antagonist for overdose reversal by a program administered or authorized by the Department of Health, other school board employees or individuals contracted by a school board to provide school health services, *resident assistants in a student housing facility at a public institution of higher education who have completed training in the administration of an opioid antagonist for overdose reversal pursuant to § 23.1-802.2*, and firefighters may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the

Department of Health.

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

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

Z. A person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

AA. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of (i) a school board, (ii) a school for students with disabilities as defined in § 22.1-319 licensed by the Board of Education, or (iii) a private school accredited pursuant to § 22.1-19 as administered by the Virginia Council for Private Education who is trained in the administration of injected medications for the treatment of adrenal crisis resulting from a condition causing adrenal insufficiency to administer such medication to a student diagnosed with a condition causing adrenal insufficiency when the student is believed to be experiencing or about to experience an adrenal crisis. Such authorization shall be effective only when a licensed nurse, an advanced practice registered nurse, a physician, or a physician assistant is not present to perform the administration of the medication.

Agenda Item: Adoption of Guidance Document 110-20 to address HB2378

Included in your agenda package:

- Draft Guidance Document 110-20;
- HB2378.

Staff notes: Following discussions with stakeholders and the patron of HB2378, Board staff believes this guidance document will address questions related to new requirements under HB2378.

Action needed:

- Motion to adopt Guidance Document 110-20 as presented.

Virginia Board of Pharmacy
Guidance regarding Eligibility of Dispensing Therapeutically Equivalent Drugs

A manufacturer of a drug is presumed to have established adequate provisions for pharmacies to return outdated drugs, through the distributor or otherwise, in accordance with § 54.1-3408.03 if the drug product is available for order by pharmacies.

Relevant statutes and regulations:

[Va. Code § 54.1-3408.03](#)

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 270

An Act to amend and reenact § 54.1-3408.03 of the Code of Virginia, relating to prescription drugs; dispensing of therapeutically equivalent drug products; provisions for return of outdated drugs.

[H 2378]

Approved March 21, 2025

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3408.03 of the Code of Virginia is amended and reenacted as follows:

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

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

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

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

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

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

E. A therapeutically equivalent drug shall be eligible for dispensing only if the manufacturer has established adequate provisions for the return of outdated drugs, through the distributor or otherwise, by pharmacies. Such provisions shall permit pharmacies to return drugs in both full and partial containers up to six months after the label expiration date for full credit or replacement.

Agenda Topic: Amend Guidance Document 110-6, *Guidance for Pharmacies within Opioid Treatment Programs*

Background: In 2021, DEA published a final rule allowing narcotic (opioid) treatment programs to operate a mobile component associated with a DEA-registered opioid treatment program without needing separate registration.

Hampton Roads Clinic was recently approved to operate a mobile medication unit under the limited-use pharmacy permit issued to its opioid treatment program. Several waivers of regulation were necessary for compliance. Amending Guidance Document 110-6 will inform other opioid treatment programs of how to gain approval from the Board of Pharmacy to operate a mobile medication unit.

•Included in agenda packet:

- SAMHSA article on Mobile Medication Units (provided as background info)
- Draft amendments to Guidance Document 110-6

Action Needed: Amend Guidance Document 110-6 as presented or amended.

Mobile Medication Units and Health Clinics

About the Issue – Expanding Access to Opioid Use Disorder Treatment

Opioid use disorders (OUDs) have been identified by the U.S. Department of Health & Human Services as a national public health crisis.¹ The impact of opioid misuse and use disorders on individuals, families, communities, the healthcare system, and society is far-reaching and often devastating. In 2021, an estimated 9.2 million Americans ages 12 or older used opioids without a prescription, and 5.6 million were determined to have an OUD.² People who misuse opioids or have an OUD are at a much higher risk of early death, primarily from accidental overdose, trauma, suicide, and infectious disease, and there is a higher rate of involvement in the criminal-legal system.³ There has been an increase in opioid-involved overdose deaths in the past decade, with 21,089 reported in 2010 and 80,411 reported in 2021.⁴ Mobile medication units (MMUs)

FDA-APPROVED MEDICATIONS FOR OPIOID USE DISORDER

Methadone • Buprenorphine • Naltrexone

of opioid treatment programs (OTPs) and mobile health clinics (MHCs) for opioid conditions can be a promising solution by expanding access to effective prevention, harm reduction, treatment, and recovery support services and offer important means to address the opioid crisis.

The Need – Medications for Opioid Use Disorder

Extensive research shows the efficacy of medications for opioid use disorder (MOUD), but MOUD remains underutilized across the United States.⁵ The Controlled Substances Act of 1970 required that methadone for the treatment of an addiction to opioids had to be dispensed in specialty addiction treatment clinics, known as OTPs. OTPs must be registered with the Drug



Vehicles for Change – Mobile Medication Units and Health Clinics

Two service models for expanding access to MOUD are the use of MMUs and MHCs for the treatment of OUD. MMUs are large, modified recreational vehicles (RVs) that travel to multiple locations to dispense MOUD, primarily methadone, and to provide other services typically provided in an OTP, including harm reduction, substance use disorder (SUD) treatment, recovery supports, and referrals to other needed services. These are satellites of OTPs that are registered with the DEA and certified by SAMHSA. MHCs for opioid conditions are similarly outfitted vehicles that can offer a range of primary care, harm reduction, and SUD treatment services, including the provision of naltrexone and prescriptions for or referral to other forms of MOUD.

MMUs and MHCs expand people's ability to access MOUD. These advantages include the ability to serve patients in multiple geographic locations within a single day and to provide access to MOUD for persons in correctional settings, residential treatment programs, or nursing homes. MMUs and MHCs can provide better access in communities where there are obstacles to receiving care and can support continuity of services, as patients are more likely to remain connected to services that are offered in multiple locations. Mobile programs can also be used during natural disasters and other emergencies to ensure patients continue to receive their medications. States and community providers can work together to implement MMUs or MHCs as a strategy to better reach and serve persons with OUD.

Enforcement Administration (DEA), certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), and adhere to respective state regulations. OTPs have often been disconnected from mainstream healthcare systems and are inaccessible in many geographic areas.⁶ Unfortunately, due to numerous constraints large portions of the country still lack access to lifesaving services and MOUD that improve the quality of life for those in need of treatment.

To access treatment at an OTP, some people must travel long distances for dosing daily. Further, research shows that MOUD can be especially difficult to access for underserved populations, including racial and ethnic minoritized individuals, persons experiencing homelessness, people who live in rural areas or in areas with limited public transportation, persons lacking health insurance, or those who are unemployed.⁷ These challenges have an adverse effect on successful treatment outcomes through hindering service engagement and treatment adherence.

What Are Mobile Medication Units?

MMUs emerged in the 1980s to enhance access to methadone treatment in rural communities and in urban areas where there was opposition to opening brick-and-mortar OTPs.⁸ After a hiatus on establishment of new units, in July 2021, the DEA finalized new rules that allowed OTPs to establish and operate MMUs without obtaining a separate DEA registration for each mobile component, and in November 2021, SAMHSA issued new guidelines on services that can be provided on MMUs and the use of SAMHSA funds for this purpose. The new rules expanded the opportunity for OTPs to reach people where they live and work and areas without access to MOUD treatment. Existing OTPs may add a mobile component to their services, and they can provide the full range of services available within OTPs. The MMUs are required to return to their respective DEA registered OTP daily and re-secure all medications within the physical building, as the OTP is responsible for medication ordering, storage, security, and recordkeeping.⁹

Mobile Medication Units are tied to existing OTPs and may travel to multiple locations to administer and dispense MOUD.

MMUs may travel to multiple locations to administer and dispense medications for OUD treatment and provide the full range of services available within OTPs, including intake/initial psychosocial and medical assessments, medication induction, case management, recovery support and harm reduction services and counseling services. MMUs can prescribe and/or administer all forms of FDA-approved MOUD, including methadone, buprenorphine, and naltrexone. MMUs have been used to ensure continuity of care in natural disasters and in emergencies in which an OTP's services otherwise would have been disrupted due to fire or flooding.

Mobile Health Clinics for people who use opioids offer a range of primary care, harm reduction, and substance use services.



What Are Mobile Health Clinics for People Who Use Opioids?

MHCs for people who use opioids are specialized vehicles that travel to communities to address OUD and provide a range of health care services. MHCs offer a range of services which may include primary care, harm reduction, and SUD services such as MOUD, counseling, toxicology testing, recovery support services, and referral to wraparound services. Harm reduction services may include syringe services and naloxone distribution. Primary care services may include sexually transmitted infection screenings and wound care.

Through MHCs, clinicians can prescribe buprenorphine or naltrexone or refer patients to OTPs for methadone treatment. Depending on the medication, they can be provided on the mobile clinic, or prescriptions may be offered. MHCs offer a low-barrier approach for medication access and increased service flexibility.

State Highlights

Across the country, states have implemented mobile initiatives to extend the reach of harm reduction, SUD treatment, MOUD, and recovery supports into communities. States have taken a variety of approaches to provide mobile services and are in different stages of their implementation and expansion activities. This brief will highlight efforts in two states: New Jersey and Colorado.

Mobile Medication Units in Practice: New Jersey State Highlight

The New Jersey Department of Human Services, Division of Mental Health and Addiction Services (DHS-DMHAS) initially established MMUs in 2008 through their Medication Assisted Treatment Initiative (MATI). The MMUs were part of an innovative strategy to deliver treatment services directly to neighborhoods where there was great need for MOUD services. Using state funds, New Jersey purchased vehicles to start their MMU program. Services were, and continue to be, supported by state funding and third-party payors, including Medicaid.

New Jersey's MMUs are large custom-built RVs. One part of the vehicle is used to dispense medication and another part is used for medical and counseling services. The vehicle has lavatories and space for exams and blood tests, as well as space to safely store medication. The vehicles have security components to meet the medication security requirements of the DEA. The state's mobile units are staffed with personnel including

a nurse and physician on board. SUD counselors can be accessed onsite, remotely, or by provided transportation in some cases. These units are satellites of their associate OTP, with DEA approval, SAMHSA certification and state licensure with a special designation for the vehicle as an OTP/narcotic treatment program (NTP).

For patients to receive treatment and other support services through the MATI, providers ensure program and clinical eligibility. These eligibility requirements include being a New Jersey resident, having a history of injection drug use, testing positive for opioids or having a year history of OUD, and not being enrolled in an MOUD program or currently under the care of a medical practitioner who prescribes buprenorphine.

New Jersey has extensive experience implementing MMUs in several settings. In 2017, one of the existing MATI RVs was re-assigned to serve a correctional facility in Atlantic City. The program initiates MOUD with incarcerated individuals and continues MOUD after release from jail. From 2017 through 2022, programming has shown positive results with over 1,500 persons released on MOUD and over 80% beginning or maintaining treatment in the community.

New Jersey's mobile units have succeeded in engaging underserved populations and reducing barriers to care by reaching people who might otherwise not be able to engage in treatment. New Jersey's MMU patients are more likely to be unhoused/unsheltered, or uninsured/underinsured than those who receive services at an OTP.



From 2008 to 2022, **9,522** unduplicated clients were served by NJ's five mobile medication units.

76%

were intravenous
drug users

67%

were uninsured

49%

were self-referred
to the program

12%

were referred by
friends and family

As part of the agency's implementation efforts, New Jersey's DMHAS has worked to develop strong community acceptance for MMU placements by establishing community stakeholder consortia in each community where units operate. MMUs also established relationships with other substance use services and programs, including harm reduction providers. The units are licensed to offer outpatient treatment and are connected to other levels of SUD treatment for patients who may require a higher level of care. MMUs offer a person-centered approach to OUD treatment by directly providing or connecting individuals with services and resources that meet their personal needs.

Looking to the Future

After the 2021 DEA regulations were finalized, New Jersey developed a new initiative, through State Opioid Response (SOR) grant funds, to expand the use of mobile services. The state has recently contracted with two OTPs to deploy new MMUs to communities and provide low-barrier medication services. State officials hope that over time the units will become a familiar and trusted presence in high-risk communities. The MMUs, referred to by the state as mobile outreach vehicles, will provide case management and recovery support services and administer methadone as well as buprenorphine.

Mobile Health Clinics for People Who Use Opioids in Practice: Colorado State Highlight

In 2019, the Colorado Department of Human Services Behavioral Health Administration (DHS-BHA) implemented six mobile health clinics, referred to in the state as "mobile health units" (MHUs), to improve access to MOUD in rural and underserved areas. The MHUs primarily deliver MOUD treatment to towns and rural areas with limited access to OTPs or other MOUD programs. The MHUs are operated and managed by subcontracted providers. The state provided SOR grant funding for start-up costs, which included purchasing and customizing the vehicle. The MHUs bill Medicaid and private insurance for services where applicable.

Colorado's MHUs are custom built RVs that function as health clinics. They travel to 32 counties across the state, and each mobile health unit is staffed by a program supervisor, nurse, counselor, peer recovery coach, and an MOUD prescriber via telehealth. One team travels by sport utility vehicle (SUV) to enable them to travel through an area with narrow mountain roads. A typical daily journey for the mobile clinics includes delivery of services in two communities per day, beginning and ending the day at the units' home clinic.



The MHUs provide patients with access to both an MOUD prescriber and counselor. Providers on the MHUs complete an SUD screening for each patient. Services offered include counseling, toxicology testing, overdose education and naloxone distribution, referral to wraparound services, syringe disposal, and telehealth sessions with MOUD prescribers. Patients may be prescribed naltrexone, which can be administered by a nurse on the unit or filled in a pharmacy, or buprenorphine, which must be filled at a pharmacy. Patients for whom methadone is recommended are referred to an OTP.

The clinical teams use a patient-centered approach to support people at any step in their recovery journey. They connect patients to resources depending on their specific needs, including connecting them with outpatient counseling, local resources such as food banks, or recovery support services. Clinical staff can stay in touch with patients even when the MHU is not in the area through an electronic patient portal or telephone.

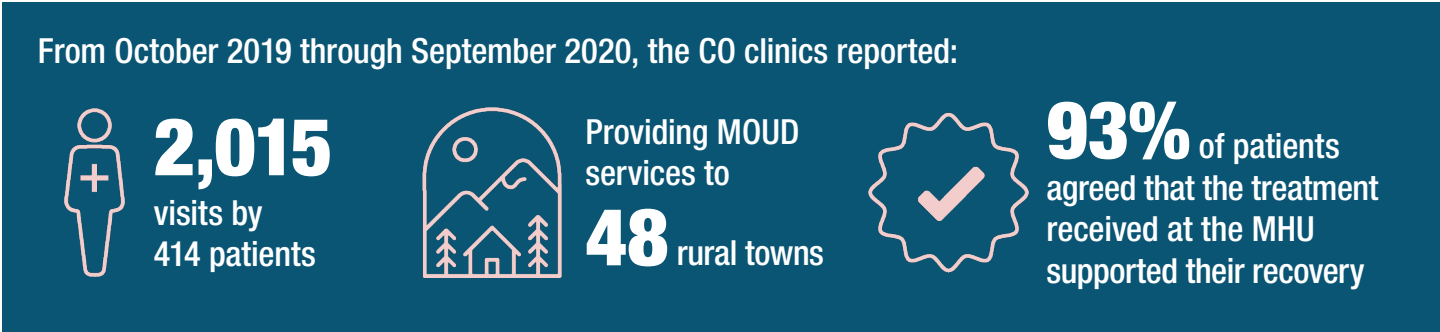
To raise awareness of the services offered by the MHUs, the state’s SOR team and subcontracted

providers conduct community outreach to engage and educate the community about mobile services being offered. In some communities, the MHUs had pre-existing relationships with SUD service provider organizations in or near the planned MHU service areas. These partnerships allowed some mobile unit providers to initially offer MOUD services at temporary clinics set up in a community partner’s space while waiting to receive their vehicles.

The state’s SOR team contracted with the Evaluation Center at the University of Colorado, Denver, to assess program reach, measure client satisfaction and access to services, and document the challenges and the activities to support program implementation. The university’s evaluation found that the mobile nature of the MHUs was a major asset for improving access to treatment services. Patients valued the convenience of having the MHU travel to locations closer to where they live — eliminating the need to travel long distances. Patients reported positive engagement in treatment and indicated satisfaction with access to both the same prescribing doctor and counselor through the MHUs whenever it was possible.¹⁰

Looking to the Future

At this time, Colorado is working on long-term planning to sustain mobile services in the current areas covered by the MHUs. The state is also working toward deploying two new MMUs, with the ability to prescribe and dispense medications in a private and appropriate area. The vehicles for the units have been built out, and subcontracted service providers have been identified.



Lessons Learned & Opportunities for Maximizing Mobile Services

- 1.** Mobile units require regular maintenance and can encounter mechanical issues while on the road. Planning for vehicle maintenance and repairs is necessary. States and providers are encouraged to include vehicle maintenance in their budgets and to develop a plan for preventative maintenance and repairs.
- 2.** Medicaid can help support approved state services provided in mobile units for Medicaid eligible individuals.
- 3.** Mobile unit implementation plans work best when initiated with community outreach. Early stakeholder engagement not only establishes key relationships for operations and referrals, but also helps to reduce stigma and increase local community support.
- 4.** States can use mobile units as part of an emergency management strategy when MOUD guest dosing is not an option. For example, after Hurricane Sandy, downed wires and trees kept people from easily moving around New Jersey. The state used their units to deliver medications to people in need, including individuals in shelters. The units allowed people to access treatment during that difficult time.
- 5.** States and communities can use MMUs to ensure continuity of care by bringing MOUD to patients in settings that are unable to provide this care, such as residential treatment programs, nursing homes, or correctional facilities.
- 6.** Mobile units can provide outreach to high-need areas where people diagnosed with OUD may face added barriers to accessing services, such as homeless shelters, tent cities, and correctional facilities. Mobile units are a successful means to engage people in these settings with treatment services.
- 7.** Mobile units provide an opportunity to bring not just medication, but also medical care, education services, harm reduction services, counseling, recovery support, and referral to additional services to people in need.



Resources

Mobile Units

Federal Guidance for OTP and MMU Certification SAMHSA	This webpage outlines requirements, guidelines, and application processes for OTPs and the establishment of MMUs.
Letter Regarding Use of Block Grant Funds to Purchase Vehicles SAMHSA	This letter provides clarification regarding the use of Block Grant funds to purchase mobile unit vehicles, including for for-profit entities.
Mobile Addiction Services Toolkit Kraft Center for Community Health	This practical guide outlines implementation considerations for mobile clinics, including licensure, budgeting, staffing, outreach and engagement, clinical encounters, van maintenance, and safety.
Mobile Methadone Medication Units: A Brief History, Scoping Review, and Research Opportunity Journal of Substance Abuse Treatment	This research article reviewed and examined the research related to MMUs to identify and assess the extent of mobile MOUD research and inform the development and implementation of new mobile services.
“How to” Webinar – Expanding the Use of Mobile Vans American Association for the Treatment of Opioid Dependence (AATOD)	This webinar described how OTPs can expand their blueprint throughout the country by expanding the use of mobile vans. The webinar featured federal speakers and providers who have been operating mobile units for many years.
“How to” Webinar – Expanding the Use of Mobile Vans 2 AATOD	AATOD produced a second webinar on expanding the use of mobile vans connected to OTPs. Speakers discussed details on federal guidance in support of developing mobile units, the cost of purchasing the units, reimbursement mechanisms to support the use of mobile units, and how the units can work with correctional facilities to expand access to MOUD.
Mobile Health Units Delivering MAT Treatment Year Two Evaluation Report Colorado Department of Human Services Office of Behavioral Health	This evaluation reports on the first two years of Colorado’s mobile health unit initiative. It describes the program’s reach, client satisfaction, and implementation factors.

DEA Mobile Component Rule Change

Registration Requirements for Narcotic Treatment Programs with Mobile Components DEA	This Federal Register excerpt outlines the final rule to revise existing regulations for OTPs to allow the operation of a mobile component associated with a DEA-registered OTP.
Letter Regarding DEA Mobile Component Rule Change SAMHSA	This letter from SAMHSA leadership to OTP Directors, State Opioid Treatment Authorities (SOTAs), and State Directors provides information on the final rule change and guidance on what services may be provided in MMUs.

References

- 1 U.S. Department of Health & Human Services. (2023, July 7). Renewal of Determination that a Public Health Emergency Exists. Administration for Strategic Preparedness & Response. <https://aspr.hhs.gov/legal/PHE/Pages/Opioid-7July2023.aspx>
- 2 Substance Abuse and Mental Health Services Administration. (2022). *Key substance use and mental health indicators in the United States: Results from the 2021 National Survey on Drug Use and Health* (HHS Publication No. PEP22-07-01-005, NSDUH Series H-57). Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. <https://www.samhsa.gov/data/report/2021-nsduh-annual-national-report>
- 3 Biancuzzi, H., Dal Mas, F., Brescia, V., Campostrini, S., Cascella, M., Cuomo, A., Cobiauchi, L., Dorken-Gallastegi, A., Gebran, A., Kaafarani, H. M., Marinangeli, F., Massaro, M., Renne, A., Scaioli, G., Bednarova, R., Vittori, A., & Miceli, L. (2022). Opioid misuse: A review of the main issues, challenges, and strategies. *International Journal of Environmental Research and Public Health*, 19(18), 11754. <https://doi.org/10.3390/ijerph191811754>
- 4 National Institute on Drug Abuse (NIDA). (2023, June 30). *Drug overdose death rates*. National Institutes of Health. <https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates>
- 5 NIDA. (2021, December 2). *Medications to treat opioid use disorder research report*. National Institutes of Health. <https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/overview>
- 6 Hser, Y. I., Mooney, L. J., Saxon, A. J., Miotto, K., Bell, D. S., Zhu, Y., Liang, D., & Huang, D. (2017). High mortality among patients with opioid use disorder in a large healthcare system. *Journal of Addiction Medicine*, 11(4), 315–319. <https://doi.org/10.1097/ADM.0000000000000312>
- 7 Mongelli, F., Georgakopoulos, P., & Pato, M. T. (2020). Challenges and opportunities to meet the mental health needs of underserved and disenfranchised populations in the United States. *Focus (American Psychiatric Publishing)*, 18(1), 16–24. <https://doi.org/10.1176/appi.focus.20190028>
- 8 Chan, B., Hoffman, K. A., Bougatsos, C., Grusing, S., Chou, R., & McCarty, D. (2021). Mobile methadone medication units: A brief history, scoping review and research opportunity. *Journal of Substance Abuse Treatment*, 129, 108483. <https://doi.org/10.1016/j.jsat.2021.108483>
- 9 Registration Requirements for Narcotic Treatment Programs with Mobile Components. 86 Fed. Reg. 33861 (June 28, 2021). (to be codified at 21 CFR Parts 1300, 1301, and 1304). <https://www.federalregister.gov/d/2021-13519>
- 10 The Evaluation Center, University of Colorado Denver. (2020). *State Opioid Response Grant: Mobile Health Units Delivering MAT Treatment Year Two Evaluation Report*. Report submitted to the Colorado Department of Human Services, Office of Behavioral Health. <https://drive.google.com/file/d/18ATZ3FSoRrMNJfiuh8qfcUgbg-EhX1hy/view?pli=1>

Mobile Medication Units and Health Clinics

Acknowledgements

This Issue Brief was prepared for the Substance Abuse and Mental Health Services Administration (SAMHSA) under contract number HHSS2832017 000191_75S20322F42003 (Ref. No. 283-17-1903) with SAMHSA, U.S. Department of Health and Human Services (HHS). Michelle Gleason served as contracting officer representative. SAMHSA coauthors/contributors include Patti Juliana, PhD (Director, Center for Substance Abuse Treatment, Division of Pharmacologic Therapies), Erica McCoy, MPA (Public Health Advisor, Center for Substance Abuse Treatment, Office of Performance Analysis and Management), Talisha Searcy, MPA, MA (Director, Center for Substance Abuse Treatment, Office of Performance Analysis and Management) and LCDR Dantrell Simmons, DrPH, MBA, MA (Lead Public Health Advisor, Center for Substance Abuse Treatment, Office of Performance Analysis and Management).

Disclaimer

The views, opinions, and content of this publication are those of the author and do not necessarily reflect the views, opinions, or policies of SAMHSA. Listings of any nonfederal resources are not all-inclusive. Nothing in this document constitutes a direct or indirect endorsement by SAMHSA or HHS of any nonfederal entity's products, services, or policies, and any reference to nonfederal entity's products, services, or policies should not be considered as such.

Public Domain Notice

All material appearing in this publication is in the public domain and may be reproduced or copied without permission from SAMHSA. Citation of the source is appreciated. However, this publication may not be reproduced or distributed for a fee without the specific, written authorization of the Office of Communications, SAMHSA, HHS.

Recommended Citation

Substance Abuse and Mental Health Services Administration: *Issue Brief: Mobile Medication Units and Health Clinics*. Rockville, MD: Center for Substance Abuse Treatment. Substance Abuse and Mental Health Services Administration, 2024.

Originating Office

Office of Performance Analysis and Management (OPAM) Center for Substance Abuse Treatment (CSAT), Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857.

Nondiscrimination Notice

SAMHSA complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, religion or sex (including pregnancy, sexual orientation, and gender identity). SAMHSA does not exclude people or treat them differently because of race, color, national origin, age, disability, religion, or sex (including pregnancy, sexual orientation, and gender identity).

SAMHSA cumple con las leyes federales de derechos civiles aplicables y no discrimina por motivos de raza, color, nacionalidad, edad, discapacidad, religión o sexo (incluido el embarazo, la orientación sexual y la identidad de género). SAMHSA no excluye a las personas ni las trata de manera diferente debido a su raza, color, nacionalidad, edad, discapacidad, religión o sexo (incluido el embarazo, la orientación sexual y la identidad de género).

Publication No. PEP24-02-001
Released 2024

Photos are for illustrative purposes only.
Any person depicted in a photo is a model.

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. 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 the ordering physician, the 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 the 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 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.

Mobile Medication Unit

- To operate a mobile medication unit, an OTP may request waivers of applicable regulations associated with the pharmacy permit issued to the fixed location. These waivers may be in addition to other waivers approved for the fixed location. The following requirements may be waived to authorize the specific allowances listed:
 - 18VAC110-20-190 – To authorize a licensed nurse or prescriber to access the pharmacy to transfer methadone and take-home doses to and from the mobile medication unit on days that the mobile medication unit is being used for methadone dosing and delivery of take-home doses. Take-home doses must continue to be verified by a pharmacist.
 - 18VAC110-20-150(A) – To authorize the square footage of the mobile medication unit, if necessary.
 - 18VAC110-20-150(C) – To authorize the use of a mobile medication unit that is moveable.
 - 18VAC110-20-150(F) – To authorize a sink to be located outside of the dispensing area within the mobile medication unit, as long as it is readily accessible by staff.

Relevant statutes and regulations:

[Va. Code § 54.1-3321](#)

[Va. Code § 54.1-3408](#)

[18VAC110-20-190](#)

[21 CFR § 290.5](#)

Agenda Item: Adoption of exempt regulatory action to conform to General Assembly scheduling legislation

Included in your agenda package:

- Draft amended regulatory language removing scheduled drugs and chemicals now in statute; and
- Chapter 118 of the 2025 Acts of Assembly.

Action needed:

- Motion to adopt exempt regulatory action to remove drugs and chemicals from Board regulations that are now in statute.

Board of Pharmacy

Conformity of Board scheduling to 2025 General Assembly legislation

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

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

~~1. Synthetic opioid.~~

~~a. _____ N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other name: N-desethyl-Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.~~

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

~~2. _____ Cannabimimetic _____ agent. _____ Ethyl-3,3-dimethyl-2-[(1-(pent-4-enyl)indazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

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

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

~~1. 1 (3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA, 3C-P, 1 (3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~2. 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

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

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

~~1. Compounds expected to have hallucinogenic properties:~~

~~a. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

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

~~c. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~2. Compound classified as a cannabimimetic agent. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until April 8, 2026, unless enacted into law in the Drug Control Act.~~

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

~~1. The following compounds expected to have hallucinogenic properties:~~

~~a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro-methylbenzylpiperazine), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~b. 4-fluoro- α -pyrrolidinoisohexiophenone (other name: 4-fluoro- α -PiHP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), its salts, isomers (optical, position, and geometric), and salts of~~

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

~~2. The following cannabimimetic agent: Methyl 2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.~~

~~The placement of drugs listed in this subsection shall remain in effect until April 8, 2026, unless enacted into law in the Drug Control Act.~~

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

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

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;
2. Adds Dronabinol ((-)-delta-9-trans tetrahydrocannabinol) in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II;
3. Deletes naldemedine from Schedule II;
4. Deletes naloxegol and 6 β -naltrexol from Schedule II;
5. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);
6. Adds 4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (4,4'-Dimethylaminorex, 4,4'-DMAR) to Schedule I;
7. Adds 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (5F-CUMYL-P7AICA) to Schedule I;

8. Adds ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (fentanyl carbamate) to Schedule I;
9. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]prop-2-enamide (ortho-fluoroacryl fentanyl) to Schedule I;
10. Adds N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (ortho-fluoroisobutyryl fentanyl) to Schedule I;
11. Adds N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (para-fluoro furanyl fentanyl) to Schedule I;
12. Adds N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl) to Schedule I;
13. Adds N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (4'-methyl acetyl fentanyl) to Schedule I;
14. Adds N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (β' -phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl) to Schedule I;
15. Adds N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (β -methyl fentanyl) to Schedule I;
16. Adds N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (ortho-fluorobutyryl fentanyl; 2-fluorobutyryl fentanyl) to Schedule I;
17. Adds N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl acetyl fentanyl; 2-methyl acetyl fentanyl) to Schedule I;
18. Adds 2-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (ortho-methyl methoxyacetyl fentanyl; 2-methyl methoxyacetyl fentanyl) to Schedule I;

19. Adds N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-methylfentanyl; 4-methylfentanyl) to Schedule I;
20. Adds N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (thiophene fentanyl) to Schedule I;
21. Adds N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (para-chloroisobutyryl fentanyl) to Schedule I;
22. Adds 24. 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (Butonitazene) to Schedule I;
23. Adds N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (Flunitazene) to Schedule I;
24. Deletes Samidorphan from Schedule II;
25. Adds N-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine) to Schedule I;
26. Adds N-phenyl-N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate (other name: mesocarb) to Schedule I;
27. Adds 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol) to Schedule I; and
28. Adds 7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine) to Schedule I; and
- ~~29. Adds zuranolone to Schedule IV.~~

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 118

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

[H 1587]

Approved March 19, 2025

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3446 and 54.1-3452 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-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238);

1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol (other name: zipeprol);

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

2-(4-ethoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne);

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);

7-[(3-chloro-6-methyl-5,5-dioxo-11H-benzo[c][2,1]benzothiazepin-11-yl)amino]heptanoic acid (other name: *Tianeptine*);

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;

Ethyl N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]carbamate (other name: fentanyl carbamate);

Ethylmethylthiambutene;

Etonitazene;

Etoxadine;

Furethidine;

Hydroxypethidine;

Ketobemidone;
 Levomoramide;
 Levophenacetylmorphan;
 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-piperidyl]-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)piperidin-4-yl]prop-2-enamide (other name: ortho-fluoroacryl fentanyl);
 N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl);
 N-(2-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (other name: ortho-fluoroisobutryl fentanyl);
 N-(2-fluorophenyl)-N-[1-[2-(2-fluorophenyl)ethyl]piperidin-4-yl]propanamide (other names: 2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl);
 N-[1-[2-(4-methylphenyl)ethyl]piperidin-4-yl]-N-phenylacetamide (other name: 4'-methyl acetyl fentanyl);
 N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other name: N-desethyl Isotonitazene);
 N,3-diphenyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (other names: beta'-phenyl fentanyl; beta'-phenyl fentanyl; 3-phenylpropanoyl fentanyl);
 N-phenyl-N-[1-(2-phenylpropyl)piperidin-4-yl]propanamide (other name: beta-methyl fentanyl);
 N-(2-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: ortho-fluorobutryl fentanyl; 2-fluorobutryl fentanyl);
 N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other names: ortho-methyl acetyl fentanyl; 2-methyl acetyl fentanyl);
 N-(4-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (other names: para-methylfentanyl; 4-methylfentanyl);
 N-(4-chlorophenyl)-2-methyl-N-[1-(2-phenylethyl)piperidin-4-yl]propanamide (other name: para-chloroisobutryl fentanyl);
 N-(3-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidyl]-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-piperidyl]-N-phenylpropanamide (other name: 3-methylthiofentanyl);
 N-(4-chlorophenyl)-N-[1-(2-phenylethyl)-4-piperidyl]-propanamide (other names: para-chlorofentanyl, 4-chlorofentanyl);
 N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidyl]-propanamide (other name: para-fluoroisobutryl fentanyl);
 N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (other name: para-fluorofuranyl fentanyl);
 N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidyl]-butanamide (other name: para-fluorobutrylfentanyl);
 N-(4-fluorophenyl)-N-1-(2-phenylethyl)-4-piperidyl]-propanamide (other name: para-fluorofentanyl);
 N,N-diethyl-2-[2-[(4-fluorophenyl)methyl]-5-nitrobenzimidazol-1-yl] ethanamine (other name: Flunitazene);
 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,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene);
 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);
 N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]thiophene-2-carboxamide (other name: thiophene fentanyl);
 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-methoxy-N-(2-methylphenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other names: ortho-methyl methoxyacetyl fentanyl; 2-methyl methoxyacetyl fentanyl);
 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name names: 2-methyl butyryl fentanyl, *alpha*'-methyl butyryl fentanyl);
 2-[2-[(4-butoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N,N-diethylethanamine (other name: Butonitazene);
 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);
 2-(4-isopropoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other name: N-Pyrrolidino Isotonitazene);
 N-(2-fluorophenyl)-2-methoxy-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Ocfentanil);
 N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl);
 N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl fentanyl);
 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-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl 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);
 5-nitro-2-(4-propoxybenzyl)-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other names: N-

Pyrrolidino Protonitazene, Protonitazepyne).

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;
 Hydromorphanol;
 Methyldesorphine;
 Methyldihydromorphine;
 Morphine methylbromide;
 Morphine methylsulfonate;
 Morphine-N-Oxide;
 Myorphine;
 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;

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-alpha-methylphenethylamine; 4-bromo-2,5-DMA);

4-methoxyamphetamine (some trade or other names: 4-methoxy-alpha-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-pyrrolidinoveralphenone (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);

Acetoxymethyltryptamine (other names: AcO-Psilocin, AcO-DMT, Psilacetin);

Benocyclidine (other names: BCP, BTCP);

Alpha-pyrrolidinobutyrophenone (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: Ephedrine);
 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 name: N-heptyl-3,4-DMA);
 N-hexyl-3,4-dimethoxyamphetamine (other 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);
 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone);
 1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone);
 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP);
 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP);
 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA);
 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone);
 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK);
 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone);
 3,4-methylenedioxy-alpha-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone);
 3,4-methylenedioxy-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone);
 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone);
 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin);
 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline);
 Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV);
 1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA, 3C-P, 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine);
 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT);
 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone);
 1-(1,3-benzodioxol-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone);
 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr);
 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine);
 4-fluoro-alpha-pyrrolidinoisohexiophenone (other name: 4-fluoro-alpha-PiHP);
 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam).
 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;
 6-(4-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: 4'-chloro Deschloroalprazolam, 4'Cl-Deschloroalprazolam);
 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam);
 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-

Chlorodiazepam);

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

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);

Fenethylamine;

Methcathinone (some other names: 2-(methylamino)-propionophenone; alpha-(methylamino)-propionophenone; 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-methyl-1-(thiophen-2-yl)propan-2-amine (other name: methiopropamine);

N,N-dimethylamphetamine (other names: N,N-alpha-trimethyl-benzeneethanamine, N,N-alpha-trimethylphenethylamine);

N-phenyl-N'-(3-(1-phenylpropan-2-yl)-1,2,3-oxadiazol-3-ium-5-yl)carbamimidate (other name: mesocarb);

Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 4-fluoromethylphenidate);

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

2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine);

4-chloro-N,N-dimethylcathinone;

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

4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA);

4-methyl-5-(4-methylphenyl)-4,5-dihydro-1,3-oxazol-2-amine (other names: 4,4'-Dimethylaminorex, 4,4'-DMAR);

7-[(10,11-dihydro-5H-dibenzo[a,d]cyclohepten-5-yl)amino]heptanoic acid (other name: amineptine).

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-cyclopropylindole 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-adamantylindole 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-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA);

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-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-quinoliny)(1-pentylindol-3-yl)carboxylate (other name: PB-22);

(8-quinoliny)(1-(5-fluoropentyl)indol-3-yl)carboxylate (other name: 5-fluoro-PB-22);

(8-quinoliny)(1-cyclohexylmethyl-indol-3-yl)carboxylate (other name: BB-22);

N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-BUTINACA);

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-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);

Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA);

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 (other name: ADB-FUBINACA);

Methyl 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-methylbutanoate (other names:

AMB-FUBINACA, FUB-AMB);
 N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other names: FUB-AKB48, 5F-APINACA);
 N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48);
 N-(adamantan-1-yl)-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-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 names: 5-fluoro MDMB-PICA, 5F-MDMB-PICA);
 Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA);
 Ethyl-3,3-dimethyl-2-[(1-(pent-4-enyl)indazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-PINACA);
 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-carboxamido]-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-butyldiazole-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);
 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)pyrrolo[2,3-b]pyridine-3-carboxamide (other name: 5F-CUMYL-P7AICA);
 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);
 Ethyl 2-[1-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA);
 N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA);
 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);
 Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA);

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

§ 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;

Daridorexant;

Delorazepam;

Diazepam;

Dichloralphenazone;

Estazolam;

Ethchlorvynol;

Ethinamate;

Ethyl loflazepate;

Fludiazepam;

Flunitrazepam;

Flurazepam;

Fospropofol;

Halazepam;

Haloxazolam;

Ketazolam;

Lemborexant;

Loprazolam;

Lorazepam;

Lormetazepam;

Mebutamate;

Medazepam;

Methohexital;

Meprobamate;

Methylphenobarbital;

Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Remimazolam;

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;
Zuranolone.

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

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;
Fenproporex;
Mazindol;
Mefenorex;
Modafinil;
Phentermine;
Pemoline (including organometallic complexes and chelates thereof);
Pipradrol;
Serdexmethylphenidate;
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.

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 cannot be determined for periods of commitment to the custody of the Department of Juvenile Justice.

Agenda Item: Adoption of exempt regulatory action – addition of chemicals to Schedule I

Included in your agenda package:

- Recommendation from the Department of Forensic Science to place certain chemicals in Schedule I; and
- Amendments to 18VAC110-20-322.

Action needed:

- Motion to adopt exempt changes to 18VAC20-322 to add chemicals to Schedule I.



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: April 15, 2025
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 two (2) compounds for recommended inclusion into the Code of Virginia.

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

1. **N,N-dipropyl-1H-indole-3-ethanamine (other names: Dipropyltryptamine; N,N-DPT)**, its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

2. **N-(1-amino-3-methyl-1-oxobutan-2-yl)-3-(dimethylsulfamoyl)-4-methylbenzamide (other name: AB-MDMSBA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.


Robyn Weimer
Chemistry Program Manager

Project 8292 - Final

Board of Pharmacy

May 2025 scheduling of chemicals in Schedule I

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

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

1. Synthetic opioid.

a. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other name: N-desethyl Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

2. Cannabimimetic agent. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

1. 1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA, 3C-P, 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
2. 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

1. Compounds expected to have hallucinogenic properties:
 - a. 1-(1,3-benzodioxol-5-yl)-2-(isobutylamino)-1-pentanone (other name: N-isobutylpentylone), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - b. 1-(1,3-benzodioxyl-5-yl)-2-(tert-butylamino)-1-pentanone (other name: N-tert-butyl pentylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 1-Phenyl-N-propylcyclohexanamine (other names: N-(1-phenylcyclohexyl)propanamine, PCPr), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Compound classified as a cannabimimetic agent. Methyl N-(1H-indazol-3-ylcarbonyl)-3-methyl-valinate (other name: MDMB-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until April 8, 2026, unless enacted into law in the Drug Control Act.

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

1. The following compounds expected to have hallucinogenic properties:

a. 1-[(4-fluorophenyl)methyl]-4-methylpiperazine (other names: 4-fluoro-MBZP, 4-fluoro methylbenzylpiperazine), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

c. 8-bromo-1-methyl-6-pyridin-2-yl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: pyrazolam), its salts, isomers (optical, position, and geometric), and salts of

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

2. The following cannabimimetic agent: Methyl-2-(1-butyl-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-BUTINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until April 8, 2026, unless enacted into law in the Drug Control Act.

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

1. The following compound expected to have hallucinogenic properties: N,N-dipropyl-1H-indole-3-ethanamine (other names: Dipropyltryptamine; N,N-DPT), 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; and

2. The following cannabimimetic agent: N-(1-amino-3-methyl-1-oxobutan-2-yl)-3-(dimethylsulfamoyl)-4-methylbenzamide (other name: AB-MDMSBA), 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 30, 2026].

Agenda Item: Adoption of exempt regulatory change pursuant to HB2307 of the 2025 Session

Included in your agenda package:

- Draft exempt regulatory changes to 18VAC110-21-41; and
- HB2307, which expanded training opportunities for pharmacy technician trainees.

Staff notes: HB2307 was an agency bill that was requested by the Board of Pharmacy.

Action needed:

- Motion to adopt exempt regulatory changes as presented.

Board of Pharmacy

**Amendment to pharmacy technician training program options pursuant to 2025
legislation**

18VAC110-21-141. Requirements for pharmacy technician training .

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Completion of a pharmacy technician training program that is:

- a. Jointly accredited by the ASHP and ACPE;
- b. An accredited training program operated through the Department of Education's Career and Technical Education Program;
- c. Operated through a federal agency or branch of the military; ~~or~~
- d. Accredited by an accreditation body approved by the board; or
- e. Recognized by the Pharmacy Technician Certification Board or the National Healthcareer Association.

2. Successfully having passed a national certification examination administered by PTCB or NHA.

C. A pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

D. A person who successfully completed or was enrolled in a board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a board-approved pharmacy technician training program and passing examination score.

E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a board-approved pharmacy technician training program prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination.

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 168

An Act to amend and reenact §§ 54.1-2522.1, as it is currently effective and as it shall become effective, and 54.1-3321 of the Code of Virginia, relating to Prescription Monitoring Program; requirements of practitioners; pharmacy technicians; training programs.

[H 2307]

Approved March 19, 2025

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2522.1, as it is currently effective and as it shall become effective, and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2522.1. (Effective until July 1, 2027) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber ~~who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing~~ of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. A prescriber shall not be required to meet the provisions of subsection B if:

1. The opioid is prescribed to a patient currently receiving hospice or palliative care;
2. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;
3. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;
4. The opioid is prescribed to a patient for pain management related to sickle cell anemia;
5. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or
6. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

D. Prior to issuing a written certification for the use of cannabis oil in accordance with § 4.1-1601, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-2522.1. (Effective July 1, 2027) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber ~~who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing~~ of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis, cancer treatments, or sickle cell anemia.

D. Prior to issuing a written certification for the use of cannabis oil in accordance with § 4.1-1601, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 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 of a prescription for a Schedule III through Schedule VI drug and clarification of quantity or refills for a prescription issued for a Schedule VI drug from a prescriber or his authorized agent, so long as there is no other change to the original prescription;
8. The acceptance of an electronic transfer of a refill for a Schedule VI drug upon order of the pharmacist-in-charge or pharmacist on duty if the refill is not an on-hold prescription;
9. 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
10. 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. 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) *recognized by the Pharmacy Technician Certification Board or the National Healthcareer Association*; or (iii) 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.

Agenda Item: Adoption of amendments to Guidance Document 110-34 to align with current practices

Included in your agenda package:

- Draft changes to Guidance Document 110-34.

Action needed:

- Motion to adopt amendments to Guidance Document 110-34 as presented.

Virginia Board of Pharmacy

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

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

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

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

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

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

Pursuant to 18VAC110-50-80, the responsible party named on an application for change of responsible party of an existing wholesale distributor, third-party logistics provider, nonresident wholesale distributor, or nonresident third-party logistics provider or new application for such permit or registration, shall submit with the application a pdf version of a federal criminal history record check. ~~conducted through Fieldprint. An applicant may do so by requesting an FBI Identity History Summary either on the [FBI Identity History Summary Checks webpage](#) or through an FBI-approved channeler. Local law enforcement offices may provide fingerprinting services to submit with the background check request.~~

The federal criminal history record check should be completed no more than 90 days prior to the date of submission of the application to the Board. If the responsible party was previously subject to a federal criminal background check conducted within this time period, such report may be submitted for board consideration. ~~The link to obtain this background check as well as~~

~~other pertinent information regarding the requirements may be found here:~~
~~<https://fieldprintusa.com/FBIHomePage.aspx?PostingID=540&ChannelID=264>~~ Criminal history results are available online for 30 days from the time Fieldprint receives the results from the Federal Bureau of Investigations. If the responsible party does not access the results in this 30-day period, Fieldprint is required to purge the records from its system. Once the responsible party accesses the results, the results may be saved for seven days. After this seven-day period, the results are removed from the system. Additionally, results that are not saved will be removed immediately after accessing them. In all cases, once the results have been removed from the Fieldprint system, they can no longer be accessed and the complete process must be completed again to obtain a new copy. Additional helpful information from Fieldprint is found here:
~~https://fieldprintusa.com/FBISubPage_FullWidth.aspx?ChannelID=272~~

Agenda Topic: Amend Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*

Background: Suggested amendments of deficiencies 111, 138, and 139 to conform with new laws and regulations.

Action Needed: Amend Guidance Document 110-9 as presented or amended.

Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	2000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		1000
3. Unregistered persons performing duties restricted to pharmacy technician without first becoming registered as a pharmacy technician trainee	54.1-3321 and 18VAC110-20-111	per individual	First documented occurrence = no penalty Repeat = \$ penalty 250
4. Pharmacists/pharmacy technicians/pharmacy interns/pharmacy technician trainees performing duties on an expired license/registration	18VAC110-21-60, 18VAC110-21-110, 18VAC110-21-141, and 18VAC110-21-170.	per individual	First documented occurrence = no penalty Repeat = \$ penalty 100

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
5. Pharmacy technicians, pharmacy interns, or pharmacy technician trainees performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320 18VAC110-20-112		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320 18VAC110-20-112	per each technician over the ratio	First documented occurrence = no penalty Repeat = \$ penalty 100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	First documented occurrence = no penalty; drugs may be embargoed Repeat = \$ penalty 100 Drugs may be embargoed
9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.	18VAC110-20-180 and 18VAC110-20-190		1000

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.	18VAC110-20-180		250
10. Unauthorized access to alarm or locking device to the prescription department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty 500
12. Storage of prescription drugs not in the prescription department	18VAC110-20-190		500

Page 4 of 17

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
15. Perpetual inventory not being maintained as required as it does not: • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug “on-hand” at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 reconciliations not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
21b. Presterilization procedures for Category 2 or Category 3 CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better.	54.1-3410.2		500
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months, whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months, whenever there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow quality, and/or certification does not include airflow testing, HEPA filter integrity testing, total particle count testing, and dynamic airflow smoke pattern test.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
24. Sterile compounding of hazardous drugs performed in a non-compliant clean room	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for Category 2 CSPs and/or Category 3 CSPs when required by USP	54.1-3410.2		5000
25a. No documentation of initial and at least every 3 months media-fill testing or gloved fingertip testing for persons performing compounding of Category 3 CSPs.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the third month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. Category 3 compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Category 1 or 2 CSPs intended for use are improperly stored	54.1-3410.2		500

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
25d. No documentation of results of the evaluation to determine cause of failure for a person who failed a media-fill test or gloved fingertip and thumb sampling	54.1-3410.2		5000 if performing Category 3 500 if performing Category 1 and 2
26. No documentation of initial and at least every 6 months media-fill testing or gloved fingertip testing for persons performing compounding of Category 1 and Category 2 CSPs.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated.	500
26a. Repealed 12/2023			
26b. No documentation of initial and at least every 12 months media-fill testing or gloved fingertip testing for persons who have direct oversight of compounding personnel, but do not compound.	54.1-3410.2		500
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or \$5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		First documented occurrence and no drug loss = no penalty Drug loss or repeat = \$ penalty 500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	First documented occurrence and no known patient harm = no penalty Repeat = \$ penalty 250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Immediate use, Category 1, or Category 2 CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
33a. Category 3 CSPs assigned inappropriate BUD	54.1-3410.2		5,000
34. Combined with Deficiency 142 – 12/2013.			

Deficiency	Law/Reg Cite	Conditions	\$ Monetary Penalty
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Other Deficiencies

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

Deficiency	Law/Regulation Cite	Conditions
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit. Temperature not being recorded daily or record of such not maintained properly.	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation

Deficiency	Law/Regulation Cite	Conditions
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold
110. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

Deficiency	Law/Regulation Cite	Conditions
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200 and 18VAC110-20-490	
112. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
114. Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
115. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 18VAC110-20-270	10% threshold
117. Deficiency 117 combined with Deficiency 116 – 6/2011		
118. Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
119. Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255, 18VAC110-20-310, and 18VAC110-20-320	
120. Offer to counsel not made as required	54.1-3319	

Deficiency	Law/Regulation Cite	Conditions
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Repealed.		
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	

Deficiency	Law/Regulation Cite	Conditions
131. Required “other documents” for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations and/or who have direct oversight of compounding personnel, but do not compound, do not comply with cleansing and garbing requirements	54.1-3410.2	
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device and/or remote dispensing system loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.

Deficiency	Law/Regulation Cite	Conditions
139. Emergency medical services procedures or records not in compliance	18VAC110-20-50091	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. Repealed 6/21/2018		
144. Repealed 6/21/2018		
145. Repealed 6/21/2018		
146. Repealed 6/21/2018		
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

Deficiency	Law/Regulation Cite	Conditions
149. Surface sample testing not being performed	54.1-3410.2	

NOTE: A “repeat” deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

Examples:

Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.

Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.

Routine inspection on 7/1/20 – No deficiency.

Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.

Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.

Agenda Item: Review of potential legislative requests of the agency regarding fees and finances

Included in your agenda package:

- Draft legislation allowing recovery of costs related to investigation and disciplinary proceedings; and
- Draft legislation amending the Callahan Act to allow fee actions to be implemented by exempt regulatory action and allow the Department to request general funds for discrete costs.

Staff notes: These are internal draft legislative proposals only. The Director of the agency determines which legislative proposals are submitted to the Governor's office. The Governor's office, in turn, determines which legislative proposals the agency may pursue. After approval from the Governor's office, the agency can begin locating patrons for bills.

Action needed:

- None. For review only.

Proposed language for disciplinary cost legislation – 2026 General Assembly

§ 54.1-2401.1. Recovery of disciplinary and monitoring costs.

A health regulatory board may recover from any person licensed, registered, permitted, or certified or issued a multistate licensure privilege by any health regulatory board against whom the health regulatory board issued a finding of a violation of law or regulation reasonable administrative costs associated with investigation, disciplinary proceedings, monitoring, and confirming compliance with any terms and conditions imposed as set forth in an order which includes the finding of a violation of law or regulation. All administrative costs recovered pursuant to this section shall be paid by the person or entity licensed, registered, permitted, or certified or issued a multistate licensure privilege to the health regulatory board. Such administrative costs shall be deposited into the account of the health regulatory board and shall not constitute a fine or penalty.

§ 54.1-113. Regulatory boards to adjust fees; certain transfer of moneys collected on behalf of health regulatory boards prohibited.

A. Following the close of any biennium, when the account for any regulatory board within the Department of Professional and Occupational Regulation maintained under § 54.1-308 shows that unspent and unencumbered revenue exceeds \$100,000 or 20 percent of the total expenses allocated to the regulatory board for the past biennium, whichever is greater, the regulatory board shall (i) distribute all such excess revenue to current regulants and (ii) reduce the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses.

B. ~~Following the close of any biennium~~ Annually, when the account for any regulatory board within the Department of Health Professions maintained under § 54.1-2505 shows expenses allocated to it for the past ~~biennium~~ year to be more than 10 percent ~~greater or~~ less than moneys collected on behalf of the regulatory board, it ~~shall~~ may revise the fees levied by it for certification, licensure, registration, or permit and renewal thereof so that the fees are sufficient but not excessive to cover expenses. Any regulatory board within the Department of Health Professions maintained under § 54.1-2505 shall not issue an exempt regulatory action for a one-time fee decrease unless an annual review of accounts for that regulatory board shows expenses allocated to it for the previous year to be more than 25 percent less than moneys collected on behalf of the regulatory board.

C. Nongeneral funds generated by fees collected on behalf of the health regulatory boards and accounted for and deposited into a special fund by the Director of the Department of Health Professions shall be held exclusively to cover the expenses of the health regulatory boards, the Health Practitioners' Monitoring Program, and the Department and Board of Health Professions and shall not be transferred to any agency other than the Department of Health Professions, except as provided in §§ 54.1-3011.1 and 54.1-3011.2.

D. In order to appropriately maintain operating funds, the regulatory boards of the Department of Health Professions or the Department of Professional and Occupational Regulation may amend regulations to increase or decrease fees as needed and demonstrated by the regulatory board. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq.), with the exception of § 2.2-4031. Regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.). Any regulatory board amending fees pursuant to this section shall conduct a public hearing prior to making such amendments. Thirty days prior to conducting such hearing, the regulatory boards shall give written notice by mail or electronic means of the date, time, and place of the hearing to the public and publish notice of its intention to amend fees in the Virginia Register of Regulations. The public notice shall identify the fee increase to be considered by the regulatory board with reasonable specificity and shall include evidence demonstrating the need for a fee increase. During the public hearing, interested parties shall be given reasonable opportunity to be heard prior to final adoption of any regulatory amendments regarding fees.

E. The Department of Health Professions and the Department of Professional and Occupational Regulation may, at the discretion of the General Assembly, receive monies from the general fund to address defined expenditures of the agency.

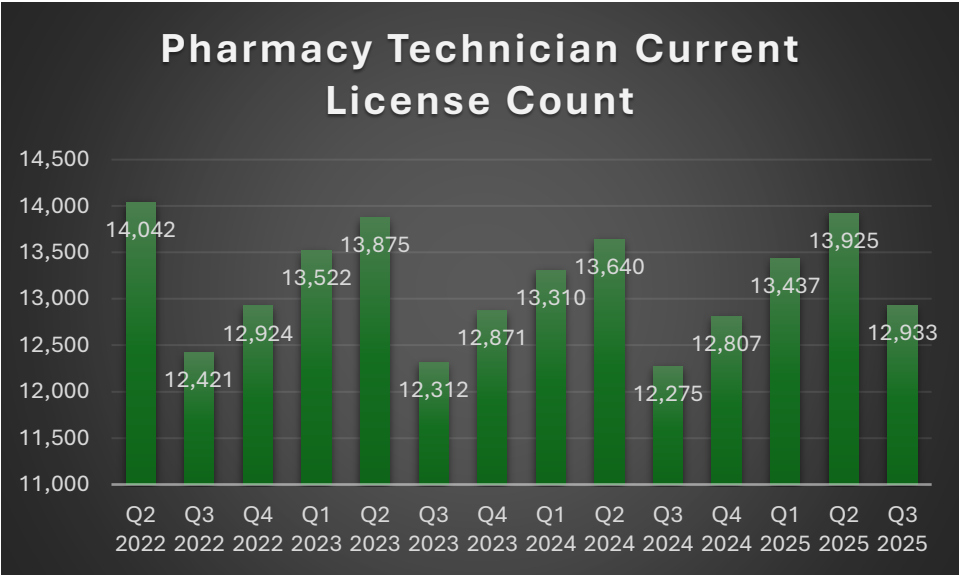
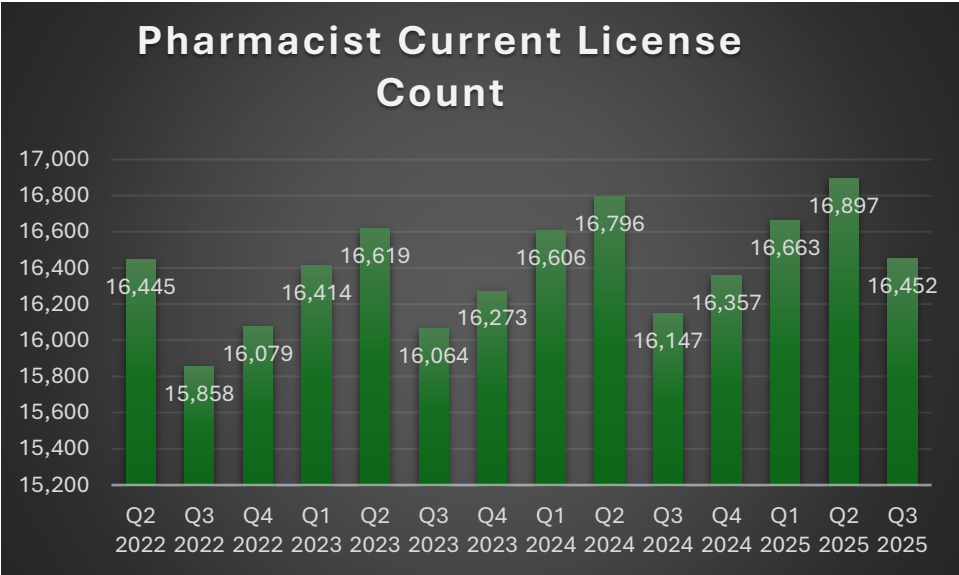
For discussion only

Virginia Board of Pharmacy

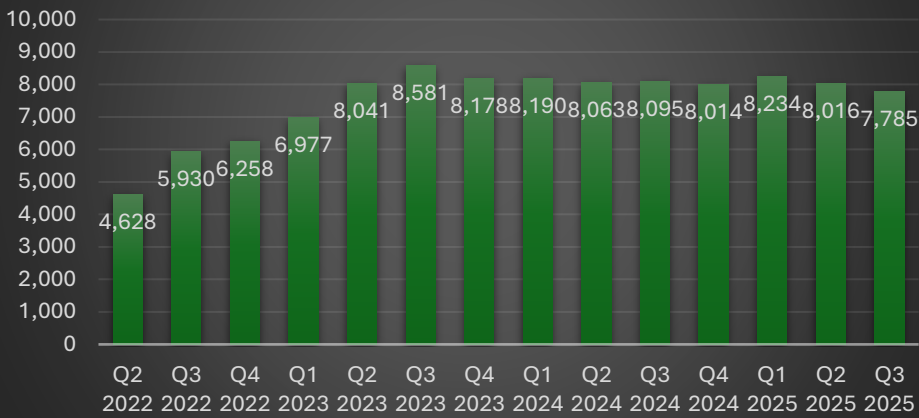
May 19, 2025

Licenses Issued

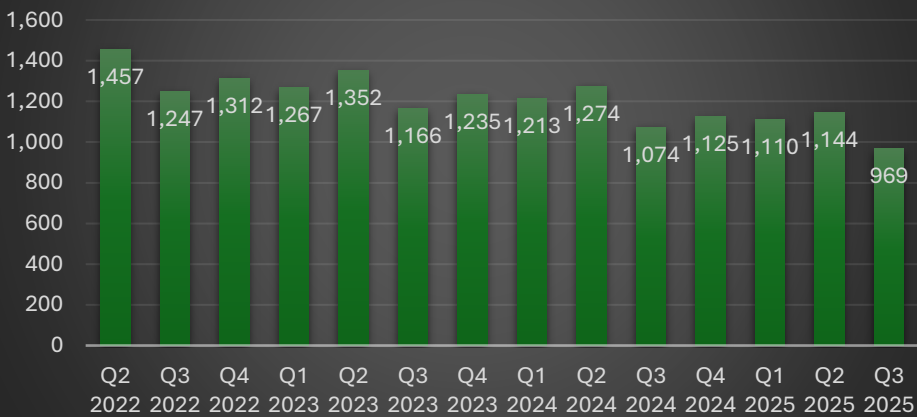
	11/1/23 - 1/31/24	2/1/24 - 4/30/24	5/1/24 - 7/31/24	8/1/24 - 10/31/24	11/1/24 - 1/31/25	2/1/25 - 4/30/25	License Count 5/5/2025
Business CSR	20	47	49	114	74	69	1,685
CE Courses	0	0	0	0	0	0	0
EMS Designated Locations				403	199	75	666
Limited Use Pharmacy Technician	0	0	0	0	0	0	4
Medical Equipment Supplier	4	3	8	6	1	3	211
Non-restricted Manufacturer	0	0	2	1	0	0	36
Outsourcing Facility	0	0	0	0	0	0	1
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	131	164	212	262	177	187	16,549
Pharmacist Volunteer Registration	0	0	0	0	0	0	0
Pharmacy	13	18	7	11	5	12	1,714
Pharmacy Intern	74	79	52	72	121	77	1,000
Pharmacy Technician	327	407	461	527	427	477	13,141
Pharmacy Technician Trainee	1,085	864	964	1,175	900	941	7,581
Physician Selling Controlled Substances	23	15	18	46	17	37	574
Limited Use Practitioner Dispensing	2	2	1	1	4	3	17
Nonresident Manufacturer	8	5	4	13	1	5	235
Nonresident Medical Equipment Supplier	15	9	16	9	8	10	371
Nonresident Outsourcing Facility	0	3	1	2	4	2	37
Nonresident Pharmacy	23	26	27	33	12	27	988
Nonresident Third Party Logistics Provider	6	6	8	12	7	11	256
Nonresident Warehouser	4	9	15	9	17	11	174
Nonresident Wholesale Distributor	8	9	12	12	7	17	631
Physician Selling Drugs Location	5	1	8	3	9	5	125
Pilot Programs	1	4	0	1	0	2	11
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	28
Third Party Logistics Provider	0	0	0	0	0	1	6
Warehouser	2	1	2	1	2	0	123
Limited Use Facility Dispensing	1	0	1	1	1	0	6
Wholesale Distributor	1	1	2	1	3	1	61
Total	1,753	1,673	1,870	2,715	1,996	1,973	46,233



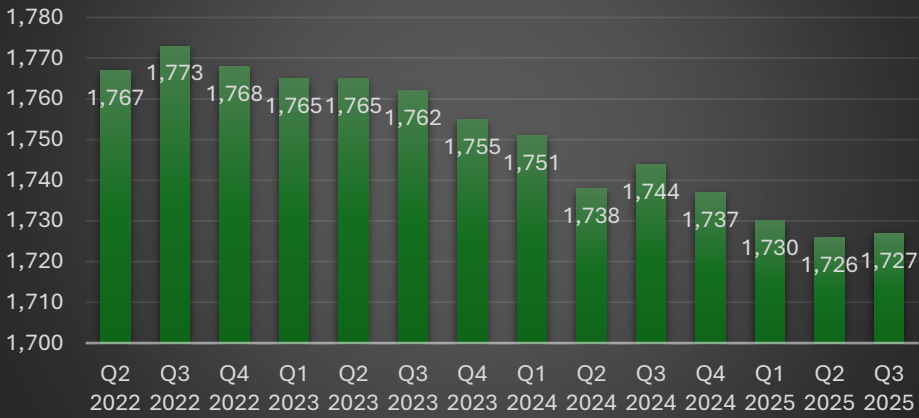
Pharmacy Technician Trainee Current License Count



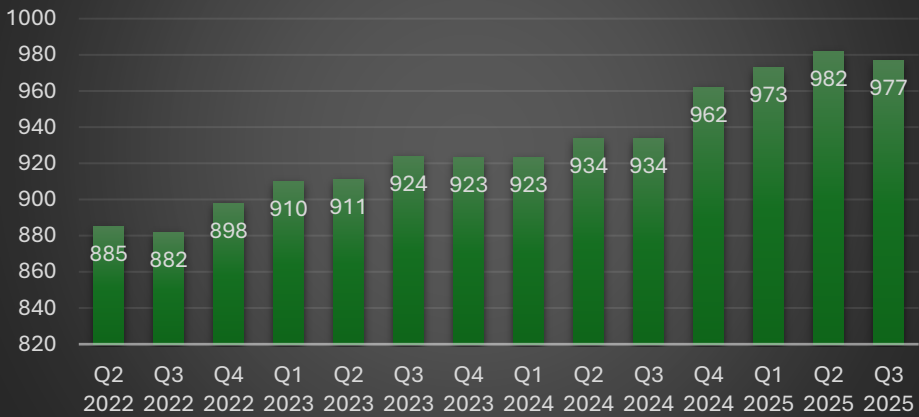
Pharmacy Intern Current License Count



Resident Pharmacy Current Permit Count



Non-Resident Pharmacy Current Permit Count



May 19, 2025 - Full Board of Pharmacy Meeting

Quarterly Inspection Completed Review by License Type – Date Range: 1/01/2025 – 3/31/2025

Insp Status	License Type	Change of Location	Compliance	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	6		27		3	10	64	110
	Third Party Logistics Provider						1		1
	Limited-Use Facility Dispensing							2	2
	Medical Equipment Supplier	1		2			1	2	6
	Non-restricted Manufacturer								0
	Pharmacy	7	3	9		9	27	170	223
	Physician Selling Drugs Location	1		5				11	17
	Pilot Programs								0
	Warehouser	4		1				5	10
	Wholesale Distributor	1		1				4	6
Completed Total		20	3	45		12	39	258	375
Completed Virtual	Business CSR	1		31		1	9		42
	Medical Equipment Supplier			2					2
	Pharmacy					2	14		16
Completed Virtual Total		1		33		3	23		60
Grand Total		21	3	78	0	15	62	258	435

May 19, 2025 - Full Board of Pharmacy Meeting

Routine Pharmacy Inspections – Date Range: 1/01/2025 – 3/31/2025

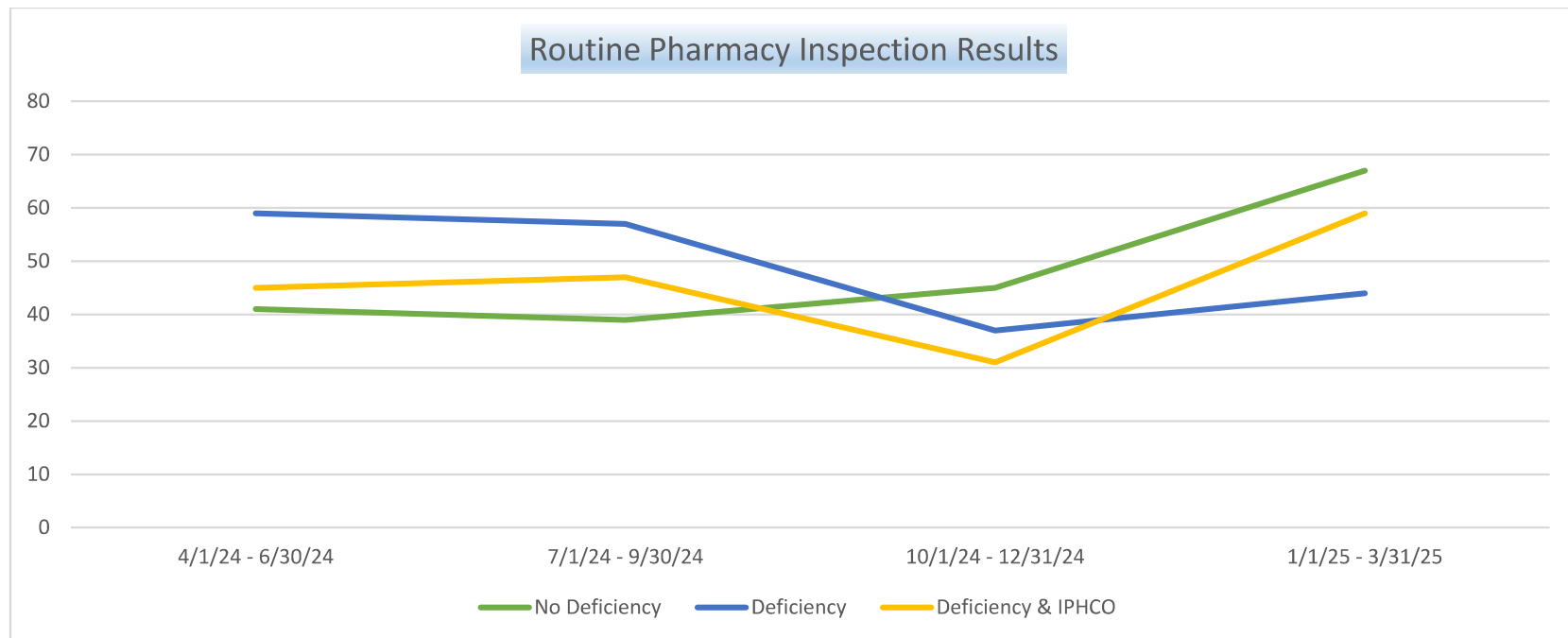
Top 5 cited deficiencies

Description	Number of times cited
2. Pharmacist-In-Charge in place, inventory taken, but application not filed with Board within the required timeframe.	18
15. Perpetual inventory not being maintained as required as it does not: • Include all Schedule II drugs received or dispensed; • Accurately indicate the physical count of each Schedule II drug “on-hand” at the time of performing the inventory; • Include a reconciliation of each Schedule II drug at least monthly; or • Include a written explanation of any difference between the physical count and the theoretical count. Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required.	17
124. Labels do not include all required information.	15
130. Required compounding/dispensing/distribution records not complete and properly maintained.	14
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container).	12

May 19, 2025 - Full Board of Pharmacy Meeting

Routine Inspection Results - 1/01/2025 – 3/31/2025

License Type	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	30		34	64
Limited-Use Facility Dispensing	1		1	2
Wholesale Distributor			4	4
Medical Equipment Supplier			2	2
Pharmacy	44	59	67	170
Physician Selling Drugs Location	6		5	11
Warehouser	1		4	5
Grand Total	82	59	117	258



May 19, 2025 - Full Board of Pharmacy Meeting





Cases Received, Open & Closed
Agency Summary
Quarter 3 – Fiscal Year 2025

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	CURRENT Q3 2025
Number of Cases Received	1,884	1,621	1,556	1,481	1,773	1,898	2,050	1,961	2,054	1,881	1,941	1,876	1,929
Number of Cases Open	4,112	4,246	4,174	4,392	4,672	4,783	4,792	5,079	5,174	5,107	5,183	5,114	5,186
Number of Cases Closed	2,045	1,533	1,754	1,586	1,857	1,952	2,075	1,674	2,036	1,934	1,832	1,949	1,854



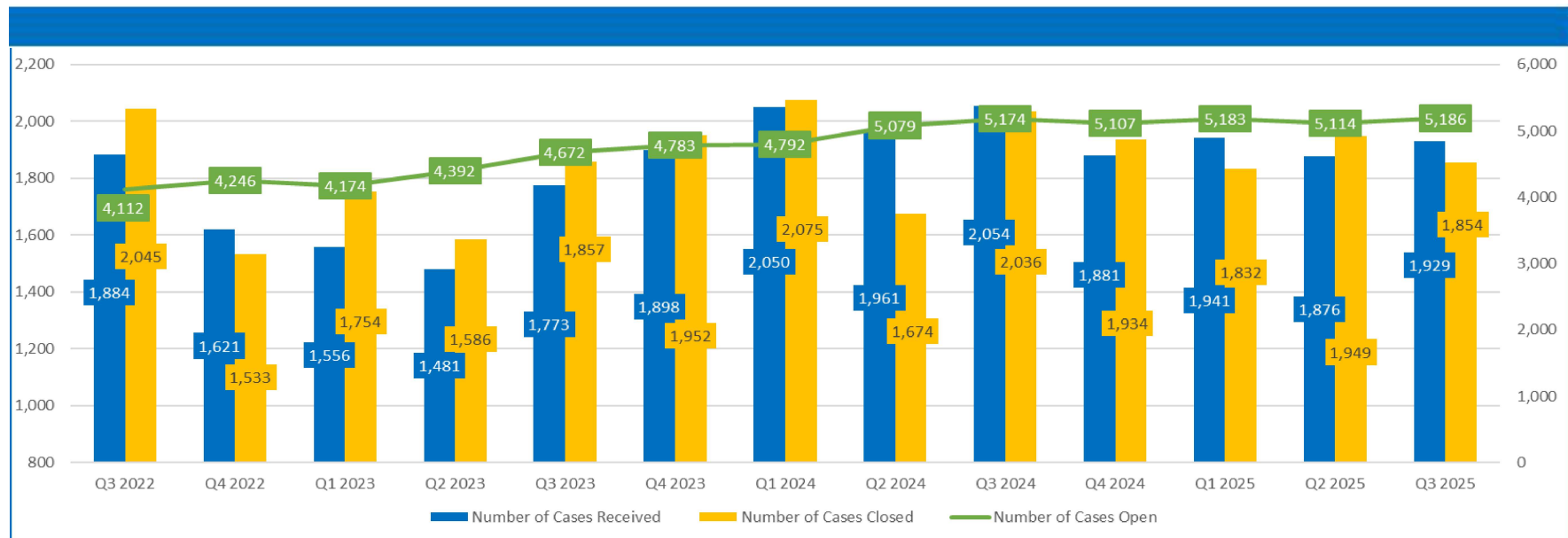
Cases Received, Open & Closed

Agency Summary

Quarter 3 – Fiscal Year 2025

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30





Cases Received, Open & Closed

Agency Summary

Quarter 3 – Fiscal Year 2025

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

														CURRENT
		Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025
Pharmacy	Number of Cases Received	220	185	215	210	204	249	206	179	204	172	174	167	200
	Number of Cases Open	399	409	416	437	384	442	390	372	383	348	321	310	341
	Number of Cases Closed	154	181	228	214	288	220	257	199	195	210	200	179	174
Physical Therapy	Number of Cases Received	15	3	15	13	10	4	10	27	10	9	18	15	16
	Number of Cases Open	46	39	35	34	36	35	31	55	52	33	39	46	48
	Number of Cases Closed	18	10	21	18	8	5	14	4	15	29	12	9	15
Psychology	Number of Cases Received	24	34	20	18	22	31	39	35	32	45	46	41	28
	Number of Cases Open	144	162	163	169	174	172	167	157	154	159	170	167	154
	Number of Cases Closed	39	22	26	16	24	49	44	43	37	40	35	43	42



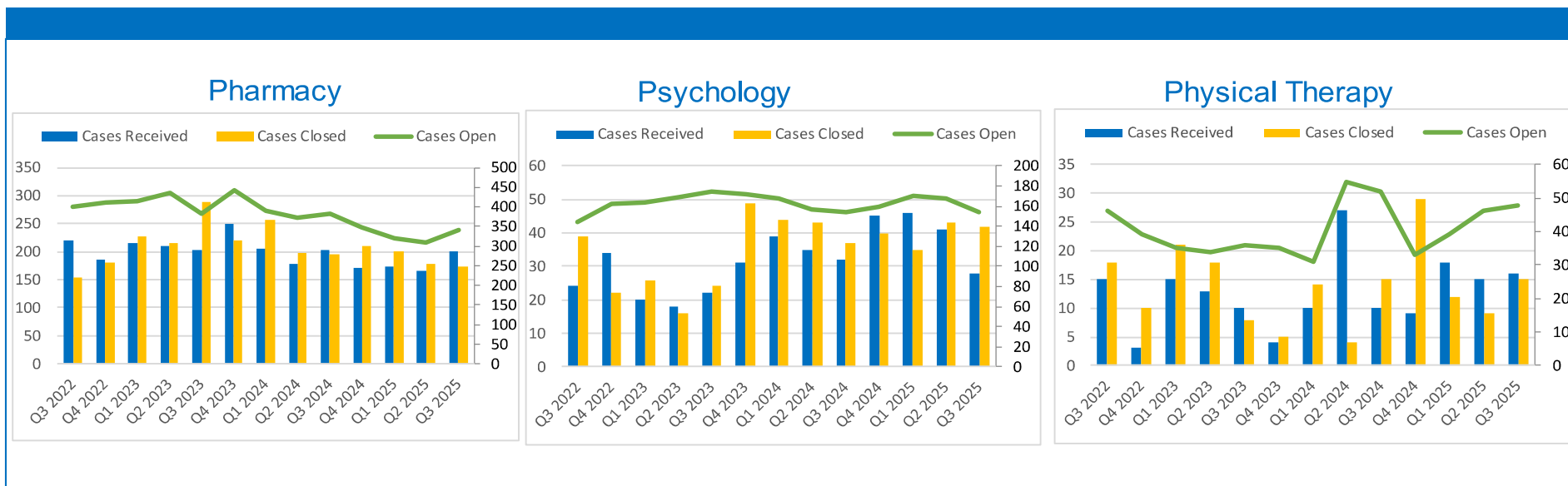
Cases Received, Open & Closed

Agency Summary

Quarter 3 – Fiscal Year 2025

The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30



Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q3 2021 - Q3 2025

Arne W. Owens

Director

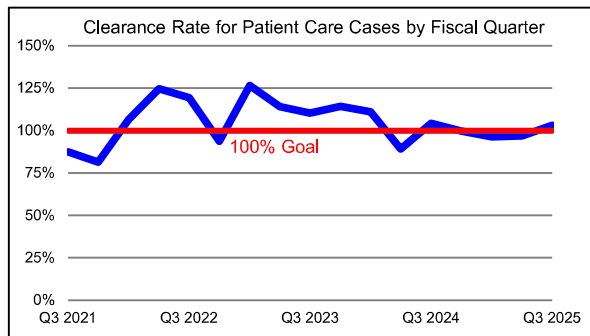
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."

DHP Mission Statement

In order to uphold its mission relating to discipline, DHP continually assesses and reports on its disciplinary case processing performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement; these three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days that a case was in the continuance activity.

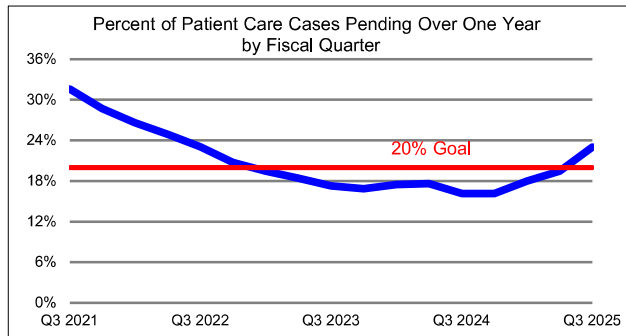
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 103%, with 1,227 patient care cases received and 1,265 closed.



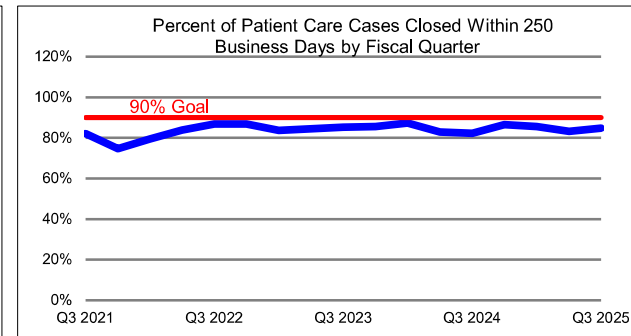
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 250 business days at no more than 20%.

The current quarter shows 23% patient care cases pending over 250 business days, with 863 of the 3,752 patient care cases pending over 250 business days.



Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 250 business days.

The current quarter shows 85% patient care cases pending over 250 business days, with 1,028 of the 1,212 cases closed within 250 business days.



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days), by Board

Medicine

Clearance Rate: 101%

408 Cases Received

414 Cases Closed

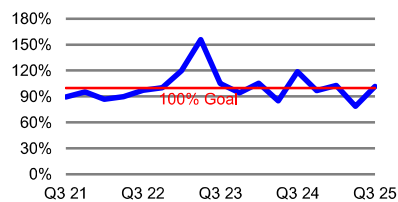
Pending Caseload: 8%

59 cases out of 731 are pending over 250 Days

Time to Disposition: 97%

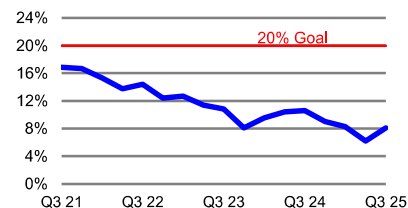
396 cases out of 407 were closed within 250 Days

Clearance Rate

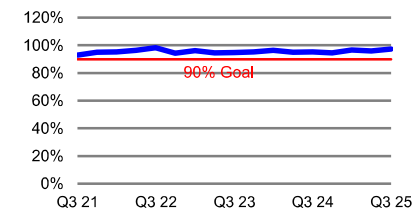


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition



Dentistry

Clearance Rate: 102%

98 Cases Received

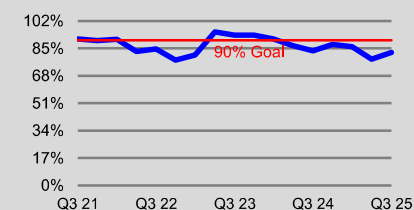
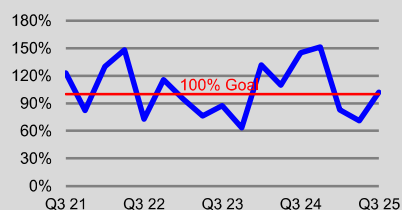
100 Cases Closed

Pending Caseload: 14%

44 cases out of 315 are pending over 250 Days

Time to Disposition: 82%

80 cases out of 97 were closed within 250 Days



Pharmacy

Clearance Rate: 101%

85 Cases Received

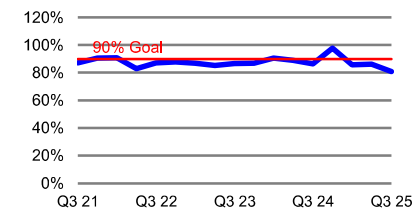
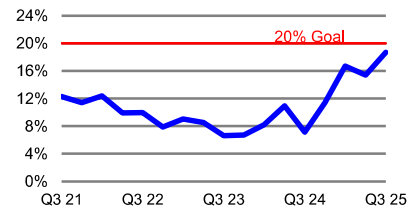
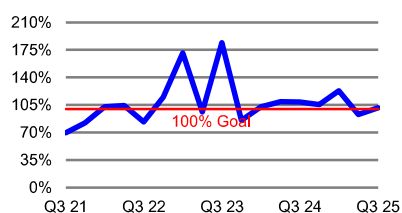
86 Cases Closed

Pending Caseload: 19%

35 cases out of 187 are pending over 250 Days

Time to Disposition: 81%

68 cases out of 84 were closed within 250 Days



Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Note: If no cases are received and some cases are closed, we assign 100% as clearance rate

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q3 2021 - Q3 2025

Arne W. Owens
Director

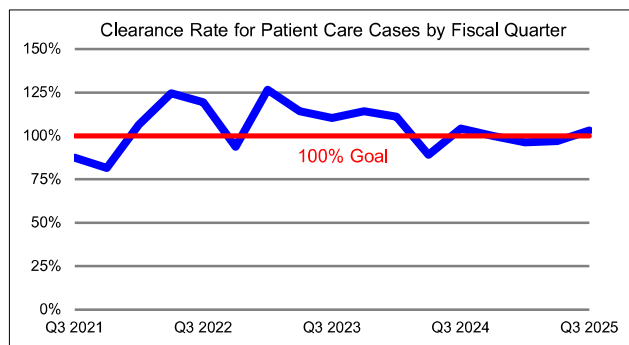
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."

DHP Mission Statement

In order to uphold its mission relating to discipline, DHP continually assesses and reports on its disciplinary case processing performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement; these three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days that a case was in the continuance activity.

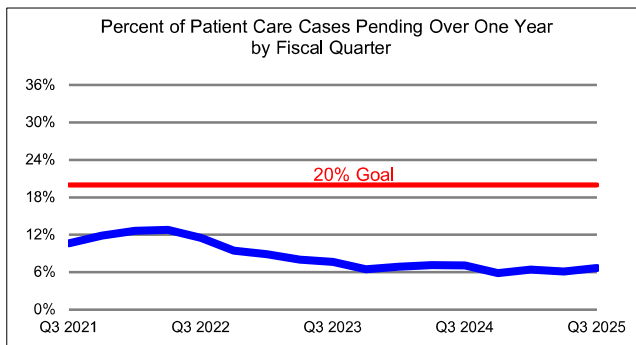
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 103%, with 1,227 patient care cases received and 1,265 closed.



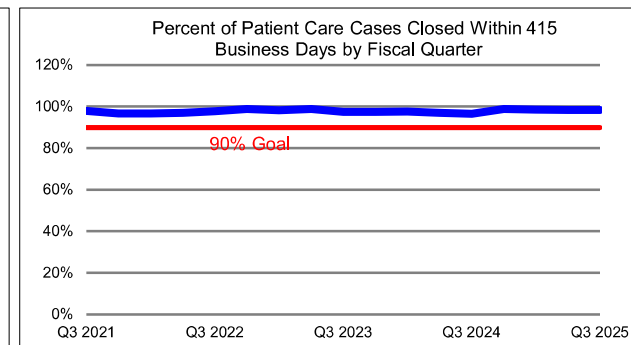
Age of Pending Caseload - the percent of open patient care cases over 415 business days old. This measure tracks the backlog of patient care cases older than 415 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 415 business days at no more than 20%.

The current quarter shows 7% patient care cases pending over 415 business days, with 250 of the 3,752 patient care cases pending over 415 business days.



Time to Disposition - the percent of patient care cases closed within 415 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 415 business days.

The current quarter shows 98% of patient care cases being resolved within 415 business days, with 1,192 of the 1,212 cases closed within 415 business days.



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days), by Board

Medicine

Clearance Rate: 101%

408 Cases Received

414 Cases Closed

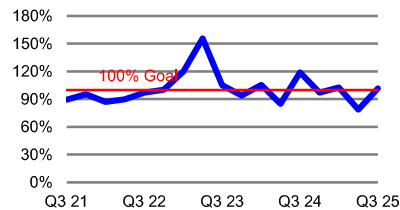
Pending Caseload Over 415 Days: 3%

22 cases out of 731 are pending over 415 Days

Time to Disposition Within 415 Days: 100%

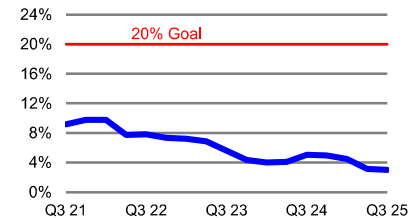
406 cases out of 407 were closed within 415 Days

Clearance Rate

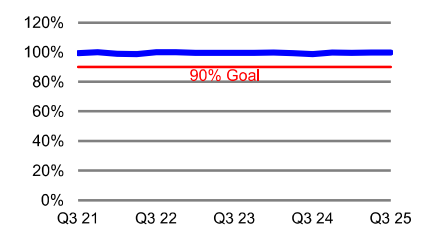


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition



Dentistry

Clearance Rate: 102%

98 Cases Received

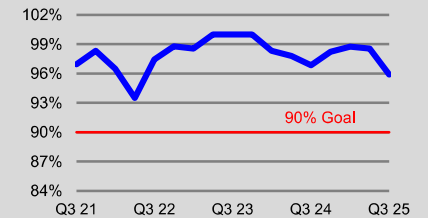
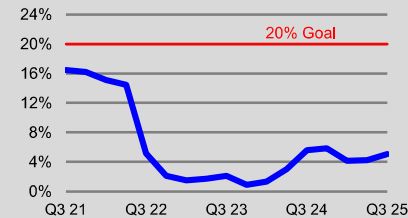
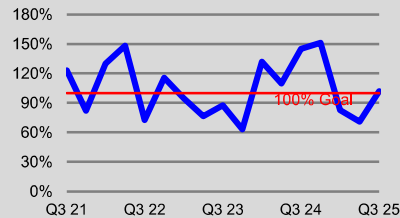
100 Cases Closed

Pending Caseload Over 415 Days: 5%

16 cases out of 315 are pending over 415 Days

Time to Disposition Within 415 Days: 96%

93 cases out of 97 were closed within 415 Days



Pharmacy

Clearance Rate: 101%

85 Cases Received

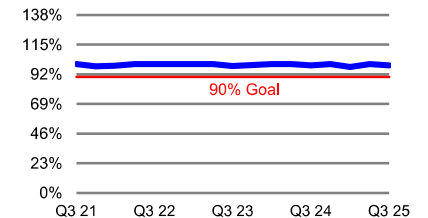
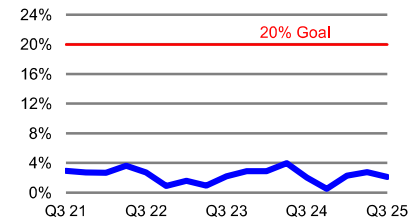
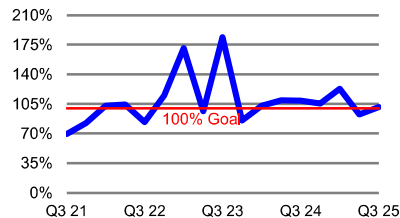
86 Cases Closed

Pending Caseload Over 415 Days: 2%

4 cases out of 187 are pending over 415 Days

Time to Disposition Within 415 Days: 99%

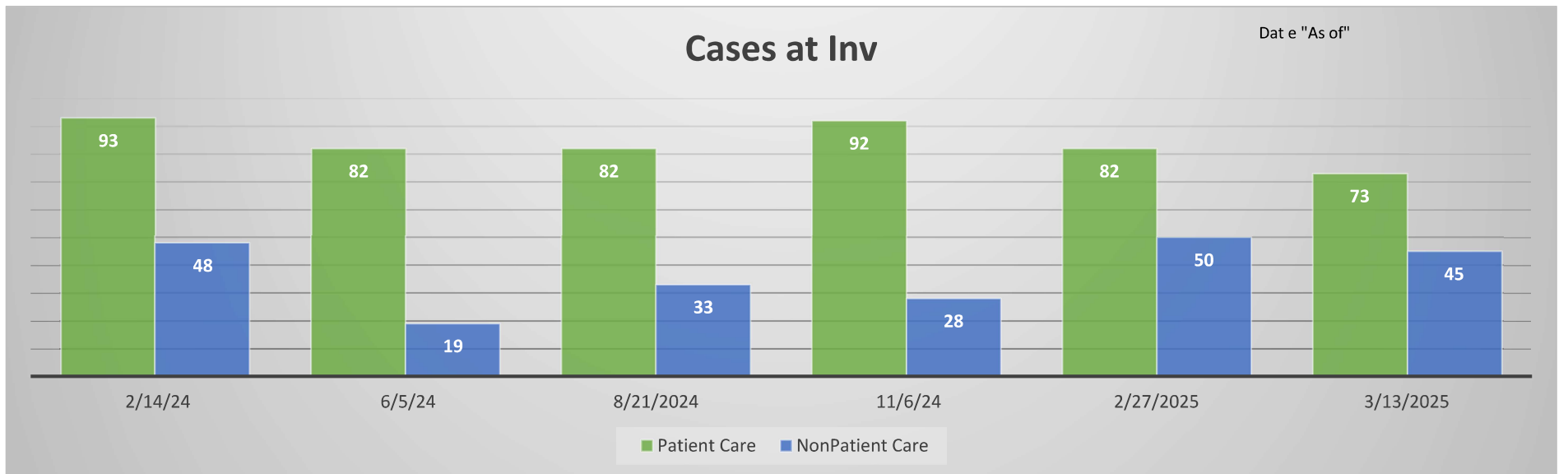
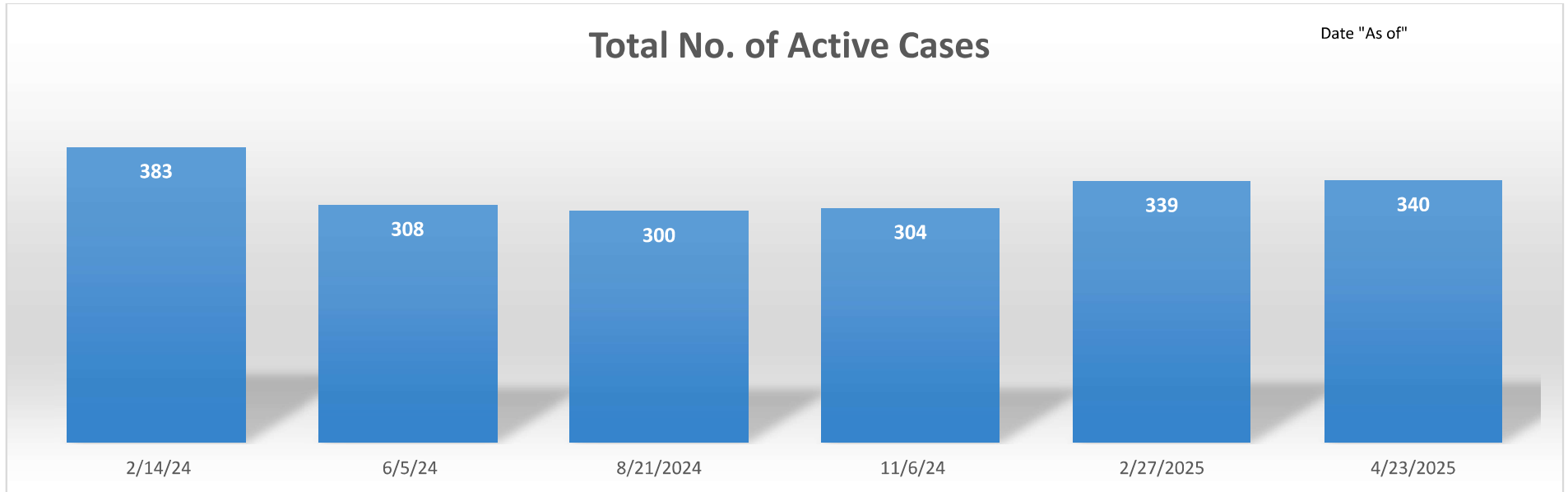
83 cases out of 84 were closed within 415 Days



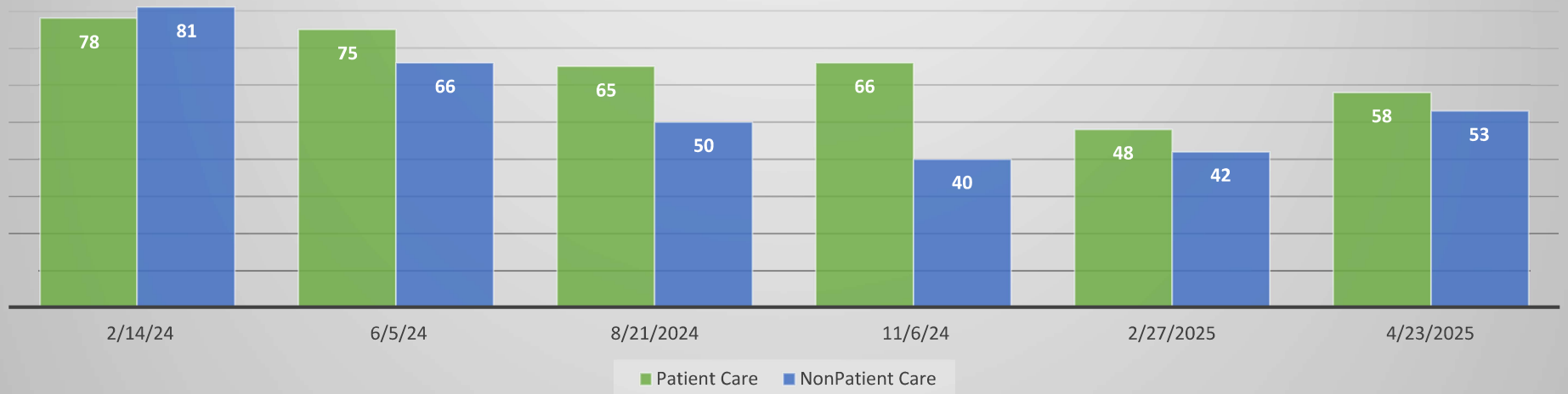
Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

Note: If no cases are received and some cases are closed, we assign 100% as clearance rate

Discipline Program Report

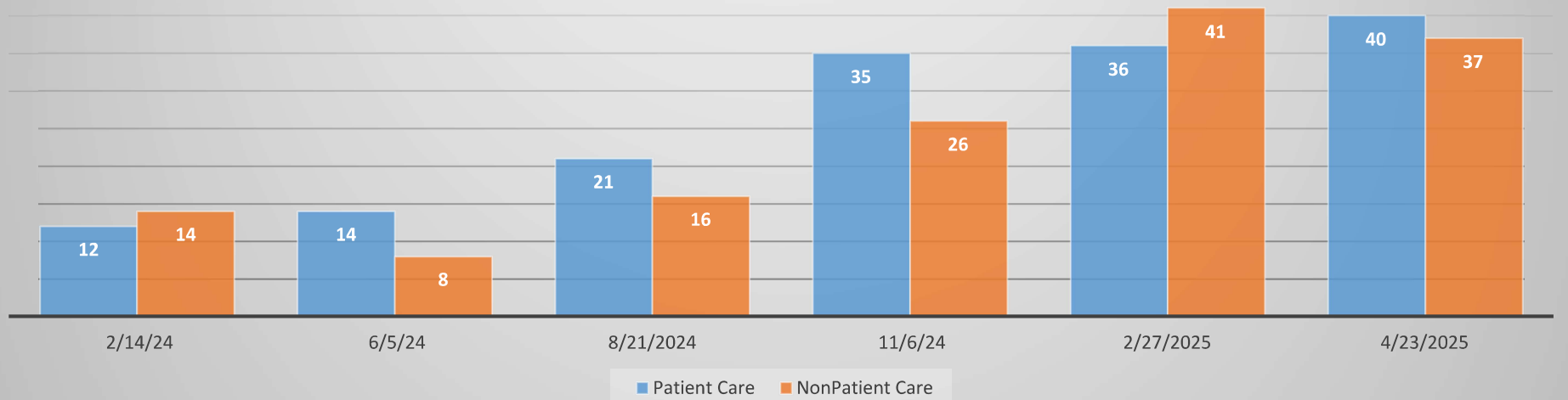


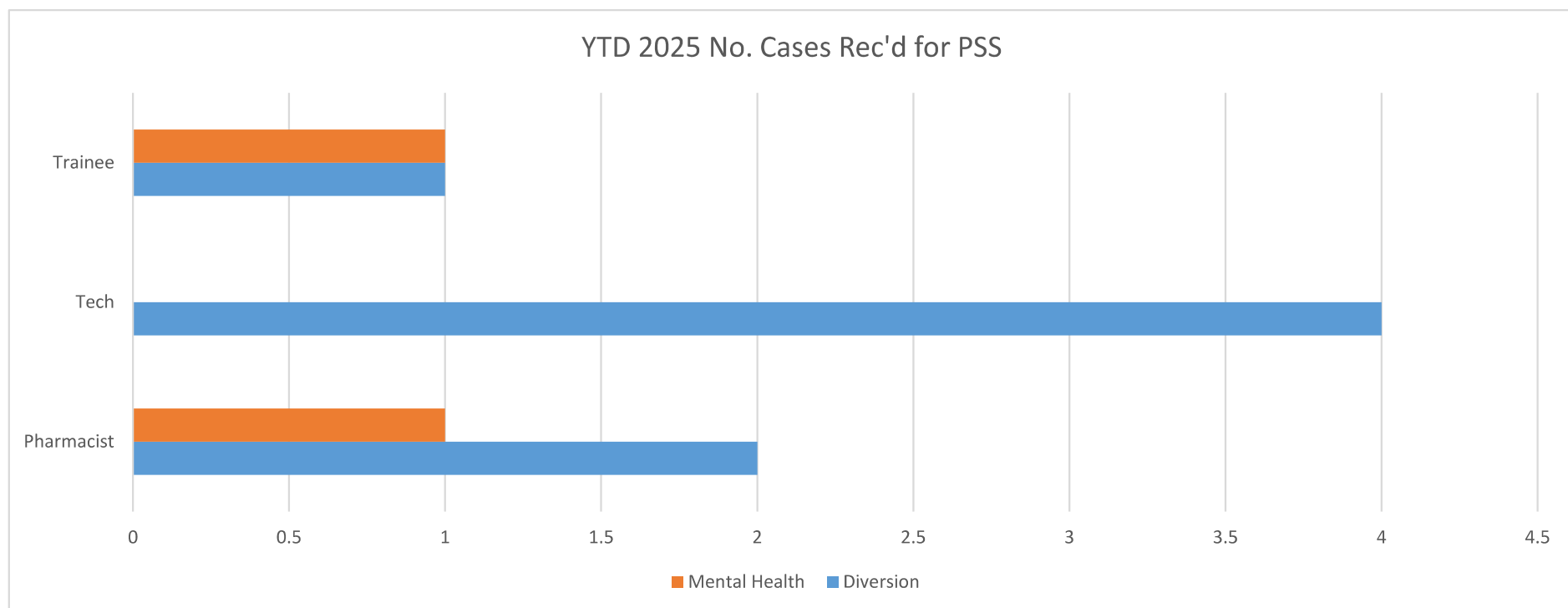
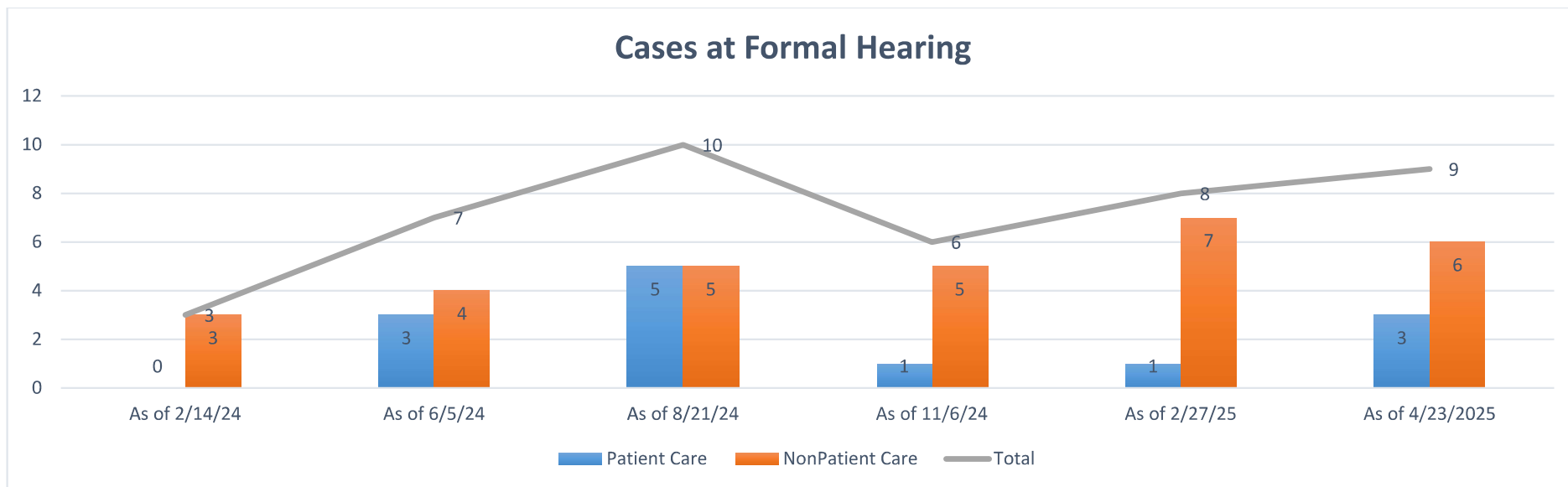
Cases at Probable Cause



Cases at APD

Date "As of"





Open Cases as of 4/23/25:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	OAG	TOTALS
Patient Care Cases	58	40	73	3	3	0	0	9	0	186
Non-Patient Care Cases	53	37	45	6	6	1	5	0	1	154
									TOTAL:	340

Upcoming Proceedings		
May 29, 2025	Ratliff/Hoffer	IFC
June 4, 2025	Garvin/Nash	IFC
June 5, 2025	Garvin Ratliff	Pilot Program
June 18, 2025	Yuan/Richards-Spruill	IFC
July 15, 2025	All Members	Formal Hearings
July 16, 2025	Agency Subord.	IFC
July 30, 2025	Ratliff/Hoffer	IFC
August 6, 2025	TBD	IFC
August 12, 2025	All Members	Formal Hearings
August 13, 2025	TBD	IFC
September 9, 2025	TBD	Pilot Program
September 10, 2025	TBD	IFC
September 16, 2025	TBD	IFC
September 30, 2025	All Members	Full Board Meeting/Formal Hearings

Executive Director's Report – May 19, 2025

Staff:

- ❖ Recruiting for vacant disciplinary administrative assistant position

In-person or Virtual Meetings Recently Attended:

- ❖ Forensic Science Board Meeting
- ❖ Monthly Regional EMS Medication Kit Transition Workgroup - O'Halloran
- ❖ VSHP Law Update at Spring Seminar
- ❖ NABP/AACP Districts 1 & 2 monthly planning meeting
- ❖ MPJE Item Writing Workshop – O'Halloran, Shinaberry, Logan

Recent Awards:

- ❖ 2025 Peninsulas EMS Council Special Recognition Award for the Virginia Regional EMS Medication Kit Transition Workgroup – Virginia Board of Pharmacy
- ❖ 2025 Governor's EMS Awards – Caroline Juran
- ❖ 2025 NABP Lester E. Hosto Distinguished Service Award – Caroline Juran