



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

Tentative Agenda of Full Board Meeting

September 30, 2025

9AM

TOPIC

PAGES

Call to Order of Public Hearing: Larry Kocot, JD, Chairman

- Welcome & Introductions

Public Hearings:

- | | |
|--|---------|
| • Placing Certain Chemicals into Schedule I | 41-52 |
| • Scheduling of Drugs Consistent with Federal Scheduling Action | 53-59 |
| • Crisis stabilization services and use of Automated Drug Dispensing Devices/Remote Dispensing Systems | 136-142 |

Adjournment of Public Hearings

Call to Order of Full Board Meeting: Larry Kocot, JD, Chairman

- Approval of Agenda

Approval of Previous Board Meeting Minutes:

- | | |
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| • May 7, 2025, Telephone Conference Call | 3-4 |
| • May 19, 2025, Full Board Meeting | 5-13 |
| • May 19, 2025, Public Hearing | 14-15 |
| • May 19, 2025, Formal Hearing | 16-17 |
| • June 11, 2025, Telephone Conference Call | 18-19 |
| • July 2, 2025, Telephone Conference Call | 20-21 |
| • July 15, 2025, Formal Hearing | 22-28 |
| • August 11, 2025, Public Hearing | 29 |
| • August 12, 2025, Therapeutic Interchange Work Group | 30-34 |
| • September 9, 2025, Innovative Pilot Program Committee | 35-36 |

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

Verbal

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

- | | |
|--|---------|
| • Chart of Regulatory Actions | 37-40 |
| • Adopt Exempt Regulatory Action – addition of chemicals to Schedule I | 41-52 |
| • Adopt Exempt Regulatory Action to Conform to Recent Federal Scheduling Action of Fentanyl Classification | 53-59 |
| • Adopt Final Regulations for Allowances for Emergency Drugs by EMS Agencies | 60-93 |
| • Adopt Fast-Track Regulatory Amendment of 18VAC110-20-590 regarding Correctional Facilities Possessing Long-acting Medication | 94-99 |
| • Adopt Proposed Regulations related to Central Fill Pharmacies | 100-117 |
| • Adopt Proposed Regulations related to Exclusion of Private Dwellings from CSRs | 118-123 |
| • Initiate periodic review of Chapter 15 regarding Agency Subordinates | 124-126 |

- Adopt Exempt Regulatory Amendments regarding Advanced Registered Medication Aides 127-135
- Re-Adoption of Guidance Document 110-19, *Use of Automated Dispensing Drug Systems and Remote Dispensing Systems in Certain Facilities* 136-142
- Adopt Guidance Document 110-39 regarding Hospital Centralized Compounding 143-144
- Adopt Amendment to Guidance Document 110-8 to Remove Reference to TPA Formulary for Optometrists due to Legislative Change 145-160
- Amend Guidance Document 110-17 regarding TOEFL Scores 161-166

Old Business:

- Review Action Items from Previous Meetings 167-183

New Business:

- Ad Hoc Committees Verbal
- Amend Statewide Protocols 184-299

Reports:

- Chairman's Report –Larry Kocot, JD Verbal
- Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh 300-306
- Report on Nonresident Facilities and Inspection Program – Beth O'Halloran, RPh 307-310
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD 311-322
- Executive Director's Report – Caroline D. Juran, RPh 323

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

Adjourn

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

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, May 7, 2025

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

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

TIME & PURPOSE:

Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on May 7, 2025, at 9:00 AM, to consider summary suspensions in case number 245229.

PRESIDING:

Cheri Garvin, Chairman

MEMBERS PRESENT:

Kristopher Ratliff
Kelly Kale
Derek Webb
Michelle Hoffer
Wendy Nash
Larry Kocot

STAFF PRESENT:

Caroline Juran, Executive Director
Mykl Egan, Discipline Case Manager
Jim Rutkowski, Senior Assistant Attorney General
Sean Murphy, Asst. Attorney General
Jess Weber, DHP Adjudication Specialist

POLLING OF BOARD MEMBERS

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

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

TIMOTHY CHAMBERLAIN
Registration No. 0230-028935

Sean Murphy, Assistant Attorney General, presented a summary of the evidence in case no. 245229 regarding the pharmacy technician registration of Timothy Chamberlain. Mr. Murphy was assisted by Jess Weber, Adjudication Specialist.

CLOSED MEETING:

Upon a motion by Dr. Ratliff, and duly seconded by Ms. Kale, the Board voted 7-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Timothy Chamberlain. Additionally, he moved that Mykl Egan, Caroline Juran, and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Dr. Ratliff and duly seconded by Ms. Kale, the Board unanimously voted (7-0) that, with the evidence presented, the continued practice of Timothy Chamberlain poses a substantial danger to the public; and therefore, his pharmacy technician registration shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered in lieu of the formal hearing.

ADJOURN: 9:26

Mykl Egan
Discipline Case Manager

Date

(DRAFT/UNAPPROVED)

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

Monday, May 19, 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 9:05 AM.

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

MEMBERS PRESENT: **Shannon Dowdy**, PharmD
Kelly Hasty Kale, RPh
Larry Kocot, JD
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: **Jim Rutkowski**, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
Arne Owens, DHP Agency Director (arrived at 9:40 AM)
Caroline Juran, RPh, Executive Director, Virginia Board of Pharmacy (left at 11AM)
Sorayah Haden, Executive Assistant, Virginia Board of Pharmacy
Ryan Logan, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Beth O'Halloran, RPh, Deputy Executive Director, Virginia Board of Pharmacy
Mykl Egan, JD, Discipline Case Manager (Arrived at 12:30 PM)

PHARMACISTS AWARDED
1-HOUR OF LIVE OR REAL-
TIME INTERACTIVE
CONTINUING EDUCATION
FOR ATTENDING MEETING: No requests received.

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

APPROVAL OF AGENDA: An amended agenda was provided that included a new agenda item under the

Legislative/Regulatory/Guidance section entitled "Adoption of exempt regulatory action/fast-track to conform regulations to HB1582". Four handouts were also provided: a corrected version of the draft minutes from the April 25, 2025 meeting, an additional amendment of Guidance Document 110-9, information regarding the adoption of regulations to conform to HB1582, and written comments submitted by the Virginia Pharmacy Association. Hearing no comment, the amended agenda was approved as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Amendments were offered to the draft minutes included in the agenda packet.

Based on unanimous consent, the Chairman announced that the minutes for the meetings held between March 25, 2025 and April 25, 2025 were approved as presented and amended as follows:

- Amending Dr. Kale to state "Ms. Kale" on the second page of the Formal Hearing minutes held on April 15, 2025.
- Inserting an action item into the Educational Forum minutes for Board members and staff to develop a list of IT-related needs that are not currently met and submit it to relevant agency staff to determine if the Evoke software platform to be implemented in 2027/2028 can meet those needs.

PUBLIC COMMENT:

Dr. Natalie Nguyen, on behalf of the Virginia Society of Health-System Pharmacists (VSHP), thanked the board for its engagement and openness to conversation during the 2025 General Assembly session. In addition, she recognized the BOP's role in the EMS Medication Kit transition with being recognized as a 2025 PEMS Regional EMS Award Nominee. Regarding draft amendments to guidance document 110-20, she requested that the Board clarify how noncompliance with this law can be reported and the Board's authority to enforce this provision. Regarding the 2026 draft legislative proposal, she recommended the board provide talking points for how it plans to ensure checks and balances are in place to prevent incentivizing more disciplinary actions in order to increase collection of fees.

William Wynn, PharmD provided public comment on behalf of Indivior. Dr. Winn expressed his gratitude of the Boards' continued efforts to amend Guidance Document 110-44 to ensure other opioid antagonists are included in the allowance. He offered himself as a resource to the Board for any medical questions or concerns regarding nalmeferene.

DHP DIRECTOR'S REPORT:

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

- As of July 1, 2025, Beth O'Halloran, BOP Deputy Executive Director, will supervise the pharmacist inspectors, instead of the Enforcement Division.
- Mr. Owens reviews the agency's budget quarterly.

- The agency is preparing legislative proposals for the 2026 General Assembly session.
- Plans for disbanding the Board of Health Professions are underway based on passed legislation as the Board had outlived its usefulness.
- An agency efficiency workgroup continues to meet to identify cost-saving measures.

NEW BUSINESS

REVIEW OF CURRENT REVENUE AND EXPENDITURES

Ms. Juran provided an overview of the FY 2025 Budget and Current Expenditures included in the agenda packet. The overview explained the Direct Expenditures consisting of base budget expenses, other budget expenses, and salaries and benefits, along with Allocated Expenditures and Revenue. Postal services are reported as the largest base budget expense. The office building rental fee is reported as the largest other budget expense. As of February 2025, the largest allocated expenditures are from the Enforcement Division, Data Center, and Administrative Proceedings. In comparison of the projected expenses and the actual expenses, the Board is currently operating under budget.

ACTION ITEMS:

There was consensus that staff will ask the agency's Finance Department if they actively negotiate credit card fees and staff will provide a summary of revenue and expenditures annually to the board.

ELECTION OF 2025-2026 CHAIRMAN

Dr. Ratliff nominated Mr. Larry Kocot to serve as the 2025-2026 Chairman of the Virginia Board of Pharmacy.

MOTION

Hearing no additional nominations, the Board voted unanimously to close nominations for the election of Chairman. (motion by Webb, seconded by Dowdy)

MOTION

The Board voted unanimously to elect Mr. Larry Kocot to serve as the Chairman of the Virginia Board of Pharmacy for the term of July 1, 2025 through June 30, 2026.

MOTION

The Board voted unanimously to authorize the Vice-Chairman to appoint members to the special conference standing committees until a new chairman is elected should Mr. Kocot not be reappointed to serve on the Board.

ELECTION OF 2025-2026 VICE-CHAIRMAN

Dr. Yuan nominated Dr. Shannon Dowdy to serve as the 2025-2026 Vice-Chairman of the Virginia Board of Pharmacy.

MOTION

Hearing no additional nominations, the Board voted unanimously to close nominations for the election of Vice-Chairman. (motion by Kocot, seconded by Webb)

MOTION

The Board voted unanimously to elect Dr. Shannon Dowdy to serve as the Vice-Chairman of the Virginia Board of Pharmacy for the term of July 1, 2025 through June 30, 2026.

MOTION

Mr. Kocot moved, and Mr. Webb seconded to thank Ms. Cheri Garvin by acclamation for her service as the 2024-2025 Chairman of the Virginia Board of Pharmacy.

**LEGISLATIVE/
REGULATORY/GUIDANCE**

**CHART OF REGULATORY
ACTIONS**

Ms. Barrett reviewed the Regulatory Chart included in the agenda packet and provided the following updates as of May 19, 2025:

- 18VAC110-20 regarding the amendment to clarify application of 18VAC110-20-735 has been approved and set for publication as of June 16, 2025. The regulatory amendment will become effective July 31, 2025.
- 18VAC110-20 regarding the implementation of 2021 Periodic Review is currently at Governor's Office for review.
- 18VAC110-20 regarding the replacement of analytic lab regulation for pharmaceutical processors is currently at the Secretary's Office for review.
- 18VAC110-20 regarding the allowances for emergency drugs by EMS agencies is currently at the Secretary's Office for review.
- 18VAC110-20 regarding the crisis stabilization services and use of automated dispensing systems and remote dispensing systems is currently at the Secretary's Office for review.

**ADOPT FAST-TRACK AND
EXEMPT REGULATORY
AMENDMENTS TO
CHAPTER 20 REGARDING
OTHER OPIOID
ANTAGONISTS**

In response to SB 1035, the Board reviewed and discussed the adoption of the fast-track regulatory change to include "other opioid antagonists" when only naloxone is referenced. Ms. Barrett identified the amendments to state "Naloxone or other opioid antagonists" throughout the regulations.

MOTION:

The Board voted unanimously to adopt the fast-track regulatory changes to include "other opioid antagonists" in 18VAC110-20-540, 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-735 as presented. (motion by Dowdy, seconded by Webb)

**AMEND GUIDANCE
DOCUMENT 110-44,
NALOXONE OR OTHER
OPIOID ANTAGONIST
PROTOCOLS**

In response to SB 1035, the Board reviewed and discussed the adoption of amendments to Guidance Document 110-44 to include "other opioid antagonists".

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Documented 110-44 as presented. (motion by Ratliff, seconded by Kocot)

ADOPTION OF GUIDANCE
DOCUMENT 110-20 TO
ADDRESS HB2378

In response to the public comment received earlier, Ms. Juran encouraged the reporting of non-compliance through the Enforcement Division like any other complaint.

MOTION:

The Board voted unanimously to adopt Guidance Document 110-20 as presented. (motion by Ratliff seconded by Dowdy)

AMEND GUIDANCE
DOCUMENT 110-6,
*GUIDANCE FOR
PHARMACIES WITHIN
OPIOID TREATMENT
PROGRAM*

The Board reviewed and discussed the proposed amendments to Guidance Document 110-6 to inform other opioid treatment programs of how to gain approval from the Board to operate a mobile medication unit.

MOTION

The Board voted unanimously to adopt Guidance Document 110-6 as presented and amended by inserting “or other opioid antagonists” under the section entitled “Naloxone”. (motion by Yuan seconded by Webb)

Ms. Juran left the meeting to attend an awards ceremony at the Governor’s Executive Mansion downtown.

EXEMPT REGULATORY
ACTION TO CONFORM
REGULATIONS TO HB1582

The Board reviewed and discussed the draft changes to 18VAC110-40 governing collaborative practice agreements.

MOTION

The Board voted unanimously to adopt exempt regulatory changes to 18VAC110-40 as presented. (motion by Ratliff, seconded by Webb)

ADOPTION OF EXEMPT
REGULATORY ACTION TO
CONFORM TO GENERAL
ASSEMBLY SCHEDULING
LEGISLATION

The Board reviewed and discussed the draft amended regulatory language to remove scheduled drugs and chemicals now in statute.

MOTION

The Board voted unanimously to adopt exempt regulatory action to remove drugs and chemicals from Board 18VAC110-20-322 and 18VAC110-20-323 that will be scheduled in statute pursuant to HB 1587. (motion by Kale, seconded by Ratliff)

ADOPTION OF EXEMPT
REGULATORY ACTION –
ADDITION OF CHEMICALS

The Board reviewed and discussed the addition of the following chemicals to Schedule I:

TO SCHEDULE I

1. N,N-dipropyl-1H-indole-3-ethanamine (other names: Dipropyltryptamine;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.
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.

MOTION

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

- **N,N-dipropyl-1H-indole-3-ethanamine (other names: Dipropyltryptamine;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.**
- **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. (motion by Ratliff, seconded by Kocot)**

ADOPT EXEMPT
REGULATORY
AMENDMENTS 18VAC110-
21-141

The Board reviewed and discussed the draft regulatory changes to 18VAC110-21-41 and HB2307 which expanded training opportunities for pharmacy technician trainees.

MOTION

The Board voted unanimously to adopt the exempt regulatory change to 18VAC110-21-41 as presented. (motion by Dowdy, seconded by Webb)

AMEND GUIDANCE
DOCUMENT 110-34,
MANUFACTURER, THIRD-
PARTY LOGISTICS
PROVIDER, WAREHOUSER,
AND WHOLESALE
DISTRIBUTOR LICENSURE
GUIDANCE

The Board reviewed and discussed the adoption of amendments to Guidance Document 110-34 to align with current practices.

MOTION

The Board voted unanimously to adopt amendments to Guidance Document 110-34 as presented. (motion by Dowdy, seconded by Webb)

AMEND GUIDANCE
DOCUMENT 110-9,
*PHARMACY INSPECTION
DEFICIENCY MONETARY
PENALTY GUIDE*

The Board reviewed and discussed the amendments of Guidance Document 110-9, Pharmacy Inspection Deficiency Monetary Penalty Guide regarding deficiencies 111, 138, and 139 to conform with new laws and regulations.

MOTION

The Board voted unanimously to adopt Guidance Document 110-9 as presented. (motion by Webb, seconded by Ratliff)

REVIEW 2026 LEGISLATIVE
PROPOSALS REGARDING
FINANCES AND FEES OF
THE AGENCY

Ms. Barrett provided an overview of the potential legislative requests of the agency regarding fees and finances. The Board reviewed draft legislation allowing recovery of costs related to investigation and disciplinary proceedings. Additionally, the Board reviewed draft legislation amending the Callahan Act to allow fee actions to be implemented by exempt regulatory actions and allow the Department to request general funds for discrete costs.

REPORTS:

CHAIRMAN'S REPORT

The Chairman confirmed that she did not have any updates to report since the last Full Board Meeting.

NABP ANNUAL MEETING

Dr. Webb provided an overview of his experience at the recent NABP Annual Meeting held in Fort Lauderdale, FL, along with Ms. Juran and Ms. O'Halloran. He informed the Board the annual meeting consisted of a full schedule with many of the topics covering AI implementation throughout the Pharmacy industry. He stated the Board received a lot of positive feedback from the other states. Attendance at future annual meetings is highly encouraged.

LICENSURE PROGRAM

Mr. Logan provided an overview of the Licensure Program consisting of licensing data of Individuals and Facility licensees from Q2 of 2022 through Q3 of 2025. The overview included the following current license count:

- Pharmacist – 16,452
- Pharmacy Technician – 12,933
- Pharmacy Technician Trainee – 7,785
- Pharmacy Intern – 969
- Resident Pharmacies – 1,727
- Non-Resident Pharmacies – 977

He reviewed the new pharmacy permit to pharmacy permit closure ratios. As of Q3, the Board has a record of 10 pharmacy permits issued and 11 pharmacy permits closed. The Board requested to have more detailed license statistics such as practice types and locations of pharmacy openings and closures provided at the next Full Board Meeting (Nash). The Board requested staff to conduct further research of the Rite-Aid closings and their potential effects on pharmacies and manufacturers. (Kale, Kocot)

INSPECTION PROGRAM

Ms. O'Halloran provided an overview of the Inspection Program. The overview consisted of all inspections conducted during the period of January 1, 2025, through March 31, 2025. As of March 31, 2025, the Inspections Program conducted a total of 435 inspections consisting of 375 in person inspections and 60 virtual inspections. The top 5 cited deficiencies reported are as follows:

- Pharmacist-In-Charge in place, inventory taken, but application not filed with Board within the required timeframe (cited 18 times)
- 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 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. (cited 17 times)
- Labels do not include all required information. (cited 15 times)
- Required compounding/dispensing/distribution records not complete and properly maintained. (cited 14 times)
- 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) (cited 12 times)

DISCIPLINARY PROGRAM

The Board reviewed the disciplinary report included in the agenda packet.

EXECUTIVE DIRECTOR'S REPORT

The Board reviewed the executive director's report included in the agenda packet. Ms. Kale informed the Board that she attended the Peninsulas Emergency Medical Services Council regional awards ceremony at Busch Gardens on May 17, 2025 to receive a special recognition award on behalf of the Board of Pharmacy for its contributions to the EMS Medication Kit Transition Workgroup. She stated that Beth O'Halloran and Caroline Juran received similar recognition.

CONSIDERATION OF CONSENT ORDERS, SUMMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

CASE #246114:

David Robinson, Assistant Attorney General, and Christine Andreolli, DHP

BERDOVER DIAZ
BERDECIA JR (PHARMACY
TECHNICIAN TRAINEE
PERMIT #0245014011)

Adjudication Specialist presented information for a possible summary suspension regarding Berdover Diaz Berdecia, Jr (Pharmacy Technician Trainee Permit #0245014011).

CLOSED MEETING

Upon a motion by Yuan, and duly seconded by Webb, the Board unanimously voted 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 Berdover Diaz Berdecia Jr (Pharmacy Technician Trainee Permit #0245014011). Additionally, she moved that Jim Rutkowski, Sorayah Haden, and Mykl Egan attend the closed meeting because their presence is deemed necessary and will aid the board in its deliberations.

RECONVENE

Upon the motion by Yuan, and duly seconded by Kale, 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.

DECISION

Upon a motion by Dowdy, and duly seconded by Kale, the Board unanimously voted to summarily suspend the Pharmacy Technician Trainee Permit of Berdover Diaz Berdecia, Jr and offer a pre-hearing consent order for revocation in lieu of a Formal Hearing.

MEETING ADJOURNED:

1:05 PM

Caroline Juran, RPh
Executive Director

DATE:

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

Monday, May 19, 2025

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

CALL TO ORDER: A public hearing was called to order at 9:00 AM.

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

MEMBERS PRESENT: **Shannon Dowdy**, PharmD
Kelly Hasty Kale, RPh
Larry Kocot, JD
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: **Jim Rutkowski**, JD, Senior Assistant Attorney General
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
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

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

**PLACING CERTAIN
CHEMICALS INTO
SCHEDULE I**

PUBLIC COMMENT: The Chairman indicated public comment may be received on the placement of the following chemicals into Schedule I:

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.

No public comments were offered on the subject.

MEETING ADJOURNED:

9:05 AM

Caroline Juran, RPh
Executive Director

DATE:

**VIRGINIA BOARD OF PHARMACY
FORMAL HEARING**

Monday, May 19, 2025
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

CALL TO ORDER:

A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:15 PM for the purpose of convening a formal hearing.

PRESIDING:

Cheri Garvin, Chairwoman

MEMBERS PRESENT:

Dr. Ling Yuan, Vice Chair
Ms. Kelly Hasty Kale
Dr. Derek Webb
Dr. Wendy Nash
Dr. Shannon Dowdy
Dr. Kris Ratliff
Mr. Larry Kocot

STAFF PRESENT:

Mykl D. Egan, Discipline Case Manager
James Rutkowski, Sr. Assistant Attorney General
Sorayah Haden, Executive Assistant

QUORUM:

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

ALISON D. ARMBRISTER
Reg. no. 0230-028935

A formal hearing was held in the matter of Alison Armbrister, 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 March 11, 2025, and continued by notice dated March 31, 2025.

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

WITNESSES:

Scott Dillon, DHP Senior Investigator testified in person on behalf of the Commonwealth.

Joshua Hammett, Pharmacy Director of Express Care Pharmacy, testified in person on behalf of the

Commonwealth.

CLOSED MEETING:

Upon a motion by Dr. Yuan, 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 to reach a decision regarding the matter of Alison Armbrister. Additionally, she moved that Mykl Egan, 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. (Yuan/Dowdy)

DECISION:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Yuan, the Board voted 8-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth. Upon a motion by Dr. Dowdy, and duly seconded by Dr. Yuan, the Board voted 8-0 to revoke the pharmacy technician registration of Alison Armbrister

ADJOURNED:

1:50 PM

Mykl D. Egan, Discipline Case
Manager

Date

**VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, June 11, 2025

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on June 11, 2025, at 10:00 AM, to consider summary suspensions in case number 244717.

PRESIDING: Cheri Garvin, Chairman

MEMBERS PRESENT: Kristopher Ratliff
Shannon Dowdy
Derek Webb
Michelle Hoffer
Wendy Nash
Larry Kocot

STAFF PRESENT: Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
Mykl Egan, Discipline Case Manager
Jim Rutkowski, Senior Assistant Attorney General
David Robinson, Asst. Attorney General
Rebecca Ribley, DHP Adjudication Specialist

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

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

DEREK LESTER MCCOWAN
License No. 0202-219948

David Robinson, Assistant Attorney General, presented a summary of the evidence in case no. 244717 regarding the pharmacist license of Derek Lester McCowan. Mr. Robinson was assisted by

Rebecca Ribley, Adjudication Specialist.

CLOSED MEETING:

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

RECONVENE:

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

DECISION:

Upon a motion by Mr. Kocot and duly seconded by Dr. Dowdy, the Board unanimously voted (7-0) that, with the evidence presented, the continued practice of Derek L. McCowan poses a substantial danger to the public; and therefore, his pharmacist license shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered in lieu of the formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 10:35 AM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL**

Wednesday, July 2, 2025

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

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

TIME & PURPOSE:

Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on July 3, 2025, at 3:00 PM, to consider summary suspensions in case number 241716.

PRESIDING:

Larry Kocot, Chairman

MEMBERS PRESENT:

Kristopher Ratliff
Shannon Dowdy
Derek Webb
Kelly Kale
Wendy Nash
Patricia Richards-Spruill
Ling Yuan

STAFF PRESENT:

Ellen Shinaberry, Deputy Executive Director
Caroline Juran, Executive Director
Mykl Egan, Discipline Case Manager
Jim Rutkowski, Senior Assistant Attorney General
Mandy Wilson, Asst. Attorney General
Jess Weber, DHP Adjudication Specialist

POLLING OF BOARD MEMBERS

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

With eight (8) members participating, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

DEREK LESTER MCCOWAN
License No. 0202-219948

Mandy Wilson, Assistant Attorney General, presented a summary of the evidence in case no. 241716 regarding the pharmacy technician registration of

Rachel Drinkard. Ms. Wilson was assisted by Jess Weber, Adjudication Specialist.

CLOSED MEETING:

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

RECONVENE:

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

DECISION:

Upon a motion by Ms. Kale and duly seconded by Mrs. Patricia Richards-Spruill, the Board unanimously voted (8-0) that, with the evidence presented, the continued practice of Rachel Drinkard poses a substantial danger to the public; and therefore, her pharmacy technician registration shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered in lieu of the formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 3:56 PM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
FORMAL HEARINGS,
CONSIDERATION OF CONSENT ORDER and
AGENCY SUBORDINATE RECOMMENDATIONS

Tuesday, July 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 9:12 AM for the purpose of convening a formal hearing, consideration of consent order, and consideration of agency subordinate recommendations.

PRESIDING:

Larry Kocot, Chairman

MEMBERS PRESENT:

Dr. Shannon Dowdy, Vice Chair
Ms. Kelly Hasty Kale
Dr. Derek Webb
Dr. Wendy Nash
Dr. Kris Ratliff

STAFF PRESENT:

Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Sr. Assistant Attorney General
Sara Blose, Assistant Attorney General
Sorayah Haden, Executive Assistant

QUORUM:

With six (6) members of the Board present, a panel of the board was established.

EDGAR GONZALEZ
License. no. 0202-007673

A formal hearing was held in the matter of Edgar Gonzalez, pharmacist, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as provided in the notice dated February 3, 2025, and continued by notice dated March 10, 2025.

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

WITNESSES:

William Gorwood, DHP Senior Investigator testified in person on behalf of the Commonwealth.

Mr. Gonzalez testified on his own behalf.

CLOSED MEETING:

Upon a motion by Ms. Kale, and duly seconded by Dr. Webb, the Board voted 6-0, to convene a closed session pursuant to §2.2-3711(A)(16) of the Code of Virginia ("Code"), for the purpose of discussion of medical records of Edgar Gonzalez. Additionally, she moved that Ellen Shinaberry, Jim Rutkowski, Sara Blose, Jess Weber, Edgar Gonzalez, Sorayah Haden and the court reporter attend the closed meeting.

RECONVENE:

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

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Ms. Kale, the Board voted 6-0, 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 Edgar Gonzalez. Additionally, she moved that Ellen Shinaberry, Jim Rutkowski, Sara Blose 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/Webb)

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Nash, the Board voted 6-0 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. Webb, the Board voted 5-1 (Nash opposed) to reinstate the pharmacist license of Edgar Gonzalez as place him on probation for two years with certain terms and conditions.

ADDITIONAL STAFF ARRIVAL:

Mr. Egan arrived at 12:30 PM.

CONSIDERATION OF AGENCY
SUBORDINATE
RECOMMENDATION:

Dr. Shinaberry presented the agency subordinate recommendation for Case. No. 236777.

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Ratliff, the Board voted 6-0 to accept the agency subordinate recommendation as presented by staff.

CONSIDERATION OF CONSENT
ORDER:

Mr. Egan presented a proposed consent order in the matter of Case No. 249142.

DECISION:

Upon a motion by Dr. Nash, and duly seconded by Dr. Webb, the Board voted 6-0 to offer a consent order as presented by staff.

STAFF DEPARTURE:

Mr. Egan departed at 12:45.

ASHLEY SCOTT
Registration no. 0230-030693

A formal hearing was held in the matter of Ashley Scott, 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 March 17, 2025, and continued by notice dated March 31, 2025.

Rebecca Ribley, Adjudication Specialist, presented the case for the Commonwealth. Ms. Scott was not present at the hearing and was not represented by counsel.

WITNESSES:

Steven Shirley, DHP Senior Investigator testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Nash, the Board voted 6-0, 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 Ashley Scott. Additionally, she moved that Ellen Shinaberry, Jim Rutkowski, Sara Blose 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 Dr. Ratloff, and duly seconded by Dr. Nash, the Board voted 6-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth. Upon a motion by Dr. Ratliff, and duly seconded by Dr. Dowdy, the Board voted 6-0 to suspend the right to renew the pharmacy technician registration of Ashley Scott for not less than two years.

DEPARTING STAFF: Sara Blose, Assistant Attorney General, departed prior to the start of the hearing for Nathan Lee.

NATHAN LEE
Registration No.: 0245-015352

A formal hearing was held in the matter of Nathan Lee, pharmacy technician trainee, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia as provided in the notice dated April 15, 2025.

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

WITNESSES: Brian Horowitz, DHP Senior Investigator, Joy El Maalouli, Pharmacy Manager of CVS Pharmacy #8288, Abigail Leach, Pharmacy technician at CVS Pharmacy #8288, and Daniel Perkins, CVS Asset Protection Leader, 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 6-0, 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 Nathan Lee. Additionally, she moved that Ellen Shinaberry, 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/Webb)

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Webb, the Board voted 6-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth and to revoke the pharmacy technician trainee registration of Nathan Lee.

STACY ALLEN
License no. 0202-214581

A formal hearing was held in the matter of Stacy Allen, pharmacist, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia as provided in the notice dated April 15, 2025.

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

WITNESSES:

Jennifer Challis, DHP Senior Investigator, and Amy Ressler, Program Administrative Director, Healthcare Practitioners Monitoring Program, testified in person on behalf of the Commonwealth.

Ms. Allen testified on her own behalf.

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Ms. Kale, the Board voted 6-0, 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 Stacy Allen. Additionally, she moved that Ellen Shinaberry, 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/Webb)

DECISION:

Upon a motion by Ms. Kale, and duly seconded by Dr. Nash, the Board voted 6-0 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. Dowdy, the Board voted 5-1 (Nash opposed) to continue the suspension of the pharmacist license of Stacy Allen, and stay the suspension upon certain terms and conditions.

DEPARTING STAFF:

Sorayah Haden departed prior to the start of the hearing for Timothy Chamberlain.

TIMOTHY CHAMBERLAIN
Registration No.: 0230-024789

A formal hearing was held in the matter of Timothy Chamberlain, pharmacy technician, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia as provided in the notice dated June 16, 2025.

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

WITNESSES:

David Cowras, DHP Senior Investigator, and Amy Ressler, Program Administrative Director, Healthcare Practitioners Monitoring Program, testified in person on behalf of the Commonwealth. William Heath, pharmacist in charge of Kroger Pharmacy #202, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Nash, the Board voted 6-0, 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 Timothy Chamberlain. Additionally, she moved that Ellen Shinaberry and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Dr. Ratliff, and duly seconded by Dr. Webb, the Board voted 6-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth. Upon a motion by Dr. Ratliff, and duly seconded by Dr. Dowdy, the Board voted 6-0 to suspend the pharmacy technician registration of Timothy Chamberlain for not less than two years, and stay the suspension upon certain terms and conditions.

ADJOURNED:

5:45 PM

Ellen B. Shinaberry
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING ON ALLOWANCES FOR EMERGENCY DRUGS
BY EMS AGENCIES**

Monday, August 11, 2025

Department of Health Professions
Perimeter Center
Board Room 3
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A public hearing was convened at 9:00 AM.

STAFF PRESENT: **Matt Novak**, Policy and Economic Analyst, DHP
Caroline Juran, RPh, Executive Director

No public comment was offered.

MEETING ADJOURNED: 9:45AM

Caroline Juran, RPh
Executive Director

DATE:

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF THERAPEUTIC INTERCHANGE WORK GROUP**

Tuesday, August 12, 2025

Department of Health Professions
Perimeter Center
Board Room 2
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: The meeting was called to order at 1:05 PM.

PRESIDING: Larry Kocot, JD, Chairman

PARTICIPANTS PRESENT:

- Shannon Dowdy, PharmD, Vice-Chairman, Board of Pharmacy
- Ling Yuan, PharmD, Member, Board of Pharmacy
- Derek Webb, PharmD, Member, Board of Pharmacy
- Bill Hutchens, MD, Member, Board of Medicine
- Randall Mangrum, DNP, RN, Deputy Executive Director for Advanced Practice, Board of Nursing
- Jennifer Deschenes, JD, MS, Deputy Executive Director, Board of Medicine
- Sharon Gatewood, PharmD, Past-President, Virginia Pharmacy Association
- Joshua Crawford, PharmD, Legislative Committee Co-Chair, Virginia Society of Health-System Pharmacists
- Jason Spouse, PharmD, National Association of Chain Drug Stores
- Joanne Dial, PharmD, Pharmacy Operations Specialist III, Controls, Kaiser Permanente
- Scott Castro, Senior Director of Health Policy, Medical Society of Virginia (replacing Clark Barrineau)
- Craig Connors, Vice President Payor Relations & Strategy, Virginia Hospital and Healthcare Association
- Laurie Mauthe, PharmD, Pharmacy Account Director, Elevance Health (replacing Doug Gray)
- Johnny Garcia, PharmD, Pharmaceutical Care Management Association (virtual participation)
- Jared Calfee, Associate State Director for Advocacy and Outreach, AARP Virginia
- Jamie Smith, PharmD, Clinical Pharmacy Services Manager, Department of Corrections
- JoeMichael Fusco, PharmD, Pharmacy Operations Manager, Department of Medical Assistance Services

- Stephanie Wheawill, PharmD, Director, Division of Pharmacy Services, Department of Health

STAFF PRESENT:

- Caroline Juran, RPh, Executive Director, Board of Pharmacy
- Erin Barrett, JD, Director of Legislative and Regulatory Affairs, Department of Health Professions
- Arne Owens, MS, Director, Department of Health Professions
- Sorayah Haden, Executive Assistant, Board of Pharmacy

WELCOME REMARKS:

Mr. Owens welcomed and thanked everyone for their attendance.

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

No requests received.

APPROVAL OF AGENDA:

Hearing no comment, the Chairman indicated that the agenda was approved as presented.

PUBLIC COMMENT:

No comments were offered.

REVIEW OF BACKGROUND
MATERIALS IN AGENDA
PACKET AND CURRENT
AUTHORITY FOR
PHARMACISTS TO INITIATE
THERAPEUTIC
INTERCHANGE:

The Chairman stated that this meeting was convened pursuant to SB 745 which was introduced by Senator Favola and passed during the 2025 General Assembly session. He indicated that the charge of the meeting was to (i) review and analyze the current authority of pharmacists to initiate therapeutic interchange (TI) under all health carriers and plans and health care reimbursement methods, including plans covered by the Employee Retirement Income Security Act of 1974; (ii) make recommendations to streamline the existing TI process in the Commonwealth; and (iii) make recommendations for the modernization of such TI authority, particularly in cases of prescription drug shortages. From the discussion, staff will prepare a report of the work group's findings and recommendations which will ultimately be provided to the Governor and the Chairs of the House Committee on Health and Human Services and the Senate Committee on Education and Health by November 15, 2025.

Ms. Juran then provided an overview of the remaining information in the agenda packet. She explained that current Virginia law only authorizes a pharmacist to dispense a "therapeutically equivalent drug product" as defined in § 54.1-3401. TI, however, generally involves the dispensing of a drug with a different chemical structure than the drug prescribed but of the same pharmacologic or therapeutic class with usually a similar therapeutic effect and adverse-reaction profile when administered in a therapeutically equivalent dose. While it has been common practice for decades for health

systems to use multi-disciplinary pharmacy and therapeutic committees to establish a formulary system, TI is not specifically addressed in law. Furthermore, the chairman questioned if § 54.1-3457 (16-17) prohibits a pharmacist from dispensing a drug under TI when a prescriber has not authorized the alternate drug to be dispensed. When reviewing the summary of state laws authorizing TI, she reported that some states specifically authorize TI in various types of institutions and other states, e.g., Arkansas, Idaho, Iowa, Kentucky, New Hampshire, Vermont, and Washington, authorize broader authority to include pharmacists practicing outside of institutions.

DISCUSSION:

The work group offered the following points during its discussion and review of state laws already in effect:

Allowances for Facilities to Perform TI

- Creating an allowance in law for pharmacists to perform TI consistent with a drug formulary established by a facility's pharmacy and therapeutic committee is necessary to support current practices.
- There was some discussion regarding whether a proposed law should be written broadly that is site neutral. Alternatively, in lieu of Idaho's use of the term "institutional" and to be consistent with existing Virginia law, it was noted that a proposed law may need to enumerate the specific type of facilities that could perform TI which should include pharmacies servicing correctional facilities.
- It was stated that currently, a health system's electronic health record drives TI at the point of prescribing often reducing the need for pharmacists to dispense drugs other than that which was prescribed.
- Dr. Garcia stated that pharmacy benefit managers usually rely on pharmacy and therapeutic committees to develop formularies.
- Dr. Fusco commented that some drug formularies are based on disease or medical condition and not drug class.

Cost and Accessibility

- Retail/community pharmacies, including the Department of Health Pharmacy, could benefit from flexibility to adjust a prescription when insurance will not cover a particular drug strength or a particular drug product, in lieu of requiring the pharmacist to contact the prescriber for authorization and creating patient delay in accessing the drug.
- It was emphasized that a proposed law on TI should not be mandatory and that it should result in a lower cost or be cost-neutral for the patient, unless the drug was on shortage. To determine drug shortages, it was recommended that a proposed law should reference both the United States Food and Drug Administration (FDA) drug shortage list and the American Society of Health-System Pharmacists (ASHP) drug

shortage list as the ASHP list appears to be updated more frequently.

- Mr. Calfee commented that Idaho's law states that the TI must lower the cost to the patient or occur during a drug shortage, and that such language would appear to address his members' general concerns with affordability and access.
- There was discussion on requiring pharmacy benefit managers to cover the less expensive drug or a non-formulary drug that was previously on formulary and the patient was previously on (ref. Va. Code § 38.2-3407.9:01 B.3). The work group discussed the applicability of utilizing pharmacist TI authority in these cases. Those representing health plans commented that they are required to cover the less expensive drug, and that otherwise, a process for obtaining prior authorization approval exists.

Notification of Prescriber

- It was recommended that pharmacists should be required to notify the prescriber when the pharmacist performs a TI to ensure good communication between prescriber and pharmacist, and that the period for notification of "within 24 hours" was probably reasonable.

Review of Existing State Laws

- Idaho's law regarding TI appears to be a good model.
- While not directly on-point with the meeting's charge, the allowances in Idaho's law for a pharmacist to change a prescription quantity, dosage form, or package size when not commercially available would be beneficial and could be noted in the legislative report as a footnote.
- A member highlighted Arkansas' law as being a good model if it was amended to also specifically authorize TI in facilities, but that the drug class exceptions should not apply to a formulary established by a pharmacy and therapeutics committee. Another member stated that a broader law such as Arkansas may result in better utilization by retail/community pharmacies.
- It was also recommended that pharmacists not be authorized to interchange drugs included in a statewide protocol or otherwise prohibited in a collaborative practice agreement.
- A few members also highlighted Kentucky's law wherein the prescriber records authorization for the use of TI on the written prescription but stated that any proposed language written similarly should also accommodate the recording of this information in the comments section of an electronic prescription.
- Dr. Crawford commented that Minnesota had an allowance for TI in place during the COVID-19 pandemic and that he would forward the verbiage to Ms. Juran.

Authorization for Pharmacist to Adapt/Amend the Prescription

- The work group confirmed that a pharmacist amends the original

prescription through “adaptation”, a term used in some of the state laws and does not change the name of the prescriber on the prescription.

MEETING ADJOURNED: 3:10 PM

Caroline Juran, RPh
Executive Director

DATE:

DRAFT

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

September 9, 2025
Commonwealth Conference Center
Second Floor
Board Room 1

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 9:10 am.

PRESIDING: Lawrence Kocot, Committee Chairman

MEMBER PRESENT: Shannon Dowdy, Committee Member

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

Virginia Treatment Center, Inc. dba:
Lynchburg Treatment Center, Galax
Treatment Center, LLC dba
Christiansburg Comprehensive
Treatment Center, Clinch Valley
Treatment Center, New River Treatment
Center, Roanoke Treatment Center,
Galax Treatment Center, LLC dba
Winchester Comprehensive Treatment
Center

Robert Mackey Pharmacist in Charge, PharmD, Kelli Tiong Pharmacist in Charge, PharmD, and Vikki White Associate Regional Director appeared in person to discuss the proposed innovative pilot program “PROOF for remote verification of take-home doses in Opioid Treatment Program (OTP) pharmacies.” as stated in the Notice dated August 19, 2025.

DISCUSSION: Representatives of Virginia Treatment Center, Inc. dba: Lynchburg Treatment Center, Galax Treatment Center, LLC dba Christiansburg Comprehensive Treatment Center, Clinch Valley Treatment Center, New River Treatment Center, Roanoke Treatment Center, Galax Treatment Center, LLC dba Winchester Comprehensive Treatment Center presented information related to a request to amend current waivers for “PROOF for remote verification of take-home doses in Opioid Treatment Program (OTP) pharmacies.”

DECISION: Upon a motion by Shannon Dowdy, and duly seconded by Lawrence Kocot, the Committee voted unanimously to approve in part and deny in part the requests for “PROOF for remote verification of take-home doses in Opioid

Treatment Program (OTP) pharmacies.”

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

Caroline D. Juran
Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of September 17, 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	2674 days; 8.4 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	126 days 3.4 years since submission for executive branch review	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	1263 days 3.4 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	754 days	Implements changes identified during the periodic review process

18VAC110-20 18VAC110-21 18VAC110-30 18VAC110-50	Final	Increase in fees	3/27/2025	156 days	Increases fees as needed for the Board to maintain operations.
18VAC110-20	Fast-track	Replacement of analytic lab regulation for pharmaceutical processors	5/15/2024	131 days	Replaces the former 18VAC110-60-300(A) into Board of Pharmacy regulations as required by Virginia Code § 4.1-1602

In the Department of Planning and Budget

None.

In the Office of the Attorney General

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Fast-track	Inclusion of other opioid antagonists in regulations referring to naloxone	5/30/2025	73 days	Pursuant to legislative changes, the Board amended regulations referring to naloxone to include other opioid antagonists.

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date/ next steps
18VAC110-20	Fast-track	Amendment to clarify application of 18VAC110-20-735	6/16/2025	Effective 7/31/2025
18VAC110-20	NOIRA	Exclusion of private dwellings or residences from	6/2/2025	Comment period ended 7/2/2025. Proposed

		operating locations of CSRs		amendments are before the Board for action.
18VAC110-20	Emergency/ NOIRA	Requirements for use of central fill pharmacy and remote database	6/30/2025	Comment period ended 7/30/2025. Proposed regulatory amendments are before the Board for action
18VAC110-20	Proposed	Allowances for emergency drugs by EMS agencies	7/14/2025	Comment period ended 9/12/2025. Final regulatory amendments are before the Board for action.
18VAC110-20	Final	Pharmacy working conditions	7/28/2025	Effective 8/27/2025
18VAC110-20	Final	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	7/28/2025	Effective 8/27/2025
18VAC110-21	Final	2023 pharmacists initiating treatment	8/5/2025	9/24/2025
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	8/11/2025	Effective 9/25/2025
18VAC110-20	Proposed	Crisis stabilization services and use of automated dispensing systems and remote dispensing systems	8/11/2025	Comment period ends 10/10/2025. Final regulatory amendments will be before the December Board meeting for action.
18VAC110-15	Fast-track	Amendment to allow agency subordinates to hear credentials cases	8/25/2025	Effective 10/9/2025
18VAC110-20	Final/ Exempt	May 2025 Schedule I adds	9/8/2025	Effective 10/8/2025
18VAC110-40	Final/ Exempt	Conforming collaborative practice	10/6/2025	Effective 11/5/2025

		agreements to HB1582 of the 2025 GA		
18VAC110- 21	Final/ Exempt	Amendment to pharmacy technician training program options pursuant to 2025 legislation	10/6/2025	Effective 11/5/2025
18VAC110- 20	Final/ Exempt	Conformity of Board scheduling regulations to General Assembly action	10/6/2025	Effective 11/5/2025

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

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To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: July 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 seven (7) compounds for recommended inclusion into the Code of Virginia.

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

1. **N-(2-methylphenyl)-1-(2-phenylethyl)piperidin-4-amine (other name: Despropionyl o-methylfentanyl)**, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

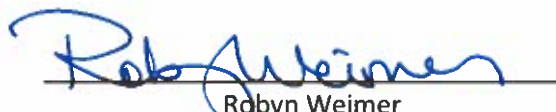
2. **[3-[2-(dimethylamino)ethyl]-1H-indol-4-yl] propanoate (other names: 4-propionoyloxy-N,N-dimethyltryptamine, 4-propanoyloxy DMT, 4-ProO DMT)**, its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
3. **1-(1,3-benzodioxol-5-yl)-2-(2-methylpropylamino)propan-1-one (other names: 3,4-methylenedioxy-N-isobutylcathinone; N-isobutyl methylone; 3,4-methylenedioxy- α -isobutylaminopropiophenone)**, its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
4. **2-bromo-Deschloroketamine (other name: 2-(2-bromophenyl)-2-(methylamino)-cyclohexanone)**, its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

5. **1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: Nitrazolam)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

6. **Naphthalen-1-yl 3-(dimethylsulfamoyl)-4-methylbenzoate (other names: NMDMSB; 1-naphthyl 3-(dimethylsulfamoyl)-4-methylbenzoate)**, 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.
7. **N-[1-(5-fluoropentyl)-2-hydroxyindol-3-yl]iminobenzamide (other names: 5-fluoro BZO-POXIZID, 5-fluoropentyl MDA 19)**, 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

Board of Pharmacy

September 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- 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.

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. Compound expected to have depressant properties. 7-Bromo-5-(2-chlorophenyl)-1,3-dihydro-2H-1,4-benzodiazepin-2-one (other name: phenazepam), 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. Cannabimimetic agent. Methyl N-[(5-methyl-1H-indazol-3-yl)carbonyl]-3-methylvalinate (other name: MDMB-5Me-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 November 21, 2026, unless enacted into law in the Drug Control Act.

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

1. The following compounds classified as synthetic opioids:

- a. 2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)benzimidazole (other names: metonitazepyne, N-pyrrolidino metonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.
- b. 2-[2-[(4-ethoxyphenyl)methyl]-5-nitrobenzimidazol-1-yl]-N-ethylethanamine (other name: N-desethyl etonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.
- c. N-(2-methylphenyl)-N-[1-(2-phenethyl)piperidin-4-yl]propanamide (other name: ortho-methylfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.
2. The following compounds expected to have hallucinogenic properties:
- a. [3-[2-(diethylamino)ethyl]-1H-indol-4-yl] acetate (other names: 4-acetoxy-N,N-diethyltryptamine; 4-acetoxy DET; 4-AcO-DET; ethacetin), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
- b. 3-[2-(diethylamino)ethyl]-1H-indol-4-ol (other names: 4-hydroxy-N,N-diethyltryptamine; 4-hydroxy DET; ethocin), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
- c. 3-methylmethcathinone (other names: 3-MMC; metaphedrone; 2-(methylamino)-1-(3-methylphenyl)propan-1-one), its salts, isomers, and salts of isomers whenever the

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

3. The following compounds classified as cannabimimetic agents:

- a. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
- b. N-cyclohexyl-2-(1-pentylindol-3-yl)acetamide (other names: cyclohexyl-PIATA, CH-PIACA, CH-PIATA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until November 21, 2026, unless enacted into law in the Drug Control Act.

G. Pursuant to subsection E of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following compounds into Schedule I of the Drug Control Act to conform to federal scheduling changes:

1. Meta-fluorofentanyl (other name: N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)propionamide);
2. Meta-fluoroisobutyryl fentanyl (other name: N-(3-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)isobutyramide);
3. Para-methoxyfuranyl fentanyl (other name: N-(4-methoxyphenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);

4. 3-furanyl fentanyl (other name: N-(1-phenethylpiperidin-4-yl)-N-phenylfuran-3-carboxamide);
5. 2',5'-dimethoxyfentanyl (other name: N-(1-(2,5-dimethoxyphenethyl)piperidin-4-yl)-N-phenylpropionamide);
6. Isovaleryl fentanyl (other name: 3-methyl-N-(1-phenethylpiperidin-4-yl)-N-phenylbutanamide);
7. Ortho-fluorofuranyl fentanyl (other name: N-(2-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide);
8. Para-methylcyclopropyl fentanyl (other name: N-(4-methylphenyl)-N-(1-phenethylpiperidin-4-yl)cyclopropanecarboxamide);
9. Methyl 2-[[1-(4-fluorobutyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 4F-MDMB-BUTICA; 4F-MDMB-BICA);
10. 5-Pentyl-2-(2-phenylpropan-2-yl)pyrido[4,3-b]indol-1-one (other names: CUMYL-PEGACLONE; SGT-151);
11. Ethyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate (other names: 5F-EDMB-PICA; 5F-EDMB-2201); and
12. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(piperidin-1-yl)ethyl)-1H-benzimidazole (other names: N-piperidinyl etonitazene; etonitazepipne).

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

1. The following compound classified as a synthetic opioid: N-(2-methylphenyl)-1-(2-phenylethyl)piperidin-4-amine (other name: Despropionyl o-methylfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted,

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

2. The following compounds expected to have hallucinogenic properties:

a. [3-[2-(dimethylamino)ethyl]-1H-indol-4-yl] propanoate (other names: 4-propionoyloxy-N,N-dimethyltryptamine, 4-propanoyloxy DMT, 4-ProO DMT), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-(1,3-benzodioxol-5-yl)-2-(2-methylpropylamino)propan-1-one (other names: 3,4-methylenedioxy-N-isobutylcathinone; N-isobutyl methylone; 3,4-methylenedioxy- α -isobutylaminopropiophenone), 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. 2-bromo-Deschloroketamine (other name: 2-(2-bromophenyl)-2-(methylamino)-cyclohexanone), its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. The following compound expected to have depressant properties: 1-methyl-8-nitro-6-phenyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other name: Nitrazolam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. The following compounds classified as cannabimimetic agents:

a. Naphthalen-1-yl 3-(dimethylsulfamoyl)-4-methylbenzoate (other names: NMDMSB; 1-naphthyl 3-(dimethylsulfamoyl)-4-methylbenzoate), its salts, isomers, and salts of

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

b. N-[1-(5-fluoropentyl)-2-hydroxyindol-3-yl]iminobenzamide (other names: 5-fluoro BZO-POXIZID, 5-fluoropentyl MDA 19), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until [June 17, 2027], unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of amendments to Schedule I pursuant to federal scheduling changes

Included in your agenda package:

- Draft changes to 18VAC110-20-323 reflecting federal Schedule I changes; and
- An excerpt of HR 27, known as the HALT act, showing changes to Schedule I to include fentanyl-related substances.

Action needed:

- Motion to amend 18VAC110-20-323 by exempt action.

Board of Pharmacy

Inclusion of fentanyl-related compounds in Schedule I consistent with federal scheduling changes

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. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);
2. Deletes Samidorphan from Schedule II; ~~and~~
3. Adds zuranolone to Schedule IV; and
4. Adds the following chemicals into Schedule I:
 - a. Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of a fentanyl-related substance, or which contains the salts, isomers, and salts of isomers of a fentanyl-related substance whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
 - b. For purposes of subsection 4 a, except as provided in subsection 4 c, the term "fentanyl-related substance" means any substance that is structurally related to fentanyl by one or more of the following modifications:
 - (1) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

(2) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxy, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(3) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxy, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(4) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle.

(5) By replacement of the N-propionyl group with another acyl group.

c. A substance that satisfies the definition of the term "fentanyl-related substance" in subsection 4 b shall not be treated as a fentanyl-related substance subject to this schedule if the substance is expressly listed in a schedule other than this schedule.

d. The absence of a substance from Schedule I in the Drug Control Act or regulation does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term "fentanyl-related substance" in subsection 4 b and does not meet the exception requirement of subsection 4 c.

21 USC 812: Schedules of controlled substances

Text contains those laws in effect on August 26, 2025

From Title 21-FOOD AND DRUGS

CHAPTER 13-DRUG ABUSE PREVENTION AND CONTROL

SUBCHAPTER I-CONTROL AND ENFORCEMENT

Part B-Authority To Control; Standards and Schedules

Jump To:

[Source Credit](#)

[Miscellaneous](#)

[Amendments](#)

[Effective Date](#)

§812. Schedules of controlled substances**(a) Establishment**

There are established five schedules of controlled substances, to be known as schedules I, II, III, IV, and V. Such schedules shall initially consist of the substances listed in this section. The schedules established by this section shall be updated and republished on a semiannual basis during the two-year period beginning one year after October 27, 1970, and shall be updated and republished on an annual basis thereafter.¹

(b) Placement on schedules; findings required

Except where control is required by United States obligations under an international treaty, convention, or protocol, in effect on October 27, 1970, and except in the case of an immediate precursor, a drug or other substance may not be placed in any schedule unless the findings required for such schedule are made with respect to such drug or other substance. The findings required for each of the schedules are as follows:

(1) SCHEDULE I.-

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has no currently accepted medical use in treatment in the United States.
- (C) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

(2) SCHEDULE II.-

- (A) The drug or other substance has a high potential for abuse.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- (C) Abuse of the drug or other substances may lead to severe psychological or physical dependence.

(3) SCHEDULE III.-

- (A) The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (C) Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

(4) SCHEDULE IV.-

- (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

(5) SCHEDULE V.-

- (A) The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
- (B) The drug or other substance has a currently accepted medical use in treatment in the United States.
- (C) Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

(c) Initial schedules of controlled substances

Schedules I, II, III, IV, and V shall, unless and until amended pursuant to section 811 of this title, consist of the following drugs or other substances,¹ by whatever official name, common or usual name, chemical name, or brand

name designated:

SCHEDULE I

(a) Unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

- (1) Acetylmethadol.
- (2) Allylprodine.
- (3) Alphacetylmethadol.²
- (4) Alphameprodine.
- (5) Alphamethadol.
- (6) Benzethidine.
- (7) Betacetylmethadol.
- (8) Betameprodine.
- (9) Betamethadol.
- (10) Betaprodine.
- (11) Clonitazene.
- (12) Dextromoramide.
- (13) Dextrophan.
- (14) Diampromide.
- (15) Diethylthiambutene.
- (16) Dimenoxadol.
- (17) Dimepheptanol.
- (18) Dimethylthiambutene.
- (19) Dioxaphetyl butyrate.
- (20) Dipipanone.
- (21) Ethylmethylthiambutene.
- (22) Etonitazene.
- (23) Etoxeridine.
- (24) Furethidine.
- (25) Hydroxypethidine.
- (26) Ketobemidone.
- (27) Levomoramide.
- (28) Levophenacymorphan.
- (29) Morpheridine.
- (30) Noracymethadol.
- (31) Norlevorphanol.
- (32) Normethadone.
- (33) Norpipanone.
- (34) Phenadoxone.
- (35) Phenampromide.
- (36) Phenomorphan.
- (37) Phenoperidine.
- (38) Piritramide.
- (39) Proheptazine.
- (40) Properidine.
- (41) Racemoramide.
- (42) Trimeperidine.

(b) Unless specifically excepted or unless listed in another schedule, any of the following opium derivatives, 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:

- (1) Acetorphine.
- (2) Acetyldihydrocodeine.
- (3) Benzylmorphine.
- (4) Codeine methylbromide.
- (5) Codeine-N-Oxide.
- (6) Cyprenorphine.
- (7) Desomorphine.
- (8) Dihydromorphine.
- (9) Etorphine.
- (10) Heroin.

- (11) Hydromorphenol.
- (12) Methyldesorphine.
- (13) Methylhydromorphenine.
- (14) Morphine methylbromide.
- (15) Morphine methylsulfonate.
- (16) Morphine-N-Oxide.
- (17) Myrophine.
- (18) Nicocodeine.
- (19) Nicomorphine.
- (20) Normorphine.
- (21) Pholcodine.
- (22) Thebacon.

(c) 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 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:

- (1) 3,4-methylenedioxy amphetamine.
- (2) 5-methoxy-3,4-methylenedioxy amphetamine.
- (3) 3,4,5-trimethoxy amphetamine.
- (4) Bufotenine.
- (5) Diethyltryptamine.
- (6) Dimethyltryptamine.
- (7) 4-methyl-2,5-dimethoxyamphetamine.
- (8) Ibogaine.
- (9) Lysergic acid diethylamide.
- (10) Marihuana.
- (11) Mescaline.
- (12) Peyote.
- (13) N-ethyl-3-piperidyl benzilate.
- (14) N-methyl-3-piperidyl benzilate.
- (15) Psilocybin.
- (16) Psilocyn.
- (17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (as defined under section 1639o of title 7).
- (18) 4-methylmethcathinone (Mephedrone).
- (19) 3,4-methylenedioxypyrovalerone (MDPV).
- (20) 2-(2,5-Dimethoxy-4-ethylphenyl)ethanamine (2C-E).
- (21) 2-(2,5-Dimethoxy-4-methylphenyl)ethanamine (2C-D).
- (22) 2-(4-Chloro-2,5-dimethoxyphenyl)ethanamine (2C-C).
- (23) 2-(4-Iodo-2,5-dimethoxyphenyl)ethanamine (2C-I).
- (24) 2-[4-(Ethylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-2).
- (25) 2-[4-(Isopropylthio)-2,5-dimethoxyphenyl]ethanamine (2C-T-4).
- (26) 2-(2,5-Dimethoxyphenyl)ethanamine (2C-H).
- (27) 2-(2,5-Dimethoxy-4-nitro-phenyl)ethanamine (2C-N).
- (28) 2-(2,5-Dimethoxy-4-(n)-propylphenyl)ethanamine (2C-P).

(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabinimimetic agents, or which 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.

(2) In paragraph (1):

(A) The term "cannabinimimetic agents" means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within any of the following structural classes:

- (i) 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.
- (ii) 3-(1-naphthoyl)indole or 3-(1-naphthylmethane)indole by 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.
- (iii) 3-(1-naphthoyl)pyrrole by 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.
- (iv) 1-(1-naphthylmethylene)indene by 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.
- (v) 3-phenylacetylindole or 3-benzoylindole by 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.

(B) Such term includes-

- (i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);
- (ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);
- (iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);
- (iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);
- (v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);
- (vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);
- (vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);
- (viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);
- (ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);
- (x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);
- (xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);
- (xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);
- (xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);
- (xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and
- (xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).

(e)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of a fentanyl-related substance, or which contains the salts, isomers, and salts of isomers of a fentanyl-related substance whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

(2) For purposes of paragraph (1), except as provided in paragraph (3), the term "fentanyl-related substance" means any substance that is structurally related to fentanyl by 1 or more of the following modifications:

(A) By replacement of the phenyl portion of the phenethyl group by any monocycle, whether or not further substituted in or on the monocycle.

(B) By substitution in or on the phenethyl group with alkyl, alkenyl, alkoxyl, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(C) By substitution in or on the piperidine ring with alkyl, alkenyl, alkoxyl, ester, ether, hydroxyl, halo, haloalkyl, amino, or nitro groups.

(D) By replacement of the aniline ring with any aromatic monocycle whether or not further substituted in or on the aromatic monocycle.

(E) By replacement of the N-propionyl group with another acyl group.

(3) A substance that satisfies the definition of the term "fentanyl-related substance" in paragraph (2) shall nonetheless not be treated as a fentanyl-related substance subject to this schedule if the substance-

(A) is controlled by action of the Attorney General under section 811 of this title; or

(B) is otherwise expressly listed in a schedule other than this schedule.

(4)(A) The Attorney General may by order publish in the Federal Register a list of substances that satisfy the definition of the term "fentanyl-related substance" in paragraph (2).

(B) The absence of a substance from a list published under subparagraph (A) does not negate the control status of the substance under this schedule if the substance satisfies the definition of the term "fentanyl-related substance" in paragraph (2).

SCHEDULE II

(a) Unless specifically excepted or unless listed in another schedule, any of the following substances whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(1) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate.

(2) Any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (1), except that these substances shall not include the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) coca ³ leaves, except coca leaves and extracts of coca leaves from which cocaine, ecgonine, and derivatives of ecgonine or their salts have been removed; cocaine, its salts, optical and geometric isomers, and salts of isomers; ecgonine, its derivatives, their salts, isomers, and salts of isomers; or any compound, mixture, or preparation which contains any quantity of any of the substances referred to in this paragraph.

Agenda Item: Adoption of final regulatory action for allowances for emergency drugs by EMS agencies

Included in your agenda package:

- Draft final language regarding allowances for emergency drugs by EMS agencies.

Staff note: The public comment period was ongoing at the time this agenda was prepared. At the time of preparation there was no public comment recorded on the action. If any public comment is received prior to the close of the comment period on September 12, 2025, that comment will be distributed as a hand out.

Action needed:

- Motion to adopt final regulations as presented or amended by the Board.

Board of Pharmacy

Allowances for emergency drugs by EMS agencies

18VAC110-20-10. Definitions.

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

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

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

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

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

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

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

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

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

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

- a. Incorrect drug;
 - b. Incorrect drug strength;
 - c. Incorrect dosage form;
 - d. Incorrect patient; or
 - e. Inadequate or incorrect packaging, labeling, or directions.
2. Failure to exercise professional judgment in identifying and managing:
- a. Known therapeutic duplication;
 - b. Known drug-disease contraindications;
 - c. Known drug-drug interactions;
 - d. Incorrect drug dosage or duration of drug treatment;
 - e. Known drug-allergy interactions;
 - f. A clinically significant, avoidable delay in therapy; or
 - g. Any other significant, actual, or potential problem with a patient's drug therapy.
3. Delivery of a drug to the incorrect patient.
4. Variation in bulk repackaging or filling of automated devices, including:
- a. Incorrect drug;
 - b. Incorrect drug strength;
 - c. Incorrect dosage form; or
 - d. Inadequate or incorrect packaging or labeling.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. "Room temperature" means the temperature prevailing in a working area.
3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.
4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).
5. "Excessive heat" means any temperature above 40°C (104°F).
6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.
7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- a. The date of verification;
- b. A description of all discrepancies identified, if any; and
- c. The initials of pharmacist₁ verifying the accuracy of the process.

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

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

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

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

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

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

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

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

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

a. The date of verification;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6. Destruction of partially used Schedules II, III, IV, and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, prescriber, pharmacy technician, or a second EMS provider. Documentation shall be maintained in the pharmacy for a period of two years from the date of destruction.
7. The record of the drugs administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.
8. Intravenous and irrigation solutions provided by a pharmacy to an emergency medical services agency may be stored separately outside the kit.
9. Any drug showing evidence of damage or tampering shall be immediately removed from the kit and replaced.
10. In lieu of exchange by a hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, prescriber, or pharmacy technician if the kit contents include Schedule II, III, IV, or V drugs.
11. Drug kits shall be secured on the EMS vehicle or other EMS vehicle at all times, unless the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service. The EMS agency is not required to obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia to participate in a pharmacy kit exchange in accordance with this section unless the EMS agency needs to temporarily store a secured drug kit within the EMS building when a vehicle is incapable of maintaining appropriate drug storage temperature or is out of service and the EMS agency does not otherwise serve as a designated location of a current, active controlled substances registration. An alarm system consistent with requirements in 18VAC110-20-710 is not required under these conditions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.
2. Controlled substances registration applications that indicate a requested inspection date or requests that are received after the application is filed shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6. An alarm system is not required for researchers; animal control officers; humane societies; alternate delivery sites as provided in 18VAC110-20-275; ~~emergency medical services agencies;~~ registered EMS agencies or regional EMS councils, or designated locations of registered EMS agency headquarters or regional EMS councils stocking only ~~intravenous fluids with no added drug,~~ Schedule VI drugs or temporarily securing a secured drug kit that may contain Schedules II through VI drugs when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service; persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal; and teaching institutions possessing only Schedule VI drugs.

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

1. A registered location of the EMS agency or regional EMS council;
2. A designated location of the EMS agency or regional EMS council of which the board has been notified and DEA has granted approval if stocking drugs in Schedules II through V;
3. In an EMS vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional EMS council or other location where an EMS agency approves an EMS vehicle to be stored; or
4. In an EMS vehicle or other EMS vehicle used by the EMS agency that is traveling from or returning to a registered location or designated location of the EMS agency or EMS council or other location where an EMS agency approves an EMS vehicle to be stored in the course of responding to an emergency or otherwise actively in use by the EMS agency.

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

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for ~~Schedule~~ Schedules II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia to include the reporting of any drug theft or unusual loss and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.
2. All Except as provided in subdivision 9 of this section, all records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by § 54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An

entity ~~which~~ that is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

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

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

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

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

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

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

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

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

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

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

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

a. Name of the drug;

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

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

d. Number of commercial containers acquired;

e. Date of the acquisition;

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

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

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

a. Name of the drug;

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

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

d. Number of commercial containers distributed;

e. Date of the distribution;

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

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

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

a. Name of the drug;

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

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

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

e. Date of the delivery;

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

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

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

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

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

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

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

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

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

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

Agenda Topic: Adopt Fast-Track Regulatory Amendment of 18VAC110-20-590 regarding Correctional Facilities Possessing Long-acting Medication

Included in Agenda Packet:

- SB 1367
- Draft amendments of 18VAC110-20-590

Action Needed:

- Motion to adopt fast-track regulatory amendments of 18VAC110-20-590 as presented or amended.

CHAPTER 283

An Act to amend and reenact § 54.1-3423 of the Code of Virginia, relating to Board of Pharmacy; long-acting injectable or extended-release prescription drugs; correctional facilities.

[S 1367]

Approved March 21, 2025

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3423 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to conduct research; application and fees.

A. The Board shall register an applicant to manufacture or distribute controlled substances included in Schedules I through V unless it determines that the issuance of that registration would be inconsistent with the public interest. In determining the public interest, the Board shall consider the following factors:

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;
2. Compliance with applicable state and local law;
3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;
4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;
5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;
6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and
7. Any other factors relevant to and consistent with the public health and safety.

B. Registration under subsection A does not entitle a registrant to manufacture and distribute controlled substances in Schedule I or II other than those specified in the registration.

C. Practitioners must be registered to conduct research or laboratory analysis with controlled substances in Schedules II through VI or marijuana. Practitioners registered under federal law to conduct research with Schedule I substances, other than marijuana, may conduct research with Schedule I controlled substances within the Commonwealth upon furnishing the evidence of that federal registration.

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed

in subsection A in determining whether the registration shall be issued. Notwithstanding the exceptions listed in *subsection A of § 54.1-3422* ~~★~~, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping. *Notwithstanding the provisions of this subsection or Board regulations, the Board may register a correctional facility to maintain a floor stock of long-acting injectable or extended-release prescription drugs for the treatment of mental illness or substance use disorder. Such long-acting injectable or extended-release prescription drugs shall be stored in an area accessible only to persons who are licensed to administer such prescription drugs, regardless of whether the prescriber is on site. Each correctional facility shall maintain an ongoing perpetual inventory of all such drugs in Schedules II through V. Such perpetual inventory shall (a) accurately indicate the physical count of each drug on hand at the time the inventory is performed and (b) no less than once per month, include a reconciliation of each drug with a written explanation for any difference between the physical count and the theoretical count.*

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

F. The Board may register a facility, as defined in § 37.2-100, that provides crisis stabilization services and is licensed by the Department of Behavioral Health and Developmental Services. Such facility may maintain a stock of Schedules II through VI controlled substances necessary for immediate treatment of patients admitted to such facility, which may be accessed and administered by a person licensed to administer drugs pursuant to a written or oral order of a prescriber in the absence of a prescriber.

G. The Board may register an entity at which a patient is 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 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. In determining whether the registration shall be issued, the Board shall consider (i) the factors listed in subsection A, (ii) whether there is a documented need for such registration, and (iii) whether the issuance of the registration is consistent with the public interest.

H. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

I. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible

party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

18VAC110-20-590. Drugs in correctional facilities.

A. All prescription drugs at any correctional facility shall be subject to the following conditions:

1. Notwithstanding the allowances in subsections B, C, ~~and D~~, and E of this section, prescription drugs shall be obtained only on an individual prescription basis.
2. All prepared drugs shall be maintained in a suitable locked storage area with only the person responsible for administering the drugs having access.
3. Complete and accurate records shall be maintained of all drugs received, administered and discontinued. The administration record shall show the:
 - a. Patient name;
 - b. Drug name and strength;
 - c. Number of dosage units received;
 - d. Prescriber's name; and
 - e. Date, time and signature of the person administering the individual dose of drug.
4. All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Schedule VI drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within 30 days of discontinuance.
 - a. The provider or secondary pharmacy shall conduct random audits of returned drug administration records for accountability.
 - b. The drug administration records shall be filed in chronological order by the provider or secondary pharmacy and maintained for a period of one year or, at the option of the facility, the records may be returned by the pharmacy to the facility.
 - c. Drugs may be returned to pharmacy stock in compliance with the provisions of [18VAC110-20-400](#).
 - d. Other drugs shall be disposed of or destroyed by the provider pharmacy in accordance with local, state, and federal regulations.
5. After performing the audit required by subdivision 4 a of this subsection and ensuring the proper maintenance of the administration records, drugs in Schedules II through V shall be destroyed at the site of the correctional facility using a method of destruction that renders the drug unrecoverable.
 - a. The destruction shall be performed by a nurse, pharmacist, or physician and witnessed by the nurse supervisor, a pharmacist, or a physician.
 - b. Destruction of drugs shall occur within 30 days of discontinuance.

c. A complete and accurate record of the drugs destroyed shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the destruction and maintained at the correctional facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for a correctional facility served by the pharmacy pursuant to [18VAC110-20-540](#) and [18VAC110-20-550](#) provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants.

C. A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and shall be administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

D. Except for drugs in an emergency box, stat-drug box, or a stock of intravenous fluids, irrigation fluids, sterile water, ~~and~~ sterile saline, ~~and those drugs referenced in subsection E,~~ prescription drugs, including vaccines, may be floor-stocked only at a medical clinic or surgery center that is part of a correctional facility and that is staffed by one or more prescribers during the hours of operation, provided the clinic first obtains a controlled substances registration and complies with the requirements of [18VAC110-20-690](#), [18VAC110-20-700](#), [18VAC110-20-710](#), and [18VAC110-20-720](#).

E. A floor stock of long-acting injectable or extended-release prescription drugs for the treatment of mental illness or substance use disorder may be maintained and stored in an area accessible only to persons who are licensed to administer such prescription drugs, regardless of whether the prescriber is on site, provided the correctional facility first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-720. An ongoing perpetual inventory and reconciliation shall be performed in accordance with § 54.1-3423 and maintained for a period of not less than two years from the date of transaction.

Agenda Item: Adoption of proposed regulatory action related to central fill pharmacies

Included in your agenda package:

- Draft proposed language regarding central fill pharmacies;
- Town Hall Emergency/NOIRA stage summary showing no public comments;
- Two public comments received via email by Board staff; and
- HB1068 from the 2024 General Assembly Session requiring this regulatory action.

Action needed:

- Motion to adopt proposed regulations as presented or amended by the Board.

Project 7968 - Proposed

Board of Pharmacy

Requirements for use of central fill pharmacy and remote database access

18VAC110-20-112. Supervision of pharmacy technicians.

A. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons performing the duties of a pharmacy technician at one time, except as provided in 18VAC110-20-276 and 18VAC110-20-277.

B. In addition to the acts restricted to a pharmacist in § 54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

18VAC110-20-276. Central or remote processing.

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or

8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a nondispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription

processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and ~~permit/registration~~ permit or registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records that show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record

showing each processing task, the identity of the person performing each task, and the location where each task was performed.

2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist or registered as a pharmacy technician or pharmacy intern performing the duties of a pharmacy technician in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

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

18VAC110-20-277. Central fill pharmacy.

A. Notwithstanding activities authorized in 18VAC110-20-275, 18VAC110-20-276, and 18VAC110-20-515, a pharmacy located in the Commonwealth or out of state may outsource tasks associated with dispensing a prescription drug, including verification for accuracy by a pharmacist and alternate delivery to the originating pharmacy that received the prescription, to a central fill pharmacy permitted in the Commonwealth as a pharmacy or registered as a nonresident pharmacy.

B. A central fill pharmacy may operate if:

1. Sufficient automation is employed to safely support the practice of pharmacy and limit distractions for pharmacy personnel;
2. The central fill pharmacy does not accept prescriptions or communications directly from patients or providers; and
3. Dispensing is restricted to Schedule VI drugs.

C. Notwithstanding § 54.1-3321 of the Code of Virginia, an unregistered or unlicensed person may perform the following non-dispensing functions at a central fill pharmacy:

1. The movement of sealed manufacturer bottles from an inventory shelf to a pharmacy technician's workspace for the purpose of filling a canister when the filling of the canister is completed by a pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee who barcode scans or uses other technology to verify each individual bottle or package of medication prior to filling the canister.
2. Manually bagging prepared prescriptions when barcode scanning or use of other technology is used to verify the prescription product vial, prescription medication leaflet, and prescription bag label.
3. Loading an automated robotic dispenser with the pharmacist-verified and sealed canister when barcode scanning or other technology is used to verify accurate placement of each canister.
4. Performing monthly cycle counts of sealed manufacturer-packaged products and sealed canisters; however, the opening of a sealed manufacturer-packaged product or canister and the counting of an unsealed manufacturer-packaged product or canister is not permitted.

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

E. Notwithstanding 18VAC110-20-270 B, pharmacist verification of a canister of medication after it is filled and sealed but prior to being loaded into a barcoded automated robotic dispenser serves as the final product verification of a prescription. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of the contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards. This provision shall not constitute a waiver of the requirement for a pharmacist to verify the accuracy of data entry of the prescription.

F. A central fill pharmacy shall ensure that each pharmacy receiving dispensed drugs from the central fill pharmacy shall provide a one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public as its notification of the dispensing and delivery process. 18VAC110-20-275 B 2 h shall not apply to central fill pharmacies and those pharmacies receiving dispensed drugs from central fill pharmacies.

G. A written policy and procedure must be maintained by the central fill pharmacy and complied with and shall include, at minimum, procedures for ensuring:

1. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes and the method for ensuring pharmacist verification of all packaged and repackaged drugs compliant with this section and assigned barcodes;

2. Accurate stocking and restocking of the robotic pharmacy system;

3. Removing expired drugs;

4. Proper handling of drugs that may be dropped by the robotic pharmacy system;

5. Performing routine maintenance of the robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

6. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

7. Maintaining quality assurance reports.

H. All manual picks for dispensing at a central fill pharmacy shall be verified for accuracy by a pharmacist.

I. If it is identified that the robot at a central fill pharmacy selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operation of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

J. One prescription per automated dispensing device per quarter shall be redirected to a pharmacist to audit for prescription product accuracy in all components. Quarterly quality assurance records related to these audits shall be maintained for two years from the date the audit is performed.

K. A central fill pharmacy may deliver the dispensed drug to the patient's residence or the originating pharmacy that received the prescription pursuant to § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-275.

L. An out-of-state pharmacy solely returning a drug that was not delivered to the patient to the central fill pharmacy that dispensed the drug as authorized in § 54.1-3411.1 of the Code of Virginia shall be exempt from obtaining registration as a nonresident pharmacy.

M. The transfer of the prescription between the originating pharmacy that received the prescription and the central fill pharmacy shall not be required if the pharmacies share a common electronic file or have technology that allows sufficient information necessary for dispensing the prescription.

Draft



Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [\[18 VAC 110 - 20\]](#)

Action: Requirements for use of central fill pharmacy and remote database access

Emergency/NOIRA Stage

Action 6505 / Stage 10383

[Edit Stage](#) [Go to RIS Project](#) [Request Emergency Extension](#)

Documents		
Emergency Text	8/20/2024 12:22 pm	Sync Text with RIS
Agency Background Document	7/8/2024	Upload / Replace
Attorney General Certification	8/20/2024 (modified 9/5/2024)	
Governor's Review Memo	6/10/2025	
Registrar Transmittal	6/11/2025	

Status	
Public Hearing	Will be held at the proposed stage
Governor's Review Needed By	1/1/2025
Emergency Authority	Ch. 407 of the 2024 GA
Attorney General Review	Submitted to OAG: 7/8/2024 Review Completed: 8/20/2024 Result: Certified
DPB Review	Submitted on 8/20/2024 Policy Analyst: Melanie West Review Completed: 9/10/2024
Secretary Review	Secretary of Health and Human Resources Review Completed: 3/24/2025
Governor's Review	ORM Review: ORM Approved 6/10/2025 Governor Review Completed: 6/10/2025 Result: Approved
Virginia Registrar	Submitted on 6/11/2025 The Virginia Register of Regulations Publication Date: 6/30/2025 Volume: 41 Issue: 23
Comment Period	Ended 7/30/2025 0 comments

Effective Date	6/16/2025
Expiration Date	12/15/2026

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This person is the primary contact for this chapter.

This stage was created by [Erin Barrett](#) on 06/10/2024 at 11:36am

This stage was last edited by [Erin Barrett](#) on 06/10/2024 at 11:36am

Mark Johnston, R.Ph, Pharm D (hon)
Executive Director,
Pharmacy Advocacy and Regulatory Affairs

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7/29/2025

Virginia Board of Pharmacy,

I am writing to you in my role as Executive Director of Pharmacy Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide care with diverse access points to patients in the Commonwealth of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on proposed amendments to 18VAC110-20-276, Central or remote processing and 18VAC110-20-277 Central fill pharmacy. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns, pharmacy technicians and pharmacy technician trainees serving Virginia patients.

Pharmacists are highly educated and trained professionals who have become an integral part of the healthcare team. The COVID-19 pandemic demonstrated that pharmacists are one of the most accessible health care providers in the nation. With the shortage of primary care providers, pharmacists fill the gaps in patient care across the country while at the same time pharmacies are experiencing a staffing shortage. In April 2025, the U.S. Bureau of Labor Statistics projected there would be 14,200 job openings for pharmacists, each year, on average, throughout the next decade.¹ The Bureau also reported pharmacy technicians would see 47,400 job openings, each year, on average throughout the next decade.² The Institute for Patient Safety and Quality Health Care published an article in March 2022 detailing that, “organizations need a multifaceted approach to effectively address persistent pharmacy staffing and medication safety challenges, and technology should underpin such a strategy.”³ The Institute for Patient Safety and Quality Health Care article also discussed how utilizing new technology allows “pharmacists to apply their clinical expertise to impact patient outcomes instead of counting medications and verifying orders.”³

A summit of individuals from American Pharmacists Association, the American Society of Health-System Pharmacists, and the National Association of Boards of Pharmacy (NABP), was held in June 2023. The report, “Implementing Solutions Summit: Building a Sustainable, Healthy, Pharmacy Workforce and Workplace,” outlines various solutions that employers, associations and Boards of pharmacy can implement in the near, medium, and long term to assist in addressing high stress levels and occupational burnout. In the section addressing rules and requirements, an “action” suggests that employers “identify unnecessary regulatory burdens and workplace requirements that take time away from activities that could improve the safety of patients and the well-being of pharmacy staff.” Additionally, state Boards of pharmacy are encouraged to “review currently recommended shared services model laws and rules and update as appropriate.” Therefore, this summit of national organizations recognizes the need for shared services to also assist in improving the well-being of pharmacists and pharmacy technicians.⁴

Additionally, NABP Model Rules for shared services were amended in August 2024.⁵ These amendments were first discussed on October 17 and 18, 2023 at the NABP Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites and Telepharmacy. The report published outlines suggested changes to the model Shared Services language by updating the definition of shared pharmacy services to include product verification, known in Virginia as prescription product accuracy. They also recommended striking subsections they considered to be too prescriptive and move others to improve continuity.⁶ The Committee on Law Enforcement/Legislation then met on March 5 and 6, 2024 to review the recommended changes. The committee found no issue with the suggested changes, and they were incorporated after the NABP Executive Committee approved the recommendations.⁷

18VAC110-20-276 Central or remote processing requested amendment

CVS Health is supportive of the amendments proposed allowing pharmacy technicians or interns to remotely access the pharmacy database. In support of the growing landscape of technology in the pharmacy dispensing process, CVS Health requests the Board consider amending 18VAC110-20-276(A) to add prescription product accuracy, which would allow the sharing of final product verification when images are used.

Air Support is part of our response to the evolving healthcare landscape, and the needs of our patients and our pharmacy teams. This model allows our retail pharmacies under common ownership to support each other by entering prescription and patient data into a data processing system, performing prospective DUR, data entry verification and final product verification or prescription product accuracy, where permitted. Utilization of Air Support helps drive timely and effective care for patients and provides impactful support to our pharmacies facing the challenges of labor shortages.

CVS Pharmacy has successfully implemented a pharmacy workload sharing model, with shared services including final product/order verification, in most states. Additionally, we have Board of Pharmacy approved pilots involving 135 locations, with 117 of those pharmacies located in Virginia. We have found the fully shared workload balancing model enhances patient care and is associated with a higher rate of dispensing accuracy when compared to a limited sharing model.

Suggested Language:

18VAC110-20-276 Central or remote processing

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;

4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; ~~or~~
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent-; or
9. Prescription product accuracy.

18VAC110-20-277 Central Fill Pharmacy requested amendment

CVS Health is similarly supportive of the emergency proposed rules to allow central fill. These rules align with actions recommended in the NABP Implementing Solutions Summit held in June 2023, recognizing the need for shared services to also assist in improving the well-being of pharmacists and pharmacy technicians.⁴ We request that the Board consider aligning the language in (I) related to robot incorrect medication issues with the current continuous quality improvement rule 18VAC110-20-418.

Suggested Language 18VAC110-20-277 Central fill pharmacy

I. If it is identified that the robot at a central fill pharmacy selected an incorrect medication, which led to a dispensing error, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures and comply with requirements of 18VAC110-20-418, prior to resuming full operation of the robot. ~~An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.~~

Sincerely,



Mark Johnston, R.Ph, Pharm D (hon)
Executive Director,
Board of Pharmacy Advocacy and Regulatory Affairs
CVS Health

References

1. U.S. Bureau of Labor Statistics. Occupational Outlook: Pharmacists. Available from: <https://www.bls.gov/ooh/healthcare/pharmacists.htm> (Accessed June 13, 2025)
2. U.S. Bureau of Labor Statistics. Occupational Outlook: Pharmacy Technicians. Available from: <https://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm> (Accessed June 13, 2025)
3. Staffing Shortages Aren't Just a Business Problem, They're a Patient Safety Threat. Available from: <https://www.psqh.com/analysis/staffing-shortages-arent-just-abusiness-problem-theyre-a-patient-safety-threat/> (Accessed June 13, 2025).
4. Implementing Solutions, Building a sustainable, healthy pharmacy workforce and workplace." Available from: [Implementing-Solutions-Report.pdf \(nabp.pharmacy\)](#) (Accessed August 27, 2024)
5. Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. Available from: <https://nabp.pharmacy/wp-content/uploads/2023/08/NABP-Model-Act.docx> (Accessed August 27, 2024)
6. Report of the Task Force on Shared Pharmacy Services, Automated Pharmacy Systems, Remote Dispensing Sites and Telepharmacy. Available from: [Report-of-the-Task-Force-on-shared-Pharmacy-Services-Automated-Pharmacy-Systems-Remote-Dispensing-Sites-and-Telepharmacy.pdf \(nabp.pharmacy\)](#) (Accessed August 27, 2024).
7. Report of the Committee on Law Enforcement/Legislation. Available from: [Report-of-the-Committee-on-Law-Enforcement-Legislation-2024.pdf \(nabp.pharmacy\)](#) (Accessed August 27, 2024).



The Kroger Co.
Kroger Health
www.krogerhealth.com

1014 Vine St
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July 29, 2025

Executive Director Caroline Juran, RPh
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463

Re: Regulations Governing the Practice of Pharmacy [\[18 VAC 110 - 20\]](#) – Requirements for use of central fill pharmacy and remote database access

Dear Director Juran:

The Kroger Co. appreciates the opportunity to comment on the Virginia Board of Pharmacy's Central Fill Emergency Regulations – Requirements for use of central fill pharmacy and remote database access. Kroger also appreciates the Board's timely issuance of this emergency temporary rule to allow for the operation of remote central fill as Kroger, Harris Teeter and other companies welcomed new patients from several Rite Aid locations that recently closed. As the Board looks to make these temporary rules permanent, we would recommend the following changes to maximize the ability for pharmacies to meet increasing patient demand while maintaining the highest safety standards.

18VAC110-20-276 B.3 – Central or Remote Processing

B.3 is a specific rule that does not allow out-of-state pharmacies to operationalize true remote prescription processing support.

"A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor"

Even though an out-of-state facility is actively licensed as a nonresident pharmacy with the Virginia Board of Pharmacy and has a VA-licensed Pharmacist-in-Charge, because the staff pharmacists do not have individual VA licensures, the scripts, even though they have been remotely verified, would still require a comprehensive accuracy check by a VA-licensed pharmacist, which in the current state would be the local store pharmacist. This requirement unfortunately prevents realization of the benefits that implementing remote



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central fill carries: namely by requiring additional, time-consuming verifications by store pharmacy teams of prescriptions that have already been thoroughly verified for accuracy at the central fill facility.

To remedy this duplicative verification, we would ask that 18VAC110-20-276 B.3 be amended to:

A pharmacist licensed in Virginia or a pharmacist licensed in another state working under a Virginia-licensed, non-resident pharmacy, shall perform a check for accuracy on all processing done by the remote processor.

This change would ensure that each prescription is checked for accuracy while also allowing store-based pharmacists adequate time provide additional services to patients including medication counseling, the administration of vaccines and testing, and other services.

Thank you for your consideration and please reach out with questions at evan.sarris@kroger.com.

Sincerely,

Evan Sarris, Jr

Evan Sarris
Deputy Director, Government Relations
The Kroger Co.

VIRGINIA ACTS OF ASSEMBLY -- 2024 SESSION

CHAPTER 407

An Act to direct the Board of Pharmacy to promulgate regulations related to pharmacy outsourcing and pharmacy technician remote database access.

[H 1068]

Approved April 4, 2024

Be it enacted by the General Assembly of Virginia:

1. § 1. *The Board of Pharmacy shall promulgate regulations authorizing a pharmacy located in the Commonwealth or out-of-state to outsource tasks associated with dispensing a prescription drug, including verification for accuracy by a pharmacist and alternate delivery to the pharmacy that received the prescription, to a central fill pharmacy permitted in the Commonwealth as a pharmacy or registered as a nonresident pharmacy. In accordance with the regulations, a central fill pharmacy may operate when sufficient automation is employed to safely support the practice of pharmacy and limit distractions for pharmacy personnel, the central fill pharmacy does not accept prescriptions or communications directly from patients or providers, and dispensing is restricted to Schedule VI drugs. The regulations shall authorize the following: (i) the maximum number of persons performing the duties of a pharmacy technician and support personnel a pharmacist may supervise at one time; however, each pharmacist shall determine the number of persons he can safely and competently supervise at one time, not to exceed the maximum number established by the Board of Pharmacy; (ii) pharmacist verification of a drug canister after filling but prior to being placed on a barcoded automated robotic dispenser, in lieu of pharmacist verification of each prescription product for accuracy; (iii) a one-time written notification or sign of the dispensing and delivery process at the initiating pharmacy receiving the prescription; (iv) allowance for an unregistered and unlicensed person to assist in non-dispensing functions such as inventory, delivery, receiving, or packing of completed prescription orders when supported by barcode scanning or other technology; and (v) delivery of the dispensed drug to the patient's residence or originating pharmacy that received the prescription. The transfer of the prescriptions shall not be required if the pharmacies share a common electronic file or have technology that allows sufficient information necessary for dispensing the prescription.*

§ 2. *The Board of Pharmacy shall promulgate regulations that allow for pharmacy technicians to access the pharmacy's database from a remote location for the purpose of performing certain prescription processing functions, as further defined in 18VAC110-20-276 (A) of the Virginia Administrative Code.*

2. *That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.*

Agenda Item: Adoption of proposed regulatory action to exclude private dwellings and residences from controlled substances registration locations

Included in your agenda package:

- Draft proposed language regarding exclusion of private dwelling and residences from controlled substances registration locations;
- Town Hall summary page for the NOIRA stage showing no comments.

Action needed:

- Motion to adopt proposed regulations as presented or amended by the Board.

Project 8068 - Proposed

Board of Pharmacy

Exclusion of private dwellings or residences from operating locations of controlled substance registrations (CSRs)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

G. A controlled substances registration shall not be issued to any person to operate from a private dwelling or residence.



Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [\[18 VAC 110 - 20\]](#)

Action: [Exclusion of private dwellings or residences from operating locations of ...](#)

Notice of Intended Regulatory Action (NOIRA)

Action 6580 / Stage 10479

[Edit Stage](#) [Withdraw Stage](#) [Go to RIS Project](#)

Documents		
Preliminary Draft Text	None submitted	Sync Text with RIS
Agency Background Document	9/10/2024 (modified 9/30/2024)	Upload / Replace
Governor's Review Memo	4/29/2025	
Registrar Transmittal	5/1/2025	

Status	
Public Hearing	No plan for a public hearing at the proposed stage.
DPB Review	Submitted on 10/1/2024 Policy Analyst: Jeannine Rose Review Completed: 10/10/2024
Secretary Review	Secretary of Health and Human Resources Review Completed: 4/23/2025
Governor's Review	ORM Review: ORM Approved 4/29/2025 Governor Review Completed: 4/29/2025 Result: Approved
Virginia Registrar	Submitted on 5/1/2025 The Virginia Register of Regulations Publication Date: 6/2/2025 Volume: 41 Issue: 21
Comment Period	Ended 7/2/2025 0 comments

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This stage was created by [Erin Barrett](#) on 09/10/2024 at 2:54pm

This stage was last edited by [Erin Barrett](#) on 09/10/2024 at 2:54pm

Agenda Item: Issuance of Periodic Review for Chapter 15

Included in your agenda:

- 18VAC110-15, Regulations Governing Delegation to an Agency Subordinate.

Staff Note: These regulations are overdue for a periodic review, and one should be issued.

Action Needed:

- Motion to initiate a periodic review for 18VAC110-15.

Commonwealth of Virginia



REGULATIONS

GOVERNING DELEGATION TO AN AGENCY SUBORDINATE

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-15-10 et seq.

**Statutory Authority: §§ 54.1-2400 and Chapter 33 of Title 54.1
of the *Code of Virginia***

Revised Date: December 11, 2019

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18VAC110-15-10. Criteria for delegation of informal fact-finding proceeding to an agency subordinate.

A. Decision to delegate. In accordance with subdivision 10 of § 54.1-2400 of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner or an entity may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;
2. Drug diversion;
3. Impairment with an inability to practice with skill and safety;
4. Indiscriminate dispensing; and
5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.

2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.

3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

Agenda Topic: Adopt Exempt Regulatory Amendments regarding Advanced Registered Medication Aides

Included in Agenda Packet:

- Excerpts of HB2468
- Draft amendments of 18VAC110-20-555 and 18VAC110-20-560

Action Needed: Motion to adopt exempt regulatory amendments as presented or amended.

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 277

An Act to amend and reenact §§ 8.01-225, 22.1-274.4:1, 32.1-127, as it is currently effective and as it shall become effective, and 54.1-2722, §§ 54.1-3041 and 54.1-3042, as they shall become effective, and §§ 54.1-3408, 54.1-3466, and 54.1-3467 of the Code of Virginia and to amend and reenact the fourth and fifth enactments of Chapter 284 of the Acts of Assembly of 2024, relating to advanced registered medication aides.

[H 2468]

Approved March 21, 2025

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-225, 22.1-274.4:1, 32.1-127, as it is currently effective and as it shall become effective, and 54.1-2722, §§ 54.1-3041 and 54.1-3042, as they shall become effective, and §§ 54.1-3408, 54.1-3466, and 54.1-3467 of the Code of Virginia are amended and reenacted as follows:

§ 8.01-225. Persons rendering emergency care, obstetrical services exempt from liability.

A. Any person who:

1. In good faith, renders emergency care or assistance, without compensation, to any ill or injured person (i) at the scene of an accident, fire, or any life-threatening emergency; (ii) at a location for screening or stabilization of an emergency medical condition arising from an accident, fire, or any life-threatening emergency; or (iii) en route to any hospital, medical clinic, or doctor's office, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such care or assistance. For purposes of this subdivision, emergency care or assistance includes the forcible entry of a motor vehicle in order to remove an unattended minor at risk of serious bodily injury or death, provided the person has attempted to contact a law-enforcement officer, as defined in § 9.1-101, a firefighter, as defined in § 65.2-102, emergency medical services personnel, as defined in § 32.1-111.1, or an emergency 911 system, if feasible under the circumstances.

2. In the absence of gross negligence, renders emergency obstetrical care or assistance to a female in active labor who has not previously been cared for in connection with the pregnancy by such person or by another professionally associated with such person and whose medical records are not reasonably available to such person shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care or assistance. The immunity herein granted shall apply only to the emergency medical care provided.

3. In good faith and without compensation, including any emergency medical services provider who holds a valid certificate issued by the Commissioner of Health, administers epinephrine in an emergency to an individual shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction.

4. Provides assistance upon request of any police agency, fire department, emergency medical services agency, or governmental agency in the event of an accident or other emergency involving the use, handling, transportation, transmission, or storage of liquefied petroleum gas, liquefied natural gas, hazardous material, or hazardous waste as defined in § 10.1-1400 or regulations of the Virginia Waste Management Board shall not be liable for any civil damages resulting from any act of commission or omission on his part in the course of his rendering such assistance in good faith.

5. Is an emergency medical services provider possessing a valid certificate issued by authority of the State Board of Health who in good faith renders emergency care or assistance, whether in person or by telephone or other means of communication, without compensation, to any injured or ill person, whether at the scene of an accident, fire, or any other place, or while transporting such injured or ill person to, from, or between any hospital, medical facility, medical clinic, doctor's office, or other similar or related medical facility, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care, treatment, or assistance, including but in no way limited to acts or omissions which involve violations of State Department of Health regulations or any other state regulations in the rendering of such emergency care or assistance.

6. In good faith and without compensation, renders or administers emergency cardiopulmonary resuscitation (CPR); cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator (AED); or other emergency life-sustaining or resuscitative treatments or procedures which have been approved by the State Board of Health to any sick or injured person, whether at the scene of a fire, an accident, or any other place, or while transporting such person to or from any hospital, clinic, doctor's office, or other medical facility, shall be deemed qualified to administer such emergency treatments and procedures and shall not be liable for acts or omissions resulting from the rendering of such emergency resuscitative

successfully completed all educational requirements established by the Board for administering drugs in a ~~certified nursing facility~~ *home licensed by the Department of Health*, which shall reflect the medically complex patient population found in ~~certified nursing facilities~~ *homes licensed by the Department of Health* and the resulting medication regime for that population.

B. The Board shall (i) make the written examination available in both electronic and non-electronic format, (ii) provide sufficient locations for the administration of any written examination required for registration under this section, to ensure adequate access to the written examination for all applicants, (iii) establish a procedure pursuant to which an examination shall be offered at or near the location of an education or training course, upon the request of five or more applicants, provided that the security of the examination and the integrity of the administration of the examination are ensured and that any additional costs are born by the requesting applicants, and (iv) provide written notice to applicants of the results of any competency examination completed by the applicants within seven days of completion of the examination.

C. Any applicant under this section who has provided to the Board evidence of successful completion of the education or training course required for registration may act as a medication aide on a provisional basis for no more than 120 days before successfully completing any required competency evaluation. However, upon notification of failure to successfully complete the written examination after three attempts, an applicant shall immediately cease acting as a medication aide.

D. Any applicant under this section who shall apply by endorsement from any state or the District of Columbia that requires registration of medication aides who has met the requirements of registration in such jurisdiction may be deemed eligible to sit for the competency evaluation required pursuant to this section, subject to approval of the Board.

§ 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

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. Advanced 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 be administered by a registered medication aide pursuant to subsection M, in addition to drugs determined permissible by the Board of Nursing, in a nursing home licensed by the Department of Health. Advanced medication aides 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 licensed nursing home's policies and procedures; and in accordance with such other regulations governing their practice promulgated by the Board of Nursing.

O. 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. P.~~ 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. Q.~~ 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

engaged in breeding or raising livestock, poultry, or other animals to which hypodermic injections are customarily given in the interest of health, safety, or good husbandry; or to hospitals, physicians, pharmacists, dentists, podiatrists, veterinarians, funeral directors and embalmers, persons to whom a permit has been issued, manufacturers, wholesalers, or their authorized agents or employees when in the usual course of their business, if the controlled paraphernalia lawfully obtained continue to be used for the legitimate purposes for which they were obtained.

F. The provisions of this section and of § 18.2-265.3 shall not apply to (i) a person who dispenses naloxone in accordance with the provisions of subsection ~~Y~~ Z of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes for injecting such naloxone or (ii) a person who possesses naloxone that has been dispensed in accordance with the provisions of subsection ~~Y~~ Z of § 54.1-3408 and possesses hypodermic needles and syringes for injecting such naloxone in conjunction with such possession of naloxone.

G. The provisions of this section and of § 18.2-265.3 shall not apply to (i) a person who possesses or distributes controlled paraphernalia on behalf of or for the benefit of a comprehensive harm reduction program established pursuant to § 32.1-45.4 or (ii) a person who possesses controlled paraphernalia obtained from a comprehensive harm reduction program established pursuant to § 32.1-45.4.

§ 54.1-3467. Distribution of hypodermic needles or syringes, gelatin capsules, quinine or any of its salts.

A. Distribution by any method, of any hypodermic needles or syringes, gelatin capsules, quinine or any of its salts, in excess of one-fourth ounce shall be restricted to licensed pharmacists or to others who have received a license or a permit from the Board.

B. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized by the State Health Commissioner pursuant to a comprehensive harm reduction program established pursuant to § 32.1-45.4 who are acting in accordance with the standards and protocols of such program for the duration of the declared public health emergency.

C. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone in accordance with the provisions of subsection ~~Y~~ Z of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes. Nothing in this section shall prohibit the dispensing of hypodermic needles and syringes for the administration of prescribed drugs by prescribers licensed to dispense Schedule VI controlled substances at a nonprofit facility pursuant to § 54.1-3304.1.

D. Notwithstanding the provisions of subsection A, nothing in this section shall prohibit the distribution of hypodermic needles that are designed to be used with a reusable injector pen for the administration of insulin.

2. That the fourth and fifth enactments of Chapter 284 of the Acts of Assembly of 2024 are amended and reenacted as follows:

4. That the Department of Health shall promulgate regulations to authorize medication aides registered by the Board of Nursing (the Board) to administer drugs as determined permissible by the Board for administration to residents in a ~~certified nursing facility~~ home licensed by the Department of Health to be effective as of July 1 December 15, 2025. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

5. That the Board of Nursing and Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective as of July 1 December 15, 2025. Such regulations shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq. of the Code of Virginia).

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

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

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.
2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to [18VAC110-20-550](#) or an emergency drug kit pursuant to [18VAC110-20-540](#) and are solely administered for stat or emergency administration.
3. ~~Except as restricted in subdivision 4 c of this section~~ ~~[For facilities not required to obtain a controlled substance registration]~~, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, ~~or~~ prescriber, or advanced registered medication aide, or a registered pharmacy technician for the purpose of stocking or reloading.
4. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:
 - a. No drug may be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order, except as provided in subdivision 4 c of this section.
 - b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.
 - c. Drugs that would be stocked in an emergency drug kit pursuant to [18VAC110-20-540](#) or a stat drug box pursuant to subsection B of [18VAC110-20-550](#) may be accessed pursuant to a valid prescription or lawful order of a prescriber and prior to receiving electronic authorization from the pharmacist by a licensed nurse, pharmacist, or prescriber, provided that the absence of the emergency drug would threaten the survival of the patient or that a delay in administration of the stat drug could result in harm to the patient, and that only these licensed individuals may administer a drug accessed for this purpose.
 - d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

5. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of [18VAC110-20-355](#) relating to repackaging, labeling, and records.
6. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.
7. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.
8. At the time of loading, the delivery record for all Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.
9. At the time of loading any Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.
10. The PIC of the provider pharmacy or the PIC's designee shall conduct at least a monthly audit to review distribution and administration of Schedules II through V drugs from each automated dispensing device as follows:
 - a. The audit shall reconcile records of all quantities of Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.
 - b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or the PIC's designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with [§ 54.1-3404](#) E of the Drug Control Act.
 - c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.
 - d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.
 - e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.
 - f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist

personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

11. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

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

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

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

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible, provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

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

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

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

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

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

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained offsite or electronically, provided that (i) they can be readily retrieved upon request; (ii) they are maintained in a read-only format that does not allow alteration of the records; and (iii) a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated

dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

18VAC110-20-560. Floor stock.

In addition to an emergency box or stat-drug box, a long-term care facility in which only those persons licensed to administer, or advanced registered medication aides are administering drugs may maintain a stock of intravenous fluids, irrigation fluids, heparin flush kits, medicinal gases, sterile water and saline, and prescription devices. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

Agenda Topic: Consider Additional Amendments to Guidance Document 110-19, *Use of Automated Dispensing Devices and Remote Dispensing Systems in Certain Facilities*

Background: In June, during the administrative review process of the Board's adoption of revisions to Guidance Document 110-19, the Office of Regulatory Management offered additional language for the Board's consideration.

It was also recently identified that additional language may be needed for hospitals to operationalize centralized compounding as authorized in SB 1366 and HB 1905 which became effective on July 1, 2025.

Included in Packet:

- Relevant laws - § 54.1-3434.02 and § 54.1-3410.2

Action Needed: Motion to re-adopt Guidance Document 110-19 as presented.

VIRGINIA BOARD OF PHARMACY

Use of Automated Dispensing Drug Systems and Remote Dispensing Systems in Certain Facilities

Pursuant to Va. Code § 54.1-3434.02, “other facilities” authorized by the Board may use automated drug dispensing systems and remote dispensing systems as defined in Va. Code § 54.13401 under certain statutory conditions.

The Board interprets “other facilities” that may use an automated drug dispensing system or a remote dispensing system to mean:

- hospice facilities licensed pursuant to Title 32.1 of the Code of Virginia that only use licensed health care professionals authorized in law to administer medications; ~~and~~
- facilities that (1) hold licensure from the Department of Behavioral Health and Developmental Services, (2) provide services as an inpatient psychiatric unit, mental health residential treatment facility, partial hospitalization program, inpatient treatment center, or residential detox, and (3) only use licensed health care professionals authorized in law to administer medications; and
- facilities within health systems under common ownership with a pharmacy distributing compounded drug products to such facilities in accordance with § 54.1-3410.2 (C) that are administered only to patients within the hospital or health system.

The Board further interprets “other facilities” that may use a remote dispensing system whereby the patient or a person not licensed to administer medication is intended to administer medication from the system and which must fully comply with the labeling requirements in Va. Code §§ 54.13410 and 54.1-3463 and Board regulations to mean the following:

- a pharmacy;
- a facility permitted by the Board as a practitioner of the healing arts to sell controlled substances;
- an outpatient medical clinic wherein a provider pharmacy verifies the accuracy of the data entry of the prescription and has obtained a controlled substances registration in the name of the pharmacy at the address of the clinic to operate a remote dispensing system; and
- a comprehensive harm reduction center providing opioid antagonists licensed by the Virginia Department of Health.

The Board does not interpret “other facilities” that may use a remote dispensing system whereby the patient or a person not licensed to administer medication is intended to administer medication from the system to include conveyances for mobile medication-assisted treatment programs regulated under Article 9 (18VAC1235-105-1821 *et seq.*) of Part VII of the Addiction Medicine Service Requirements.

§ 54.1-3434.02. Automated drug dispensing systems and remote dispensing systems.

A. Hospitals or nursing homes licensed pursuant to Title 32.1, state facilities as defined in § [37.2-100](#) established pursuant to Title 37.2, facilities as defined in § [37.2-100](#) that are licensed by the Department of Behavioral Health and Developmental Services and provide site-based crisis stabilization services, or other facilities authorized by the Board may use automated drug dispensing systems and remote dispensing systems, as defined in § [54.1-3401](#), upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system or remote dispensing system in such hospital, nursing home, or facility and are under the control of a pharmacy providing services to the hospital, nursing home, or facility;
2. The pharmacist-in-charge of the pharmacy providing services to the hospital, nursing home, or facility has established procedures for ensuring the accurate stocking and proper storage of drugs in the automated drug dispensing system or remote dispensing system and for ensuring accountability for and security of all drugs utilized in such system until the time such drugs are removed from such system for administration to the patients;
3. Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;
4. Adequate security for automated drug dispensing systems or remote dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) ensuring compliance with the requirements of this section;
5. Accountability for drugs dispensed from automated drug dispensing systems or remote dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the hospital, nursing home, or facility or the pharmacist-in-charge of the outside pharmacy providing pharmacy services to the hospital, nursing home, or facility;
6. Filling and stocking of all drugs in automated drug dispensing systems or remote dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into such system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling such system or the pharmacist-in-charge, if such system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system or remote dispensing system; and
7. Except when the automated drug dispensing system is used exclusively for administration of drugs for emergencies, a pharmacy located outside of the hospital, nursing home, or facility it

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

B. Except as authorized by the Board, drugs placed into and removed from automated drug dispensing systems or remote dispensing systems for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose packaging or in a liquid, injectable, or inhaled formulation may be placed in such a device if approved by the pharmacist-in-charge in consultation with pharmacy, medical, and nursing staff of the hospital, nursing home, or facility.

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

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

E. Notwithstanding this section, the Board shall promulgate regulations for the use of a remote dispensing system to store drugs previously dispensed and labeled by the provider pharmacy in compliance with current laws and regulations. Such regulations shall identify the location where such system may be placed and requirements to ensure the security of the drug, confidentiality of protected health information, and appropriate recordkeeping.

1999, c. [750](#); 2004, c. [140](#); 2009, c. [100](#); 2024, cc. [63](#), [513](#).

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

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

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an

appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

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

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

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

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

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

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

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

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

compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

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

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

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

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

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

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

H. Pharmacists shall not engage in the following:

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

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

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

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

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

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

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

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

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

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

Agenda Topic: Adopt Guidance Document for Centralized Compounding by Hospital Pharmacies

Action Needed: Motion to adopt guidance document 110-39 as presented or amended.

VIRGINIA BOARD OF PHARMACY

Centralized Compounding by Hospital Pharmacies

Hospital pharmacies that distribute non-patient specific compounded drug products within a health system under common ownership with the pharmacy under Virginia Code § 54.1-3410.2 (C) should maintain a manual or electronic record of distribution indicating the name, strength, lot, expiration date, and quantity of drug distributed from the pharmacy to the offsite location, along with date of distribution, and the names, addresses, and permit numbers associated with the pharmacy and the offsite location. The record of distribution should be maintained by the hospital pharmacy and a copy should be provided to the offsite location to be maintained with their records of receipt. Such records should be maintained completely and accurately for two years from the date of the transaction recorded.

Ambulatory care clinics using automated drug dispensing devices to store such non-patient specific compounded drug products may require a controlled substances registration as an “other facility” in accordance with Virginia Code § 54.1-3434.02. Refer to Guidance Document 110-19.

References

[Va. Code § 54.1-3410.2](#)

[Va. Code § 54.1-3434.02](#)

Agenda Item: Amendment of Guidance Document 110-8

Included in your agenda package:

- Redline of proposed changes to Guidance Document 110-8;
- Clean version of Guidance Document 110-8 with proposed changes;
- Pending exempt regulatory changes made by the Board of Optometry to implement HB1898 and SB1081; and
- HB1898.

Staff Note: HB1898 and SB1081 eliminated the Board of Optometry's TPA Formulary and TPA Formulary Committee. Guidance Document 110-8 now needs to be amended to reflect these changes.

Action needed:

- Motion to amend Guidance Document 110-8.

Virginia Board of Pharmacy Prescriptive Authority in Virginia

In Virginia all prescription drugs are categorized into schedules. Schedules I through V, for the most part, mirror the federal schedules. All prescription or legend drugs not included in Schedules II through V are placed in Schedule VI in Virginia and are also referred to as “controlled” drugs or substances within the Drug Control Act. This is sometimes confusing as the term “controlled” is usually applied only to drugs in Schedules II through V.

Before prescribing any drug in Schedules II-V, a practitioner must obtain a registration from the U.S Drug Enforcement Administration (DEA). The DEA registration must also be on any prescription written for a Schedule II-V drug.

Advanced practice registered nurses who meet certain criteria may be authorized to prescribe Schedule II-VI drugs by the Boards of Nursing and Medicine. Unless an advanced practice registered nurse has been authorized for autonomous practice, the authorization to prescribe schedules or categories of drugs will be set out in a practice agreement with a collaborating physician. Advanced practice registered nurses with prescriptive authority may dispense samples of those drugs they are authorized to prescribe and may also sign for the receipt of those samples.

Physician assistants who meet criteria and have been approved by the Board of Medicine for prescriptive authority may prescribe Schedule II-VI drugs that have been approved by the collaborating physician or podiatrist. A prescription written by a physician assistant for a Schedule II-V drug must include the name of the collaborating physician or podiatrist. Physician assistants may dispense samples of those drugs they are authorized to prescribe and may sign for receipt of samples.

Advanced practice registered nurses or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For advanced practice registered nurses, there is a 10-digit license number beginning with 0024, which should be on the prescription. To verify the license, click on “License Lookup” at www.dhp.virginia.gov using “Licensed Advanced Practice Registered Nurse” for the occupation. On the screen displaying the results of the individual’s licensure information, the phrase “Rx Authority” will appear under “Specialization” if the advanced practice registered nurse is authorized to prescribe drugs. For physician assistants, there is a 10-digit license number beginning with 0011, which can be verified through the web site www.dhp.virginia.gov under “License Lookup” and checking the occupation “Physician Assistant.”

Practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine have independent prescriptive authority and may prescribe drugs in Schedules II through VI.

Optometrists who have been certified to use therapeutic pharmaceutical agents have independent authority to prescribe and administer certain controlled substances and devices to treat diseases and abnormal conditions of the human eye and its adnexa in these categories:

1. ~~Oral analgesics~~ Analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and oral analgesics in Schedule III, IV and through VI narcotic and non-narcotic agents which are appropriate to relieve ocular pain. They may also prescribe gabapentin in Schedule V.

2. Topically administered Schedule VI agents: drugs.

- a. ~~Alpha-adrenergic blocking agents;~~
- b. ~~Alpha-adrenergic agonists;~~
- c. ~~Anesthetic (including esters and amides);~~
- d. ~~Anti-allergy (including antihistamines and mast cell stabilizers);~~
- e. ~~Anti-fungal;~~
- f. ~~Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);~~
- g. ~~Anti-infective (including antibiotics and antivirals);~~
- h. ~~Anti-inflammatory;~~
- i. ~~Cycloplegics and mydriatics;~~
- j. ~~Decongestants; and~~
- k. ~~Immunosuppressive agents.~~

3. Orally administered Schedule VI agents: drugs appropriate to treat diseases and abnormal conditions of the human eye and its adnexa.

- a. ~~Aminocaproic acids (including antifibrinolytic agents);~~
- b. ~~Anti-allergy (including antihistamines and leukotriene inhibitors);~~
- c. ~~Anti-fungal;~~
- d. ~~Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);~~
- e. ~~Anti-infective (including antibiotics and antivirals);~~
- f. ~~Anti-inflammatory (including steroidal and non-steroidal);~~
- g. ~~Decongestants; and~~
- h. ~~Immunosuppressive agents.~~

4. Intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

Inquiries as to the certification of an optometrist to prescribe therapeutic pharmaceutical agents or requests for regulations may be made by checking the web site www.dhp.virginia.gov under "on-line license lookup" and checking for the occupation "TPA certified optometrist." After June 30, 2004, every person who is initially licensed to practice optometry in Virginia must meet the qualifications for a TPA-certified optometrist.

In order to be valid, prescriptions must meet the criteria set forth in § 54.1-3303 of the Code of Virginia (attached). A prescription must be written in the context of a bona fide practitioner-patient relationship, for a medicinal or therapeutic purpose, and within the course of the professional practice of the prescriber. The elements that constitute a bona fide practitioner patient relationship are set forth in this statute.

Statutes:

Va. Code § 54.1-3303

Va. Code § 54.1-3400 *et seq.*

Virginia Board of Pharmacy Prescriptive Authority in Virginia

In Virginia all prescription drugs are categorized into schedules. Schedules I through V, for the most part, mirror the federal schedules. All prescription or legend drugs not included in Schedules II through V are placed in Schedule VI in Virginia and are also referred to as “controlled” drugs or substances within the Drug Control Act. This is sometimes confusing as the term “controlled” is usually applied only to drugs in Schedules II through V.

Before prescribing any drug in Schedules II-V, a practitioner must obtain a registration from the U.S Drug Enforcement Administration (DEA). The DEA registration must also be on any prescription written for a Schedule II-V drug.

Advanced practice registered nurses who meet certain criteria may be authorized to prescribe Schedule II-VI drugs by the Boards of Nursing and Medicine. Unless an advanced practice registered nurse has been authorized for autonomous practice, the authorization to prescribe schedules or categories of drugs will be set out in a practice agreement with a collaborating physician. Advanced practice registered nurses with prescriptive authority may dispense samples of those drugs they are authorized to prescribe and may also sign for the receipt of those samples.

Physician assistants who meet criteria and have been approved by the Board of Medicine for prescriptive authority may prescribe Schedule II-VI drugs that have been approved by the collaborating physician or podiatrist. A prescription written by a physician assistant for a Schedule II-V drug must include the name of the collaborating physician or podiatrist. Physician assistants may dispense samples of those drugs they are authorized to prescribe and may sign for receipt of samples.

Advanced practice registered nurses or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For advanced practice registered nurses, there is a 10-digit license number beginning with 0024, which should be on the prescription. To verify the license, click on “License Lookup” at www.dhp.virginia.gov using “Licensed Advanced Practice Registered Nurse” for the occupation. On the screen displaying the results of the individual’s licensure information, the phrase “Rx Authority” will appear under “Specialization” if the advanced practice registered nurse is authorized to prescribe drugs. For physician assistants, there is a 10-digit license number beginning with 0011, which can be verified through the web site www.dhp.virginia.gov under “License Lookup” and checking the occupation “Physician Assistant.”

Practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine have independent prescriptive authority and may prescribe drugs in Schedules II through VI.

Optometrists who have been certified to use therapeutic pharmaceutical agents have independent authority to prescribe and administer certain controlled substances and devices to treat diseases and abnormal conditions of the human eye and its adnexa in these categories:

1. Analgesics – Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and oral analgesics in Schedule III through VI which are appropriate to relieve ocular pain.

2. Topically administered Schedule VI drugs.

3. Orally administered Schedule VI drugs appropriate to treat diseases and abnormal conditions of the human eye and its adnexa.

4. Intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

Inquiries as to the certification of an optometrist to prescribe therapeutic pharmaceutical agents or requests for regulations may be made by checking the web site www.dhp.virginia.gov under "on-line license lookup" and checking for the occupation "TPA certified optometrist." After June 30, 2004, every person who is initially licensed to practice optometry in Virginia must meet the qualifications for a TPA-certified optometrist.

In order to be valid, prescriptions must meet the criteria set forth in § 54.1-3303 of the Code of Virginia (attached). A prescription must be written in the context of a bona fide practitioner-patient relationship, for a medicinal or therapeutic purpose, and within the course of the professional practice of the prescriber. The elements that constitute a bona fide practitioner patient relationship are set forth in this statute.

Statutes:

Va. Code § 54.1-3303

Va. Code § 54.1-3400 *et seq.*

Project 8286 - Final

Board of Optometry

Removal of TPA formulary and formulary committee pursuant to SB1081

18VAC105-20-5. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Acute pain" means pain that occurs within the normal course of a disease or condition for which controlled substances may be prescribed for no more than three months.

"Active clinical practice" means an average of 20 hours per week or 640 hours per year of providing patient care.

"Adnexa" is defined as the conjoined, subordinate, or immediately associated anatomic parts of the human eye, including eyelids and eyebrows.

"Board" means the Virginia Board of Optometry.

"Chronic pain" means nonmalignant pain that goes beyond the normal course of a disease or condition for which controlled substances may be prescribed for a period greater than three months.

"Controlled substance" means drugs listed in the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) in Schedules II through V.

"MME" means morphine milligram equivalent.

"NBEO" means the National Board of Examiners in Optometry.

"Prescription Monitoring Program" means the electronic system within the Department of Health Professions that monitors the dispensing of certain controlled substances.

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"TMOD" means the treatment and management of ocular disease portion of the NBEO examination.

~~"TPA" means therapeutic pharmaceutical agents.~~

"TPA certification" means authorization by the Virginia Board of Optometry for an optometrist to treat diseases and abnormal conditions of the human eye and its adnexa and to prescribe and administer ~~certain~~ therapeutic pharmaceutical agents.

18VAC105-20-46. Treatment guidelines for TPA-certified optometrists.

A. TPA-certified optometrists may treat diseases and abnormal conditions of the human eye and its adnexa that may be treated with medically appropriate pharmaceutical agents ~~as referenced in 18VAC105-20-47.~~

B. In addition, the following may be treated:

1. Glaucoma (excluding the treatment of congenital and infantile glaucoma). Treatment of angle closure shall follow the definition and protocol prescribed in subsection C of this section.
2. Ocular-related post-operative care in cooperation with patient's surgeon.
3. Ocular trauma to the above tissues as in subsection A of this section.
4. Uveitis.
5. Anaphylactic shock (limited to the administration of intramuscular epinephrine).

C. The definition and protocol for treatment of angle closure glaucoma shall be as follows:

1. As used in this chapter, angle closure glaucoma shall mean a closed angle in the involved eye with significantly increased intraocular pressure, and corneal microcystic edema;

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2. Treatment shall be limited to the initiation of immediate emergency care with appropriate pharmaceutical agents as prescribed by this chapter;
3. Once the diagnosis of angle closure glaucoma has been established by the optometrist, the ophthalmologist to whom the patient is to be referred should be contacted immediately;
4. If there are no medical contraindications, an oral osmotic agent may be administered as well as an oral carbonic anhydrase inhibitor and any other medically accepted, Schedule III, IV or VI, oral antiglaucomatic agent as may become available; and
5. Proper topical medications as appropriate may also be administered by the optometrist.

D. An oral Schedule VI immunosuppressive agent shall only be used when (i) the condition fails to appropriately respond to any other treatment regimen; (ii) such agent is prescribed in consultation with a physician; and (iii) treatment with such agent includes monitoring of systemic effects.

E. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02. Upon written request, the board may grant a one-time waiver of the requirement for electronic prescribing, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.

18VAC105-20-47. Therapeutic pharmaceutical agents. (Repealed.)

~~A. A TPA-certified optometrist, acting within the scope of his practice, may procure, administer, and prescribe medically appropriate therapeutic pharmaceutical agents (or any therapeutically appropriate combination thereof) to treat diseases and abnormal conditions of the human eye and its adnexa within the following categories:~~

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~~1. Oral analgesics — Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III, IV, and VI narcotic and nonnarcotic agents.~~

~~2. Topically administered Schedule VI agents:~~

- ~~a. Alpha-adrenergic blocking agents;~~
- ~~b. Alpha-adrenergic agonists;~~
- ~~c. Cholinergic agonists;~~
- ~~d. Anesthetic (including esters and amides);~~
- ~~e. Anti-allergy (including antihistamines and mast cell stabilizers);~~
- ~~f. Anti-fungal;~~
- ~~g. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);~~
- ~~h. Anti-infective (including antibiotics and antivirals);~~
- ~~i. Anti-inflammatory;~~
- ~~j. Cycloplegics and mydriatics;~~
- ~~k. Decongestants; and~~
- ~~l. Immunosuppressive agents.~~

~~3. Orally administered Schedule VI agents:~~

- ~~a. Aminocaproic acids (including antifibrinolytic agents);~~
- ~~b. Anti-allergy (including antihistamines and leukotriene inhibitors);~~
- ~~c. Anti-fungal;~~
- ~~d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);~~

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- ~~e. Anti-infective (including antibiotics and antivirals);~~
- ~~f. Anti-inflammatory (including steroidal and nonsteroidal);~~
- ~~g. Decongestants; and~~
- ~~h. Immunosuppressive agents.~~

~~B. Schedules I, II, and V drugs are excluded from the list of therapeutic pharmaceutical agents with the exception of controlled substances in Schedule II consisting of hydrocodone in combination with acetaminophen and gabapentin in Schedule V.~~

~~C. Over the counter topical and oral medications for the treatment of the eye and its adnexa may be procured for administration, administered, prescribed, or dispensed.~~

~~D. Beginning July 1, 2020, a prescription for a controlled substance that contains an opioid shall be issued as an electronic prescription consistent with § 54.1-3408.02 of the Code of Virginia, unless the prescription qualifies for an exemption as set forth in subsection C of § 54.1-3408.02. Upon written request, the board may grant a one-time waiver of the requirement for electronic prescribing, for a period not to exceed one year, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the prescriber, or other exceptional circumstances demonstrated by the prescriber.~~

VIRGINIA ACTS OF ASSEMBLY - 2025 SESSION

CHAPTER 391

An Act to amend and reenact §§ 54.1-3222, 54.1-3223, 54.1-3301, and 54.1-3303 of the Code of Virginia, relating to Optometry; TPA-Formulary; TPA-Formulary Committee; dissolution.

[H 1898]

Approved March 24, 2025

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3222, 54.1-3223, 54.1-3301, and 54.1-3303 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3222. TPA certification; certification for treatment of diseases or abnormal conditions with therapeutic pharmaceutical agents (TPAs).

TPA certification shall enable an optometrist to prescribe and administer, within his scope of practice, Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedules III through VI controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) to treat diseases and abnormal conditions of the human eye and its adnexa as determined by the Board, within the following conditions:

1. Treatment with oral therapeutic pharmaceutical agents shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen, and analgesics included on Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act, which are appropriate to alleviate ocular pain and (ii) other Schedule VI controlled substances as defined in § 54.1-3455 of the Drug Control Act appropriate to treat diseases and abnormal conditions of the human eye and its adnexa.

2. Therapeutic pharmaceutical agents shall include topically applied Schedule VI drugs as defined in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.).

3. Administration of therapeutic pharmaceutical agents by injection shall be limited to the treatment of chalazia by means of injection of a steroid included in Schedule VI controlled substances as set forth in § 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.). A TPA-certified optometrist shall provide written evidence to the Board that he has completed a didactic and clinical training course provided by an accredited school or college of optometry that includes training in administration of TPAs by injection prior to administering TPAs by injection pursuant to this subdivision.

4. Treatment of angle closure glaucoma shall be limited to initiation of immediate emergency care.

5. Treatment of infantile or congenital glaucoma shall be prohibited.

6. Treatment through surgery or other invasive modalities shall not be permitted, except as provided in subdivision 3 or for treatment of emergency cases of anaphylactic shock with intramuscular epinephrine.

7. Entities permitted or licensed by the Board of Pharmacy to distribute or dispense drugs, including, but not limited to, wholesale distributors and pharmacists, shall be authorized to supply TPA-certified optometrists with those therapeutic pharmaceutical agents specified by the Board on the TPA-Formulary.

§ 54.1-3223. Regulations relating to therapeutic pharmaceutical agents.

~~A.~~ The Board shall promulgate such regulations governing the treatment of diseases and abnormal conditions of the human eye and its adnexa with therapeutic pharmaceutical agents by TPA-certified optometrists as are reasonable and necessary to ensure an appropriate standard of medical care for patients, including, but not limited to, determinations of the diseases and abnormal conditions of the human eye and its adnexa that may be treated by TPA-certified optometrists; and treatment guidelines; and the drugs specified on the TPA-Formulary.

~~In order to maintain a current and appropriate list of therapeutic pharmaceuticals on the TPA-Formulary, current and appropriate treatment guidelines, and current and appropriate determinations of diseases and abnormal conditions of the eye and its adnexa that may be treated by TPA-certified optometrists, the Board may, from time to time, amend such regulations. Such regulations and amendments thereto shall be exempt from the requirements of the Administrative Process Act (§ 2.2-4000 et seq.), except to any extent that they may be specifically made subject to §§ 2.2-4024, 2.2-4030, and 2.2-4031; the Board's regulations shall, however, comply with § 2.2-4103 of the Virginia Register Act (§ 2.2-4100 et seq.). The Board shall, however, conduct a public hearing prior to making amendments to the TPA-Formulary, the treatment guidelines or the determinations of diseases and abnormal conditions of the eye and its adnexa that may be treated by TPA-certified optometrists. Thirty days prior to conducting such hearing, the Board shall give written notice by mail or electronic means of the date, time, and place of the hearing to all currently TPA-certified optometrists and any other persons requesting to be notified of the hearings and publish notice of its intention to amend the list regulations in the Virginia Register of Regulations. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to~~

final adoption of any ~~TPA-Formulary~~ amendments. Proposed and final amendments ~~of the list~~ shall also be published, pursuant to § 2.2-4031, in the Virginia Register of Regulations. ~~Final amendments to the TPA-Formulary shall become effective upon filing with the Registrar of Regulations. The TPA-Formulary shall be the inclusive list of the therapeutic pharmaceutical agents that a TPA-certified optometrist may prescribe.~~

~~B. To assist in the specification of the TPA-Formulary, there shall be a seven-member TPA-Formulary Committee, as follows: three Virginia TPA-certified optometrists to be appointed by the Board of Optometry, one pharmacist appointed by the Board of Pharmacy from among its licensees, two ophthalmologists appointed by the Board of Medicine from among its licensees, and the chairman who shall be appointed by the Board of Optometry from among its members. The ophthalmologists appointed by the Board of Medicine shall have demonstrated, through professional experience, knowledge of the optometric profession. In the event the Board of Pharmacy or the Board of Medicine fails to make appointments to the TPA-Formulary Committee within 30 days following the Board of Optometry's requesting such appointments, or within 30 days following any subsequent vacancy, the Board of Optometry shall appoint such members.~~

~~The TPA-Formulary Committee shall recommend to the Board those therapeutic pharmaceutical agents to be included on the TPA-Formulary for the treatment of diseases and abnormal conditions of the eye and its adnexa by TPA-certified optometrists.~~

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;
2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a seven-day supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;
3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;
4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;
5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;
6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;
7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 ~~and the TPA formulary~~, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;
8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;
9. Interfere with any licensed advanced practice registered nurse with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe;
10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a

practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

§ 54.1-3303. Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, 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.

B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.

A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient via telemedicine if such prescribing is in compliance with federal requirements for the practice of telemedicine and, in the case of the prescribing of a Schedule II through V controlled substance, the prescriber maintains a practice at a physical location in the Commonwealth or is able to make appropriate referral of patients to a licensed practitioner located in the Commonwealth in order to ensure an in-person examination of the patient when required by the standard of care.

A prescriber may establish a bona fide practitioner-patient relationship for the purpose of prescribing

Schedule II through VI controlled substances by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations; (h) the establishment of a bona fide practitioner-patient relationship via telemedicine is consistent with the standard of care, and the standard of care does not require an in-person examination for the purpose of diagnosis; and (i) the establishment of a bona fide practitioner patient relationship via telemedicine is consistent with federal law and regulations and any waiver thereof. Nothing in this paragraph shall apply to (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.

C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription. A practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than for medicinal or therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists. A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal or therapeutic purpose within the course of his professional practice.

In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed.

Any person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.

E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient and (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.

F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, an advanced practice registered nurse, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

G. A licensed advanced practice registered nurse who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

H. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice ~~for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.~~

J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.

Agenda Topic: Amend Guidance Document 110-17 regarding TOEFL Scores

Included in Agenda Packet:

- Excerpt from FPGEC 2025 Candidate Application Bulletin
- Draft amendments of Guidance Document 110-17

Action Needed:

- Motion to amend Guidance Document 110-17 as presented or amended.

Step 1: Achieve the TOEFL iBT Requirement

In This Section

- [Score Requirements](#)
 - [Score Reports](#)
-

The Education Testing Service (ETS) TOEFL iBT is the sole English language proficiency examination accepted for candidates seeking FPGEC certification. A passing score on the TOEFL iBT is required to apply for FPGEC certification. The TOEFL iBT must be completed by all foreign pharmacy graduates (even those who are US citizens, US residents, or native English speakers). **There are no exceptions or waivers to these requirements.**

The TOEFL iBT must be completed in a secure testing environment in an ETS test center, which must be located in an [NABP member or associate member jurisdiction](#). This includes the 50 US states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, and 10 Canadian provinces (Alberta, British Columbia, Manitoba, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Prince Edward Island, Quebec, and Saskatchewan).

The at-home and remotely proctored TOEFL iBT is not accepted by the FPGEC program (see Secure Testing Environment below). The FPGEC also does not accept **“My Best”** scores and will not consider a total score on the TOEFL iBT.

You must pass the TOEFL iBT before applying for FPGEC certification. The TOEFL iBT score report, along with other required documentation, must be submitted before application evaluation can begin.

You must complete all four sections of the TOEFL iBT in one testing session. Scores for the four sections must be reported directly to the FPGEC on one official score report. If your score is less than the minimum required score in any section, your score report will not be accepted.

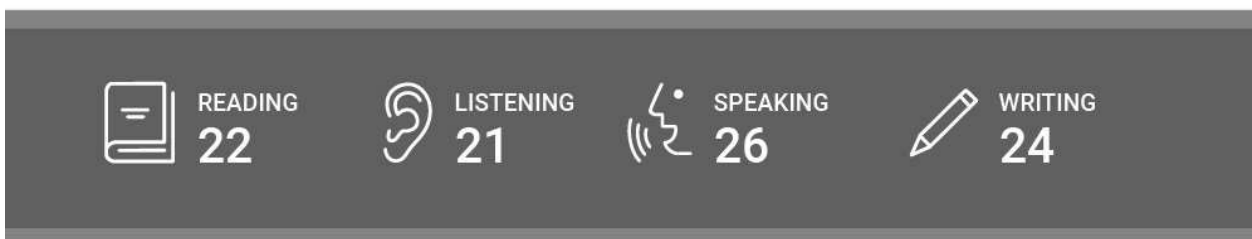
Passing TOEFL iBT scores are accepted as valid for the FPGEC program for 2 years from the date of the administration of the TOEFL iBT.

TOEFL iBT Score Requirements

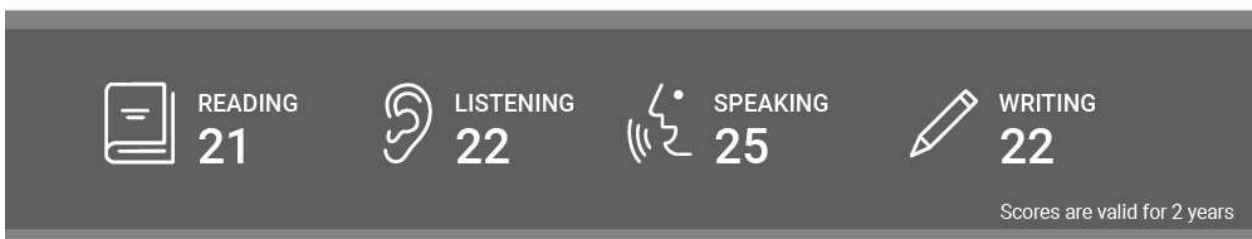
Passing scores for each TOEFL iBT section were revisited using a standard setting study and updated passing scores for each TOEFL iBT section have been approved. The updated passing scores for each TOEFL iBT section will go into effect October 25, 2025, and will apply to FPGEC applications for the 2026 FPGEE examination and beyond. TOEFL scores will remain valid for two years.

All FPGEC applications that are accepted before September 1, 2025, will require TOEFL iBT section scores that meet the current passing standards. All FPGEC applications that are accepted on or after October 25, 2025, will require TOEFL iBT section scores that meet the revised passing standards.

TOEFL requirements for FPGEC applications accepted **before September 1, 2025**



TOEFL requirements for FPGEC applications accepted **on or after October 25, 2025**



Score Reports

You must request that your TOEFL iBT score report (all four sections from a single test session) be submitted to the FPGEC directly by ETS. **Use the FPGEC identification number 9103.** The FPGEC will only accept official score reports received directly from ETS.

The official score report identifying information must exactly match what appears in your e-Profile. Score reports with discrepancies in the name, photo ID, or date of birth

your e-Profile. Score reports with discrepancies in the name, photo ID, or date of birth will not be accepted.

If you have a legal name change after obtaining a passing TOEFL iBT score, you must submit proper documentation to NABP as part of your FPGEC application. See the [Name Changes, Name Matching on Documents, and Other Guidelines](#) section for important information.

May 2025

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Virginia Board of Pharmacy

INSTRUCTIONS FOR GRADUATES OF FOREIGN SCHOOLS OF PHARMACY

Each step of the following requirements to be eligible for a pharmacist license in Virginia must be completed in the order listed:

1. FPGEC Certification Program

Graduates of foreign colleges of pharmacy must first obtain the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certification from the National Association of Boards of Pharmacy (NABP). Virginia has no alternative to this process for certifying the equivalency of pharmacy education and proficiency in written and spoken English. The FPGEC certification shows the following:

- a. That the person is a graduate of a foreign college of pharmacy and that the educational and licensure credentials have been evaluated and found to be valid and substantively equivalent to those in the United States;
- b. That the person has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).
- c. That the person has successfully completed the written and oral communication ability tests of English as follows:
 - **Beginning October 25, 2025, all new candidates for FPGEC Certification must complete the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 22, Speaking 25, Listening 22, and Reading 21.**
 - **Beginning March 1, 2014, all new candidates for FPGEC Certification must complete** the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 21, and Reading 22.
 - **Between April 1, 2010 and February 28, 2014, all new candidates for FPGEC Certification must complete** the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 18, and Reading 21; scores for this exam will no longer be accepted from an international Educational Testing Service (ETS) test site location. These candidates who are unsuccessful in meeting all requirements for certification prior to June 1, 2014, must meet the new minimum score requirements of the TOEFL iBT in order to obtain certification.

2. Practical Experience Requirement

One must obtain at least **1500 hours** practical experience within the United States. **Prior to** gaining practical experience in Virginia for credit, a person must register with this Board as a "**pharmacy intern**". The online application for registration as a pharmacy intern may be found at www.dhp.virginia.gov/pharmacy/pharmacy_forms. The applicant must submit the application, pay the required fee and provide the Virginia pharmacy location where the experience is to be gained as well as the name of the supervising pharmacist. Once the practical experience has been obtained, the pharmacy intern must submit an affidavit to the Board documenting the practical experience. These hours must meet the following requirements:

- a. Credit will not be given for more than 50 hours in any one week or for less than an average of 20 hours a week averaged over a month.
- b. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.
- c. Practical experience gained in another state within the U.S. must be certified by that state's board of pharmacy and may require registration as a pharmacy intern with that state board.
- d. A temporary intern registration may be issued without a social security number **for 90 days only**.

3. A Completed Application

Once the requirements of sections 1 and 2 above are completed, one may submit an application for licensure as a pharmacist. The applicant should also apply to take NAPLEX (if applying for initial licensure by examination) and the Multistate Pharmacy Jurisprudence Examination (MPJE) offered by NABP. If the applicant is approved, authorization to test will be granted by the Board. Detailed information about the NAPLEX and MPJE, the registration process, scheduling an appointment to test, requirements on test day, and both the NAPLEX and MPJE blueprints which contain a list of competency statements that comprise the topics covered on the exams may be found at www.nabp.pharmacy

- a. If applying for initial licensure in Virginia by examination, an applicant must apply online and submit the required fee. The applicant may omit the college affidavit section.
- b. If applying to transfer a pharmacist's license from another state within the United States (Licensure by Endorsement), an applicant must go through NABP's license transfer process . In order to be eligible to transfer a license from another state, an applicant must also have met the requirements of sections 1 and 2 above.

All forms required are available on the Board of Pharmacy website under Forms and Applications at <http://www.dhp.virginia.gov/pharmacy/default.htm>. FPGE, NAPLEX and MPJE information may be found at www.nabp.pharmacy.

Ongoing Action Items

From the Educational Forum, 4/25/25:

- There was a consensus on the following items with no vote taken:
 1. 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. *(To be discussed on 9/30/25)*
 2. 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. *(To be discussed December 10, 2025)*
 3. 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. *(Chair to address.)*
 4. Mr. Kocot informed the chairman that he would like the board to review its process for accepting a license for surrender. The subject will be discussed and voted on at a future meeting. *(Chair to address.)*
 5. Board members and staff will develop a list of IT-related needs that are not currently met and submit it to relevant agency staff to determine if the Evoke software platform to be implemented in 2027/2028 can meet those needs. *(Chair to address.)*
- The Board voted on the following item:
 6. The following topic will 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). *(Background information included in 9/30/25 agenda packet.)*

From the Full Board Meeting, 5/19/25

7. There was a consensus that staff will ask the agency's Finance Department if they actively negotiate credit card fees (completed) and staff will provide a summary of revenue and expenditures annually to the board (ongoing). *(Executive Director to address.)*

Partially Completed or Completed Action Items:

From the Educational Forum, 4/25/15

8. Staff will send a link to the staffing requests or concerns form to licensees. *(will tentatively be included in communication regarding statewide protocol revisions)*
9. 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. *(Executive Director to address.)*
10. Ms. Juran will email VPhA and VSHP to encourage them to educate members on suicide awareness. *(completed)*



Report of the Task Force on the Regulation of Pharmacy Benefit Managers

NOTE: The NABP Executive Committee accepted all of the recommendations of this Task Force with the exception of Recommendation 5:

- **Upon review of the information pertaining to the Recommendation, the Executive Committee determined that the development of a patient reporting system for collecting consumer concerns regarding Pharmacy Benefits Managers related to the practice of pharmacy to be outside the realm of NABP and that the cost and infrastructure required for NABP to internally develop such a system is prohibitive.**

Members Present:

Patricia Donato (NY), *chair*; Buford Abeldt (TX); Julia Eaton (VT); Suzan Kedron (TX); LuGina Mendez-Harper (NM); Jeffrey Mesaros (FL); Steve Parker (MS); Richard Palombo (NJ); Laura Schwartzwald (MN); Brenda Warren (TN); Cindy Warriner (VA); Stuart Williams (MN).

Others Present:

Hal Wand, *Executive Committee liaison*; Carmen Catizone, Melissa Madigan, Eileen Lewalski, Heather McComas, Cameron Orr, *NABP staff*.

Introduction:

The Task Force on the Regulation of Pharmacy Benefit Managers met October 22-23, 2013, at NABP Headquarters. This task force was established in response to Resolution 109-3-13, Review and Revise the Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy Regarding Pharmacy Benefit Managers, which was approved by the NABP membership at the Association's 109th Annual Meeting in May 2013.

Review of the Task Force Charge:

Task force members reviewed their charge and accepted it as follows:

1. Review existing current state laws and regulations addressing the regulation of pharmacy benefit managers (PBMs).
2. Identify activities in which PBMs engage that may be construed to fall under the definition of the Practice of Pharmacy.
3. Review and, if necessary, recommend amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to address appropriate regulation of pharmacy benefit managers.

Recommendation 1: NABP Should Amend the *Model Act*

The task force recommends that NABP amend the *Model Act*. Revisions are denoted below by underlines and ~~strikethroughs~~.

Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy

...

Section 105. Definitions.

...

- (x4) “Pharmacy Benefits Manager” means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, and that engages in or directs the Practice of Pharmacy.
- (y4) “Pharmacy Benefits Processor” means a Person that Administers the Prescription Drug/Device portion of health insurance plans on behalf of plan sponsors, such as self-insured employers, insurance companies, and health maintenance organizations, but that does not engage in or direct the Practice of Pharmacy.

...

Section 105(x4) (and [y4]). Comment.

It is the performance of activities that encompass the Practice of Pharmacy that distinguishes Pharmacy Benefits Managers from Pharmacy Benefits Processors. The activities that may encompass the Practice of Pharmacy by Pharmacy Benefits Managers include, but are not limited to, the following:

- Disease state management
- Disease compliance management
- Drug adherence management
- Drug interaction management
- Drug utilization management
- Formulary management ~~intervention~~
- Generic alternative program management
- Generic incentive program management
- Medical and/or Drug data analysis
- Patient Drug Utilization Review (DUR) services
- Prior authorization services
- Provider profiling and outcomes assessment
- Refill reminder program management
- Therapy guidelines management
- Stop therapy protocol management
- Wellness management

- Maintenance of confidential patient information
- Direction or design of the clinical programs for a pharmacy or a group of pharmacies

Background:

As a ground rule for its work, the task force agreed that all discussions and recommendations should remain within the scope of the practice of pharmacy and the protection of public health. Task force members recognized that many concerns surrounding PBMs relate to contractual issues, payment, or coverage, and as such, fall outside the purview of the boards of pharmacy. The group acknowledged the challenges involved in delineating which PBM-related issues fall strictly under the jurisdiction of the boards of pharmacy and expected that areas of ambiguity would arise in its discussions.

The task force then began addressing its charge by reviewing the reports of the 1999 Task Force on Licensing of Pharmacy Benefit Managers and the 2000 Task Force on Model Guidelines for Formulary Development. The task force discussed and ultimately agreed with the existing *Model Act* definitions for Pharmacy Benefits Managers and Pharmacy Benefits Processors that were created by the 1999 task force. The group recommended that the language in the associated Comment section be generalized to avoid the implication that the listed activities always constitute the practice of pharmacy by PBMs. After agreeing that formulary development may involve clinical decision-making and may constitute the practice of pharmacy, the task force recommended that the language related to formularies be broadened to include all aspects of formulary management, not just interventions. Finally, in recognition that many PBMs design the clinical programs for their associated mail order and/or network pharmacies, the task force recommended that direction and design of clinical programs for pharmacies be added to the list of activities that may constitute the practice of pharmacy by PBMs.

Recommendation 2: NABP Should Encourage States to Adopt Existing *Model Act* Language Pertaining to PBMs

The task force recommends that NABP encourage states to adopt existing *Model Act* language pertaining to PBMs.

Background:

After a thorough discussion of the current impact of PBM activities on the practice of pharmacy, the task force affirmed the 1999 task force's recommendation that PBMs engaged in the practice of pharmacy should be licensed and regulated by state boards of pharmacy. The task force supported the other findings and recommendations of both previous task forces.

Task force members noted that boards of pharmacy may not be aware of the work of the previous task forces or the existing provisions in the *Model Act* pertaining to the licensure of PBMs. The task force therefore agreed that NABP should remind its member boards of the existing sections of the *Model Act* addressing PBMs and encourage states that have yet to do so adopt this language in their state pharmacy practice acts.

Recommendation 3: NABP Should Monitor Member States' Initiatives to Regulate the Activities of PBMs as They Relate to the Practice of Pharmacy, Alert Members to

Available NABP Resources to Assist with Regulation Development, and Support the Creation of a State Ombudsman Position for PBM Issues

The task force recommends that NABP monitor member states' activities and initiatives to regulate PBMs in order to determine if an expansion of the boards' authority in these areas is appropriate. The task force further recommends that NABP support the expansion of the authority of state and federal agencies overseeing these activities to ensure that the health and safety of the patient is a primary consideration. Wherever possible, the task force recommends that states institute an ombudsman for PBM issues to assist patients and ensure that their interests and complaints are appropriately received and managed. The task force also recommends that member boards be alerted to the availability of NABP resources to assist in the drafting of rules/regulations pertaining to PBMs.

Background:

The task force acknowledged that the issues identified by the 1999 and 2000 task forces related to patient access, medications excluded from coverage, and formulary changes impacting patient care remain legitimate concerns and although involve payment and coverage they may also relate to the practice of pharmacy. The task force recognized that while PBM contractual and payment issues may impact patient care, they are outside the scope of authority of the boards of pharmacy. To address these continuing challenges, some states are now regulating PBMs through their boards of pharmacy. Notably, PBMs doing business in the state of Mississippi have been regulated by the Mississippi Board of Pharmacy since 2011. Under the Mississippi regulations, PBMs must obtain a license from the Board before operating in the state; the Board also coordinates financial examinations of PBMs.

Task force members discussed the many areas of uncertainty pertaining to this new regulation of PBMs by state boards of pharmacy, including issues related to the scope, purview, and authority of the boards. While it is too early to determine the ultimate outcome of these new efforts, the task force concurred that NABP should actively monitor states' efforts related to PBM regulation and, once this area is more fully evolved, determine if expansion of the boards' authority is warranted. Additionally, NABP should remind any states interested in pursuing new regulations in this area of available NABP resources and support. NABP's Government Affairs staff can assist states with drafting rules and regulations, offer support and education, and testify before legislative committees.

To address unmet patient needs in the area of PBM payment and contractual issues beyond the scope of pharmacy, the task force recommended that states appoint an ombudsman to assist consumers in resolving questions and complaints related to PBM services. Task force members agreed that an ombudsman, ideally, should be positioned within the board of pharmacy because of the board's expertise and primary mission of protecting the public health. However, the task force acknowledged that it may not always be possible to secure an ombudsman position in the board of pharmacy and did not want to exclude the creation of this position within another state agency, provided that oversight is effective.

Recommendation 4: NABP Should Acknowledge That Certain PBM Activities and Medication Therapy Decisions May Impact the Practice of Pharmacy and Require Accountability

The task force recommends that NABP acknowledge that there may be activities and medication therapy decisions implemented through pharmacy benefit plans and PBMs that impact the practice of pharmacy and require accountability.

Background:

The task force reviewed the PBM activities listed in the Comment to Sections 105(x4) and 105(y4) of the *Model Act* and agreed that many of these examples may be the practice of pharmacy by PBMs and may impact patient care. In particular, task force members pointed to prior authorization and formulary decisions as examples of PBM activities that can affect pharmacists' ability to provide patients with needed medications and care. Given the potential effect on public health of these PBM activities, the task force recommended that NABP acknowledge the need for accountability on these issues. By encouraging states to adopt *Model Act* language regarding PBM licensure as described in Recommendation 2, NABP will be supporting accountability and increased oversight of pharmacy practice by PBMs. Additionally, the data-gathering initiative described next in Resolution 5 will further NABP's efforts to protect the public health related to PBM activities.

Recommendation 5: NABP Should Collect Data on Patient, Pharmacy, and Board of Pharmacy Concerns Related to Prescription Drug Benefits Via Survey, Provide These Data to the States, and Educate Consumers and Licensees About PBMs Through the AWAxE Program

The task force recommends that NABP collect data on patient, pharmacy, and board of pharmacy concerns related to pharmacy benefits via survey and provide this information to the states. Additionally, the task force recommends that NABP utilize the AWAxE program to educate patients and licensees about PBMs and the availability of this survey tool to report applicable concerns.

Background:

The task force struggled with how to resolve the ongoing concerns regarding PBM activities within the scope of the authority of the boards of pharmacy. Task force members noted that concrete statistical data documenting consumer concerns with PBMs are necessary to convince legislators to take action on these issues and increase regulatory oversight of PBMs. There is no mechanism currently in place to collect consumer concerns regarding PBMs; therefore, the task force suggested that NABP serve as the conduit to gather this information. NABP staff indicated that there is precedence for the Association to function as a data clearinghouse, as illustrated by NABP's monitoring of rogue Internet drug outlets and collection of licensee disciplinary information. NABP's efforts to collect PBM-related data will provide weight and legitimacy to consumer concerns surrounding PBMs.

The task force discussed several important elements of the proposed data-collection initiative, which included the following:

- **Mission of the program:** The NABP program will operate exclusively as an information-gathering tool, not a dispute-resolution process, and this will need to be explicitly stated to consumers accessing the system. The program will focus solely on concerns related to the practice of pharmacy and will not address coverage or payment issues. The task force stressed that this must be clearly communicated to consumers and

suggested that NABP provide examples of the types of issues to be tracked by the system to enhance consumer understanding of the program.

- **Information sharing and confidentiality concerns:** For this program to have the greatest impact and scope, information will need to be shared between NABP and the boards of pharmacy. The task force recommended that NABP's reporting mechanism be structured to provide consumers with the option to concurrently submit their PBM-related concern to the appropriate state board of pharmacy. Similarly, task force members indicated that boards of pharmacy should share any PBM-related consumer reports with NABP. Consumers will need to authorize this information sharing, or the data will need to be appropriately de-identified prior to being shared with other organizations.
- **Data aggregation:** The program will collect and report PBM data both nationally and by state. This will allow for the identification of any state- or region-specific issues related to PBMs.
- **Participation:** To ensure that the program gathers the most robust data, all states will be highly encouraged to participate.
- **Education and Outreach:** Both NABP and the boards of pharmacy will need to publicize the PBM data reporting system to maximize its reach and utility. Boards of pharmacy will be responsible for informing licensees about the program, and licensees can then in turn communicate the information to consumers via personal interactions and signs posted in pharmacies. NABP will raise awareness about the program through multiple communication vehicles, to include newsletters, electronic news mailings, and the AWARe Web site.
- **Data Analysis and Review:** After the collection of sufficient data, NABP should commission another task force to review and analyze the information and recommend further actions related to PBMs, if warranted.

The task force also addressed the need for education regarding PBMs among both consumers and licensees. Task force members indicated that many patients are unaware that a PBM, not their primary health insurer, administers pharmacy benefits. Additionally, consumers often do not understand their pharmacy benefits and corresponding limitations in medication coverage and access. Pharmacists and their staff also may not be fully aware of PBM operations and how plan restrictions can impact patients' access to medications.

To address these gaps in knowledge, the task force recommended that NABP create educational resources for both consumers and licensees regarding PBMs and their activities. Through the AWARe program, NABP can increase consumers' and licensees' understanding of PBMs, as well as publicize NABP's PBM reporting system. Task force members stressed that any materials intended for a consumer audience should use simple, clear language. NABP can also use various communication outlets, including newsletters and electronic mailings, to raise awareness of the new PBM content available through the AWARe program.



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March 4, 2016

MEMORANDUM

TO: The Honorable William A. Hazel Jr. MD
Secretary of Health and Human Resources

FROM: David E. Brown, DC, Director
Department of Health Professions

RE: **Report on Pharmacy Benefit Managers**

A Workgroup was convened by the Department of Health Professions to look at issues involving Pharmacy Benefit Managers (PBMs) and to make recommendations regarding the need for additional oversight of PBMs. The Workgroup included representatives from the Virginia Boards of Pharmacy and Medicine, various state agencies (VDH, DHRM, DMAS), Virginia Bureau of Insurance, Medical Society of Virginia, Virginia Pharmacists Association, National Community Pharmacists Association, Virginia Association of Chain Drug Stores, Pharmaceutical Care Management Association, Virginia Association of Health Plans, Anthem Blue Cross and Blue Shield, and Express-Scripts.

The Workgroup concluded that there were five options but was able to reach a consensus on only two of them. There was consensus on the need to convene a meeting of key stakeholders to address concerns with the prior authorization process and for the Board of Pharmacy to review the practices of white bagging and brown bagging to address issues of concern.

A copy of the Workgroup's report is provided for your information. Please let us know if any additional information or assistance is needed.

cc: Dr. Jennifer Lee
Del. Keith Hodges
Del. Chris Jones
PBM Workgroup Members

DEB/lzr

Report of the Pharmacy Benefit Managers Workgroup

Virginia Department of Health Professions

March 4, 2016

Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Association of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

Introduction:

In a letter from United States Senator Mark R. Warner dated February 19, 2015, the Virginia Board of Pharmacy was requested to look into a constituent's concern involving pharmacy benefit managers (PBM) and provide an appropriate response. The constituent requested that Senator Warner assist him with concerns regarding pharmacy benefit manager oversight as the Virginia State Corporation Commission, Bureau of Insurance, and Board of Pharmacy had informed him that they did not have legal authority to oversee or act on his complaint. The constituent alleged CVS Caremark and other PBMs discriminate against independent pharmacies by requiring documentation during the credentialing and re-credentialing process that are not required of chain pharmacies. He stated refusing to provide the documentation will result in a termination of the contract with the PBM for reimbursement of prescriptions. The constituent indicated that the un-level playing field threatens the survival of independent pharmacies and their ability to conduct normal business.

In a letter dated February 24, 2015 on behalf of the Board Chairman, the Executive Director for the Board of Pharmacy, after speaking with a representative of the Bureau of Insurance, confirmed to Senator Warner that neither agency has the authority to license PBMs or address the concerns expressed by the constituent. The letter indicated that there appears to be a possible lack of oversight in state law in regulating pharmacy benefit managers and that the board would discuss the issue further at its next meeting in March 2015.

At the March 24, 2015 Board of Pharmacy full board meeting, the Board heard comment from the National Community Pharmacists Association, the Medical Society of Virginia, the Virginia Pharmacists Association, EPIC Pharmacies, and owners of two independent pharmacies. Concerns included: lack of oversight of PBMs; impact PBM decision-making may have on patient access to medications, particularly in a rural setting; burdensome credentialing and re-credentialing processes that lack standards and demand too much of the pharmacist's time; PBMs' ability to designate drugs as specialty drugs and requiring them to be dispensed by mail order pharmacies often owned by PBMs; concerns with mail order pharmacies complying with statutory requirement for a bona fide pharmacist-patient relationship; and, an exclusion of the Bureau of Insurance in HB 1942 and SB 1262 during the 2015 General Assembly session to adjudicate patient disputes or disagreements regarding denial of access to medications by insurance carriers or the PBMs with which the carriers contract. Commenters requested that the Regulation Committee of the Board of Pharmacy further review concerns with patient safety, medication access, and determine if registration or licensure of PBMs is warranted. A 2013 report of the National Association of Boards of Pharmacy which considered the issue of regulation of PBMs was provided by the Medical Society of Virginia for the Board's consideration. Following deliberation, the Board concluded that some of the concerns do not fall within the Board's jurisdiction, but that the issue should be referred to the Regulation Committee for a more thorough review.

The Regulation Committee of the Board of Pharmacy considered this matter on May 11, 2015. Public comments provided to the Committee addressed concerns with patient safety based on an inability to obtain prescribed drugs in a timely manner and an increasing number of drugs requiring prior authorizations or being classified as specialty drugs which require dispensing

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, David Brown, D.C., Director of the Department of Health Professions (DHP), and Caroline Juran, Executive Director of the Board of Pharmacy, recommended that Dr. Brown discuss with William A. Hazel Jr., MD, Secretary of Health and Human Resources, the possibility of forming a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human Resources Management. There is no state oversight for self-insured (Employee Retirement Income Security Act, aka ERISA) health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) has the authority to oversee the administration of benefits by fully-insured health plans but does not have authority to directly oversee the PBMs with which the health plans may contract to fulfill certain functions. Oversight of PBMs is indirect, through the contracting fully-insured health plan. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies but may not require it unless the health plan deems the drug a specialty drug which the health plan may require to be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to fully-insured health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, and a complaint system in place. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs as is the case with other subcontractors the health plan has contracted with to deliver health care benefits to beneficiaries, e.g., behavioral health, vision, and dental.

Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last

decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Health plans make decisions as to formulary management, plan design, and cost-sharing. The PBM administers the plan per the contract with the client. PBMs' clients include the federal government, state governments, large employers, and health plans. Common approaches in the industry for PBMs to mitigate the high costs of drugs include requiring prior authorizations of certain drugs, requiring certain drugs to be dispensed from a specialty pharmacy or mail order pharmacy, the development of pharmacy networks, disease management, and claims processing. In the 2013 National Association of Boards of Pharmacy *Report of the Task Force on the Regulation of Pharmacy Benefit Managers*, which updated and broadened information from the 1999 Task Force on Licensing of Pharmacy Benefit Managers, the following activities performed by a PBM were identified as activities which may encompass the practice of pharmacy: disease state management; disease compliance management; drug adherence management; drug interaction management; drug utilization management; formulary management; generic alternative program management; generic incentive program management; medical and/or drug data analysis; patient drug utilization review services; prior authorization services; provider profiling and outcomes assessment; refill reminder program management; therapy guidelines management; stop therapy protocol management; wellness management; maintenance of confidential patient information; and, direction or design of the clinical programs for a pharmacy or a group of pharmacies.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. The plan design determines which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug; and the specialty pharmacies may have a financial relationship with the PBMs or may be operated by an independent pharmacy, chain pharmacy or a Health System.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the health plan or the PBM, unless the patient is willing to pay the cash price. The purposes of prior authorization are decreasing overall healthcare costs as well as managing health and safety by ensuring the patient is receiving the least expensive, yet most effective drug therapy. Health plans determine which drugs require prior authorization, and this status can vary based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are often informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

“White bagging and brown bagging”

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient’s residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare “donut hole” faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management,

e.g., identifying prescribing errors and mitigating the significant increase in drug costs imposed by pharmaceutical manufacturers, but that process improvements for prior authorization are needed.

The Workgroup also identified the current model as a reactive prior authorization process and acknowledged that patients, prescribers, pharmacists, health plans, and PBMs would benefit from a more proactive process. Online resources for prescribers to determine drug coverage at the point of prescribing was briefly discussed, but challenges with time and accuracy of information create barriers to this solution. The National Adoption Scorecard for Electronic Prior Authorization from covermymeds® was reviewed and discussed. There was general consensus that the proactive process with electronic prior authorizations would significantly reduce the amount of time for all involved in handling prior authorizations and reduce the time delay in patients having access to the prescribed drugs. The Workgroup acknowledged that electronic prior authorizations cannot be utilized until electronic prescribing is commonplace. New York will be the first state to require all prescriptions to be electronically transmitted as of March 2016, and there is interest in monitoring the success of this requirement. In the interim, there was consensus that the Medical Society of Virginia, along with the Virginia Pharmacists Association, should meet with Virginia Health Plans and other key stakeholders with appropriate technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and expanding the use of e-prescribing by prescribers.

Credentialing process

Comment was received from several independent pharmacy owners, including the pharmacist who wrote Senator Warner, that the credentialing process of the health plans is overly burdensome, lacks standards regarding the process and frequency at which they occur, and impacts patient care by reducing the pharmacist's time available for patient care. The process often involves verification of state licensure, DEA registration, National Provider Identification number, valid Medicare participation, valid pharmacist-in-charge, liability coverage, review of any disciplinary action, and review of state and federal tax files. In response to allegations in the letter to Senator Warner that CVS Caremark discriminated against an independent pharmacy by requesting information from it that CVS Caremark did not request from chain pharmacies, a representative from CVS Caremark indicated it requests the same information from all pharmacies. There was discussion regarding why CVS Caremark needed a pharmacy floorplan, as this information is maintained confidentially by the Board of Pharmacy to reduce security risks. Presently, no uniform standards exist in State law regarding information which can be requested by a PBM during the credentialing and re-credentialing process. It was suggested that such standards could possibly be enacted through the current oversight structure of health plans. Monitoring of the PBMs for compliance of such standards and any enforcement action against the PBM would then be the responsibility of the health plan, since the current oversight model provides health plans with the responsibility for their PBM contracts.

PBM communication with patients

Comment was received from independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacy Association regarding concerns with PBMs calling patients of specific pharmacies to encourage them to use a different pharmacy. Those

representing health plans and PBMs acknowledged that patients may be notified via different methods to maximize health benefits and reduce costs. Whether it is appropriate for PBMs, or health plans to require PBMs to use their access to patient identification information for this purpose was called into question. Additionally, there was some concern that such notifications may be confusing to patients.

Filing complaints/Appeals Process

There was concern expressed by some Workgroup members that both patients and providers are generally unaware of who to contact or how to file a complaint regarding concerns with their drug coverage or access. Those members associated with health plans reported that patients receive this information in the insurance documents provided by the employer or health plan; however, it was suggested that perhaps this information should be more prominent or user-friendly. It was noted that the health plan contact information for patients who have any issues is already on their health plan benefit identification card. However, it was suggested that the card should also include the number of the appropriate regulatory entity for escalating a complaint when the patient does not feel the issue has been satisfactorily resolved by the health plan. Regarding what entity is appropriate for receiving complaints, there was some discussion that complaints should be filed with the employer, but there was concern that many employers may not know how to address such complaints. It was noted that current law within Title 38.2 of Virginia Code, along with BOI regulations, require fully-insured health plans to make available an internal appeals process, but that the timeframe for resolution within such appeal processes may vary among the health plans. The law also currently addresses an external review of adverse determinations rendered by health carriers and the qualifying conditions for such review. Furthermore, as a self-insured health plan, the insurer for state employers has an ombudsman to receive complaints; however, Virginia does not have a designated ombudsman for addressing concerns with fully-insured health plans. VDH OLC and the BOI investigate matters after identifying a pattern of complaints but do not generally investigate individual complaints.

Impact on rural communities

Independent pharmacy owners, the Virginia Pharmacists Association, and the National Community Pharmacists Association expressed concern that current PBM practices impact their ability to dispense prescriptions and are resulting in the closing of many independent pharmacies. One pharmacist indicated that four (4) pharmacies have closed recently in his rural area and should he be forced to close, patients would then have to drive 40 miles roundtrip to the nearest pharmacy. Because pharmacists are often the most accessible, if not the only, healthcare professional in rural settings, it was stated that healthcare questions may go unanswered, and compliance with optimal drug therapy may suffer. Independent pharmacies do not believe the current practices allow for a level playing field, as they feel PBMs are incentivized to drive business to the mail order and specialty pharmacies that have a financial relationship with the PBMs. During Workgroup discussions, those representing health plans and PBMs noted that other factors may also be impacting pharmacy care in rural settings such as current requirements of the Centers for Medicare and Medicaid Services (CMS), increased competition with chain pharmacies, and the willingness of other pharmacies to accept certain reimbursement rates. Additionally, they recommended that the viability of the business prior to closure should be taken into consideration, as some closures may result from the selling of a successful business.

Recent actions regarding additional oversight

An antitrust attorney commented that the Federal Trade Commission (FTC) is not adequately reviewing anticompetitive standards with current PBMs. He felt additional oversight of PBMs is warranted, because no one is currently looking after the patients' rights and that what the Workgroup is considering is very basic. Those representing health plans and PBMs indicated the FTC has repeatedly opined that PBMs operate in a competitive environment. There was also discussion of the passing of an Iowa law impacting PBMs and a federal court judge's decision that ERISA does not preempt states from regulating PBMs. The decision is currently under appeal. Those representing health plans and PBMs noted that there have been other cases that uphold the ERISA preemption, and that this case is not in the Virginia circuit. During public comment, it was stated that many states are taking reasonable reform action of PBMs and that recently 26 transparency bills and 34 audit reform bills were introduced across the states. Those representing health plans and PBMs noted that the Virginia General Assembly has already addressed and enacted bills on these subjects. The public commenter also stated that simply licensing PBMs does not equal oversight and that enforcement powers are necessary.

The National Association of Boards of Pharmacy convened a task force in 2014 to review oversight of PBMs. It identified several tasks that may constitute the practice of pharmacy for which licensure and Board of Pharmacy oversight is appropriate. Presently, the Mississippi Board of Pharmacy is the only board of pharmacy to directly oversee PBMs. Based on Virginia's current model, there was discussion that it may be more appropriate to place potential oversight with the VDH OLC. While VDH OLC does not have a formal position on this matter, it is willing to assume this oversight if resources are provided.

Establishment of drug formularies

Title 38.2 of the Code of Virginia authorizes a health plan to apply a formulary to the prescription drug benefits if the formulary is developed, reviewed at least annually, and updated as necessary in consultation with and with the approval of a pharmacy and therapeutics (P&T) committee consisting of practicing licensed pharmacists, physicians, and other licensed health care providers. While it was stated a PBM may elect to use an independent P&T committee for the clinical review of drugs, there is no express requirement in law for an independent review. The law does not address the role of PBMs in the establishment of drug formularies; however, during discussions it was stated that PBMs may negotiate costs with drug manufacturers and may offer drug formulary recommendations to health plans who determine the drug formularies. The PBMs and health plans stated that ultimately the employer determines what drugs will be covered. It was noted that one pharmacy employer commented that he has never been asked to provide input into the process.

Drug waste

Because mail order pharmacies typically dispense 90-day supplies, a concern was expressed by the National Community Pharmacists Association that requiring or incentivizing patients to use mail order pharmacies may result in wasted drugs if the patient does not complete the entire course of medication. During discussion it was noted that sources for drug waste other than mail order pharmacies may exist and that this issue should be discussed more broadly to include discussions on the appropriateness of current benefit design and if the Boards of Pharmacy or Medicine should consider restrictions on prescribing or dispensing.

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
 - a. license PBMs;
 - b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
 - c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
 - d. receive complaints against PBMs and take enforcement action when warranted.

Agenda Topic: Amend Statewide Protocols

Background: The Board has indicated in the past that statewide protocols should be reviewed annually to ensure consistency with standard of care. Suggested edits to certain statewide protocols are offered for board consideration. Additional relevant information is provided regarding vaccine recommendations.

Included in Agenda Packet:

Draft amendments for the following statewide protocols:

- Vaccine 18+
 - Relevant laws: §§ 54.1-3303.1 and 54.1-3408
 - 2025-2026 COVID-19 Vaccine Recommendations/Indications as of 9/8/2025 prepared by staff
 - FDA Licensed COVID-19 Vaccines 2025-2026 with Approved Indications
 - Key Recommendations from the American College of Obstetricians and Gynecologists
 - 2025-2026 Recommendation from the American Academy of Family Physicians (AAFP)
 - HHS Press Release regarding ACIP Recommendations (as of preparation of this agenda, CDC had not released its decision regarding ACIP's recommendations)
 - ACIP Shared Clinical Decision-Making Recommendations, 1/7/2025
 - CDC Underlying Conditions and Higher Risk for Severe COVID-19, 2/6/2025
 - Virginia Health Commissioner Standing Order for COVID-19 Vaccines for 18+
- Vaccine 3-17
 - SB 672 (2022 General Assembly Session)
 - Excerpt from Federal Register regarding extension of PREP Act
- Routine Hormonal Contraceptive
- Naloxone
- Testing and Initiation Treatment for Influenza
- TB One-Step
- TB Two-Step
- Epinephrine
- Group A Strep

Action Needed: Motion to amend statewide protocols as presented or amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older

~~Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC), a~~ A pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines ~~, including vaccines consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention ("CDC") and for COVID-19 vaccines,~~ to persons 18 years of age or older. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, current recommendations for a COVID-19 vaccines from the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

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

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine, excluding the COVID-19 vaccine, is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule (includes 18 years of age) or the Adult Immunization Schedule (includes 19 years

~~of age and older)~~ published by the CDC ~~inclusive of additional information for COVID-19 vaccination;~~

- ~~• An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC;~~
- ~~• An individual, 18 years of age or older, seeking the updated COVID-19 vaccine or and booster¹; or,~~
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for vaccine~~s~~ under this protocol:

- An individual less than 18 years of age;
- ~~• An individual for whom a vaccine, except for a COVID-19 vaccine, is not recommended by the CDC such as based on the patient's medical condition(s);~~
- ~~• An individual for whom a COVID-19 vaccine is contraindicated such as a history of a severe allergic reaction, e.g., anaphylaxis, after a previous dose or to a component of the COVID-19 vaccine; or~~
- An individual who has received all CDC recommended doses ~~or COVID-19 vaccines as recommended by the American Academy of Family Physicians or the American College of Obstetricians and Gynecologists~~ for their age, medical condition or other indicators.

COUNSELING

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

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER

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

¹ Per the American Academy of Family Physicians, all adults 18 years and older should receive a COVID-19 vaccine. It is especially important if the patient is 65 years or older, at increased risk for severe COVID-19 infection, and has never received a COVID-19 vaccine. Per the American College of Obstetricians and Gynecologists, it is recommended that patients receive an updated COVID-19 vaccine, or "booster," at any point during pregnancy, when planning to become pregnant, in the postpartum period, or when lactating.

Adopted: 9/24/2021
Revised: ~~9/26/2023~~ 9/30/2025
Effective: ~~9/26/2023~~

DRAFT

Relevant Information:

From Code of Virginia as of July 1, 2025

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

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

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § [54.1-3466](#), as may be necessary to administer such naloxone or other opioid antagonist;
2. Epinephrine;
3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
4. Prenatal vitamins for which a prescription is required;
5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;
6. Drugs as defined in § [54.1-3401](#), devices as defined in § [54.1-3401](#), controlled paraphernalia as defined in § [54.1-3466](#), and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;
7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19;
8. Tuberculin purified protein derivative for tuberculosis testing;
9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;
10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ [54.1-3400](#) et seq.), together with providing appropriate patient counseling;
11. Controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988: group A

Streptococcus bacteria infection, influenza virus infection, COVID-19 virus infection, and urinary tract infection; and

12. Tests for COVID-19 and other coronaviruses.

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

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

2. (Contingent Effective Date) Tests for COVID-19 and other coronaviruses.

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

D. A pharmacist who administers a vaccination pursuant to subdivisions A 7 and B 1 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § [32.1-46.01](#).

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

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

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

§ 54.1-3408. Professional use by practitioners.

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.

2025-2026 COVID-19 Vaccine Recommendations/Indications as of 9/23/2025

	American Academy of Pediatrics (AAP)	American College of Obstetricians and Gynecologists (ACOG)	American Academy of Family Physicians (AAFP)	US Food and Drug Administration (FDA)	Advisory Committee on Immunization Practices Recommendation (ACIP)	Centers for Disease Control and Prevention (CDC)
Infants and Children	6-23 months and children 2-17 years with risk factors or if the parent desires the vaccine		AAFP aligns with AAP	6 months – 17 years with at least one underlying condition	6 months and older, shared clinical decision-making; risk benefit for those under 65 is most favorable for those at increased risk for severe COVID-19 and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.	No decision on ACIP's recommendation as of 9/23/25
Pregnant/lactating women		All pregnant and lactating women at any point in their pregnancy	AAFP aligns with ACOG		As of 2/6/2025, CDC lists pregnancy and recent pregnancy as higher-risk for severe COVID-19.	No decision on ACIP's recommendation as of 9/23/25
Adults 18+			all adults 18 + should receive a COVID-19 vaccine	18-64 years with at least one underlying condition 65 years of age and up	6 months and older, shared clinical decision-making; risk benefit for those under 65 is most favorable for those at increased risk for severe COVID-19 and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.	No decision on ACIP's recommendation as of 9/23/25

FDA Licensed COVID-19 Vaccines 2025-2026 with Approved Indications

	Tradename	Indication
Moderna	SPIKEVAX	• 65 years and older • 6 months-64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
	MNEXSPIKE	• 65 years and older • 12-64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Pfizer	COMIRNATY	• 65 years and older • 5-64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.
Novavax	NUVAXOVID	• 65 years and older • 12-64 years with at least one underlying condition that puts them at high risk for severe outcomes from COVID-19.

Below copied from <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care>
(Emphasis added)

Key Recommendations

- **The American College of Obstetricians and Gynecologists continues to recommend that all pregnant and lactating individuals receive an updated COVID-19 vaccine or “booster.”** All clinicians should provide a strong recommendation for updated COVID-19 vaccination to their pregnant and lactating patients.
- Pregnant women have historically been at an increased risk of severe disease, adverse pregnancy outcomes, and maternal death from COVID-19 infections. All currently available COVID-19 vaccines keep up with new coronavirus strains and remain effective at reducing rates of medically attended COVID-19 illness encounters resulting in emergency room and urgent care visits, hospitalizations, and critical illness for adults 18 years or older, with protection lasting for that season ([Link-Gelles 2025](#)). Updated COVID-19 vaccines are particularly effective at reducing morbidity from COVID-19 complications in pregnant patients and their infants (measured by emergency department/urgent care encounters) ([Ciesla 2024](#)).
- Infants aged less than 6 months are at increased risk for severe COVID-19 disease but are not yet eligible for COVID-19 vaccination, and they depend on transplacental transfer of maternal antibodies for protection. They continue to be hospitalized for COVID-19 at higher rates than all age groups except adults 75 years and older ([Havers 2024](#)). COVID-19 vaccination in pregnancy reduces the rate of symptomatic and severe COVID-19 resulting in hospitalization in the infant in the first 6 months of life ([Halasa 2022 MMWR](#); [Cardemil 2024](#)). During the 2023–2024 respiratory virus season, mothers of less than 5% of infants hospitalized for COVID-19 were vaccinated during pregnancy ([Havers 2024](#)).
- COVID-19 vaccine safety during pregnancy has been well established. There is no evidence of increased risk of negative maternal, pregnancy, or infant outcomes associated with vaccination ([Ciapponi 2024](#)).
- **Vaccination may occur in any trimester, and emphasis should be on vaccine receipt at the earliest opportunity to maximize maternal and fetal health.**
- COVID-19 vaccines may be administered simultaneously with other vaccines. This includes vaccines routinely recommended during pregnancy, such as influenza, respiratory syncytial virus (RSV), and tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap).
- For patients who do not receive any COVID-19 vaccine, the discussion should be documented in the patient’s medical record. During subsequent office visits, obstetrician–gynecologists should address ongoing questions and concerns and offer vaccination again.

- Obstetrician–gynecologists and other health care practitioners should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well.
- Obstetrician–gynecologists and other health care practitioners are at high risk for exposure to COVID-19 and should lead by example by being vaccinated and encouraging eligible patients to be vaccinated as well.

COVID-19

- **All adults 18 years and older should receive a COVID-19 vaccine.**

It is especially important to get a COVID-19 vaccine if you are:

- 65 years and older;
- At increased risk for severe COVID-19 infection; and
- Have never received a COVID-19 vaccine.

- **All children ages 6-23 months should be vaccinated against COVID-19** and use a risk-based single dose approach for children and teens 2-18 years.
- **The AAFP recommends COVID-19 vaccination during pregnancy during any trimester and including during lactation.**





U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FOR IMMEDIATE RELEASE

September 19, 2025

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ACIP Recommends COVID-19 Immunization Based on Individual Decision-making

ATLANTA — SEPTEMBER 19, 2025 — The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) today unanimously recommended that vaccination for COVID-19 be determined by individual decision-making.

ACIP's recommendation applies to all individuals six months and older. It includes an emphasis that the risk-benefit of vaccination in individuals under age 65 is most favorable for those who are at an increased risk for severe COVID-19 and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.

Individual decision-making is referred to on the CDC's adult and child immunization schedules as vaccination based on shared clinical decision-making, which references providers including physicians, nurses, and pharmacists. It allows for immunization coverage through all payment mechanisms including entitlement programs such as the Vaccines for Children Program, Children's Health Insurance Program, Medicaid, and Medicare, as well as insurance plans through the federal Health Insurance Marketplace.

"I commend the committee for bringing overdue scientific debate on vaccination to the American people," said Deputy Secretary of Health and Human Services and CDC Acting Director Jim O'Neill. A recommendation from ACIP becomes part of the CDC immunization schedule if it is adopted by the CDC director.

In addition to its recommendation for the CDC immunization schedules, ACIP voted to recommend that all pregnant women be tested for Hepatitis B. This test is covered across all insurance programs. The vote encourages providers and health systems to increase the rates of testing in pregnancy to assure that women with Hepatitis B and their newborns can be properly cared for to reduce transmission of the virus from the mother to the child.

The Committee also approved a resolution for the provision of immunization from measles, mumps, rubella, and varicella (chickenpox) through the Vaccines for Children Program. This vote creates consistency in coverage for all vaccine payment mechanisms, including other entitlement programs, following ACIP's recommendation that toddlers through age three be immunized for varicella by standalone vaccination administered at the same time as the MMR vaccine, rather than the combination measles, mumps, rubella, and varicella (MMRV) vaccine. The CDC Immunization Safety Office's September 18 presentation to ACIP showed that healthy 12–23 months old toddlers have increased risk of febrile seizure seven to 10 days after MMRV vaccination compared to those given separate immunization for

varicella and measles, mumps, and rubella (MMR). The MMRV vaccine doubles the risk of febrile seizures without conferring additional protection from varicella compared to standalone vaccination.

###

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ACIP Shared Clinical Decision-Making Recommendations



For Everyone
JANUARY 7, 2025

AT A GLANCE

- Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.
- These frequently asked questions provide clarity on the ACIP's shared clinical decision-making recommendations, guidance, and implementation considerations.

Introduction

These frequently asked questions (FAQs) address the Advisory Committee on Immunization Practices' (ACIP) shared clinical decision-making recommendations and guidance and implementation considerations.

Frequently Asked Questions

[^ Collapse All](#)

What are ACIP's current shared clinical decision-making recommendations? ^

ACIP has five recommendations for vaccination based on shared clinical decision-making and these are shown in the [adult and child/adolescent the immunization schedules](#).

- Meningococcal B (MenB) vaccination for adolescents and young adults aged 16–23 years
- Hepatitis B (HepB) vaccination for adults aged 60 years and older with diabetes mellitus
- Human papillomavirus (HPV) vaccination for adults aged 27–45 years
- Pneumococcal conjugate vaccination (PCV20 or PCV21) for adults aged 65 years and older who have completed the recommended vaccine series with both PCV13 (at any age) and PPSV23 (which was administered at age ≥65 years)
- Additional doses of COVID-19 vaccination for people who are moderately or severely immunocompromised

How do shared clinical decision-making recommendations differ from routine, catch-up, and risk-based immunization recommendations? ^

Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making recommendations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian.

The key distinction between routine, catch-up, and risk-based recommendations and shared clinical decision-making recommendations is the default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the default decision should be to vaccinate the patient based on age group or other indication, unless contraindicated. For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from

vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered. There is not a prescribed set of considerations or decision points in the decision-making process.

When does ACIP make shared clinical decision-making recommendations?

Generally, ACIP makes shared clinical decision-making recommendations when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts.

For example, in June 2019, ACIP recommended shared clinical decision-making for HPV vaccination of adults aged 27–45 years. HPV acquisition generally occurs soon after first sexual activity. Vaccine effectiveness is lower in older age groups because of prior infections and lower risk of exposure (for example, among persons who are in a long-term, mutually monogamous sexual partnership). ACIP recommended shared clinical decision-making rather than catch-up vaccination because most adults in this age group would have no or minimal benefits from vaccination. However, some individuals who are not already immune to HPV through vaccination or natural infection (e.g., a previously unvaccinated person who has never had sex) and who might be at risk for acquiring a new HPV infection in the future (e.g., plans to have sex with a new partner in the future) might benefit from vaccination.

Who is considered a health care provider with regard to shared clinical decision-making recommendations?

In this context, CDC defines a health care provider as anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists.

Which patients should providers discuss shared clinical decision-making recommendations with?

It's up to the provider. Some health care providers may choose to discuss immunizations recommended for shared clinical decision-making with all or most of their patients who could receive it, while some providers may be more selective when discussing these immunizations with their patients. Health care providers should also be receptive to patient-initiated conversations about these immunizations.

What resources are available for providers who want to implement these recommendations?

ACIP and CDC provide resources to help providers implement these recommendations.

ACIP recommendations

Health care providers can find information on ACIP's recommendations on the [ACIP Vaccine Recommendations and Guidelines](#) page.

For every ACIP recommendation, CDC publishes a policy note in the Morbidity and Mortality Weekly Report (MMWR), which provides background and considerations on each recommendation.

CDC resources for shared clinical decision-making

CDC will also develop vaccine-specific guidance to help clinicians understand and apply shared clinical decision-making recommendations.

[Meningococcal B Vaccination](#) 

[Hepatitis B Vaccination](#)

[HPV Vaccination for Adults Aged 27-45 Years](#) 

[Pneumococcal Vaccination for Adults 65 Years or Older](#) 

[Additional Doses of COVID-19 Vaccination for People who are Moderately or Severely Immunocompromised](#)

Are shared clinical decision-making recommendations covered by private insurers?

Under the Affordable Care Act and its implementing regulations, ACIP recommendations that have been adopted by CDC "with respect to the individual involved" and are "listed on the Immunization Schedules of the Centers for Disease Control and Prevention" generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without

imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible). [\[A\]](#) This coverage requirement includes shared clinical decision-making recommendations when they have been adopted by CDC and are listed on the immunization schedules.

SOURCES

CONTENT SOURCE:

[National Center for Immunization and Respiratory Diseases \(NCIRD\)](#)

FOOTNOTES

- A. Section 2713(a)(2) of the Public Health Service Act, as added by section 1001 of the Affordable Care Act, implemented at 26 CFR 54.9815-2713(a)(1)(ii), 29 CFR 2590.715-2713(a)(1)(ii), and 45 CFR 147.130(a)(1)(ii). This requirement does not apply to grandfathered health plan coverage under section 1251 of the Affordable Care Act, implemented at 26 CFR 54.9815-1251, 29 CFR 2590.715-1272, and 45 CFR 147.140.



Underlying Conditions and the Higher Risk for Severe COVID-19

Health Care Providers
FEBRUARY 6, 2025

AT A GLANCE

- An updated list of high-risk underlying conditions, along with their associated evidence, is provided below. The conditions are grouped by the level of evidence, with the highest level shown in the top section.
- The list of underlying medical conditions is not exhaustive and will be updated as the science evolves.
- This list should not be used to exclude people with underlying conditions from recommended measures for prevention or treatment of COVID-19.

What you need to know

This web page provides an evidence-based resource for healthcare professionals caring for patients with underlying medical conditions who are at higher risk of experiencing severe outcomes of COVID-19. Severe outcomes of COVID-19 are defined as hospitalization, admission to the intensive care unit (ICU), intubation or mechanical ventilation, or death.

Information for the General Public

Find a list of underlying medical conditions that might cause severe COVID-19 and information on ways to prevent illness.

[People with Certain Medical Conditions and COVID-19](#)

This page summarizes data from published reports, scientific articles in press, unreviewed pre-prints, and internal data that were included in literature reviews conducted by subject matter experts. Evidence used to inform the list of underlying conditions was determined by CDC reviewers based on available literature about COVID-19 at time of review. The information reflects evidence regarding underlying medical conditions and is intended to help healthcare professionals make informed decisions about patient care and to increase the awareness of risk among their patients.

The methods used to assess the conditions have changed during the pandemic as the amount of literature and types of studies increased. For instance, preliminary versions of this list focused on providing the latest information based on descriptive data. As the literature grew, CDC investigators categorized the literature by study design.

Since May 2021, the process has been updated to include a CDC-led review process that uses rigorous systematic review methods. To learn more about the process of CDC's systematic reviews, see [CDC systematic review process](#).

Background

Age is the strongest risk factor for severe COVID-19 outcomes. Patients with one or multiple certain underlying medical conditions are also at higher risk.⁽¹⁻³⁾

Additionally, [being unvaccinated](#) or not being up to date on [COVID-19 vaccinations](#) also increases the risk of severe COVID-19 outcomes.

Providers should consider the patient's age, presence of underlying medical conditions and other risk factors, and vaccination status in determining the risk of severe COVID-19-associated outcomes for any patient.

Demographic Factors

Studies have shown that COVID-19 does not affect all population groups equally. Three important factors are age, race, and ethnicity.

Age

Age remains the strongest risk factor for severe COVID-19 outcomes, with risk of severe outcomes increasing markedly with increasing age. Based on data from the National Vital Statistics System (NVSS) at NCHS ([Risk for COVID-19 Infection, Hospitalization, and Death By Age Group](#)), compared with ages 18–29 years, the risk of death is 25 times higher in those ages 50–64 years, 60 times higher in those ages 65–74 years, 140 times higher in those ages 75–84 years, and 340 times higher in those ages 85+ years. Notably, these data include all deaths in the United States that occurred throughout the pandemic, from February 2020 to July 1, 2022, including deaths among unvaccinated individuals.

Risk of severe outcomes is increased in people of all ages with certain underlying medical conditions and in people who are 50 years and older, with risk increasing substantially at ages >65 years.^{4,5} Residents of long-term care facilities are also at increased risk, making up less than 1% of the U.S. population but accounting for more than 35% of all COVID-19 deaths.^{6–10}

Race and Ethnicity

The COVID-19 pandemic has highlighted racial, ethnic, and socioeconomic disparities in COVID-19 illnesses, hospitalizations, and deaths.^{11–13} Some racial and ethnic minority groups are also more likely to face multiple barriers to accessing health care including lack of insurance, transportation, child care, or ability to take time off from work.

Studies have identified racial and ethnic differences in at-home COVID-19 test use, vaccination coverage, and access to outpatient therapeutics.^{14–16} Data has shown that compared to non-Hispanic White people, people from racial and ethnic minority groups are more likely to be infected with SARS-CoV-2 (the virus that causes COVID-19). Once infected, people from racial and ethnic minority groups are more likely to be hospitalized, be admitted to the ICU, and die from COVID-19 at younger ages.¹⁷

We are still learning about how the environments where [people live, learn, and work](#) can influence the risk for infection and severe COVID-19 outcomes.

Summary of Conditions with Evidence

Evidence used to inform the list of underlying medical conditions that increase a person's risk of severe illness from COVID-19 is presented in alphabetical order by study design section. Conditions are categorized as higher risk, suggestive higher risk, and mixed evidence.

Higher Risk (conclusive)

Higher risk is defined as an underlying medical condition or risk factor that has a published meta-analysis or systematic review or underwent the [CDC systematic review process](#). The meta-analysis or systematic review demonstrates a conclusive increase in risk for at least one severe COVID-19 outcome.

Notice

- * Indicates presence of evidence for pregnant and non-pregnant women
- ‡ Underlying conditions for which there is evidence in pediatric patients
- ^ Risk may be further increased for people receiving dialysis

Condition	Evidence of Impact on COVID-19 Severity [Reference number]
Asthma	CDC Systematic Review [K]
Cancer Hematologic Malignancies	CDC Systematic Review [O] Meta-Analysis/ Systematic Review ^{18–22} Cohort Study ^{23–25} Case Series ^{26–28} Case Control Study ²⁹
Cerebrovascular disease	Meta-Analysis ^{30–33} Synthesis of Evidence ³⁴ Cohort Study ^{35–37}
Chronic kidney disease* People receiving dialysis^{38,39} ^	Meta-Analysis ^{33,40} Cohort Studies ^{36,41–62, 63*} Case Series ^{64–66}

Chronic lung diseases limited to:

- Bronchiectasis
- COPD (Chronic obstructive pulmonary disease)
- Interstitial lung disease
- Pulmonary embolism
- Pulmonary hypertension
- CDC Systematic Review [A]
- CDC Systematic Review [L]
- CDC Systematic Review [D]
- CDC Systematic Review [G]
- CDC Systematic Review [G]

Chronic liver diseases limited to:

- Cirrhosis
- Non-alcoholic fatty liver disease
- Alcoholic liver disease
- Autoimmune hepatitis

CDC Systematic Review [B] ²¹¹

Cystic fibrosis

CDC Systematic Review [M]

Diabetes mellitus, type 1

Meta-Analysis ⁶⁷
Case Series ⁶⁵
Cohort Study ^{35,68-73}

Diabetes mellitus, type 2*

Meta-Analysis ⁷⁴
Systematic Review ^{75*}
Gestational Diabetes Systematic Review ^{76*}
Case Series ⁶⁵
Longitudinal Study ⁷⁷
Cohort Study ^{67,71,77-82}

Disabilities‡, including Down syndrome

CDC Systematic Review [C]

For the list of all conditions that were part of the review, see the module below

Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies)

Meta-Analysis ⁸³⁻⁸⁵
Cohort Study ^{35,36}

HIV (Human immunodeficiency virus)

Meta-Analysis/ Systematic Review ⁸⁶
Cohort Study ^{54,87-89}
Case Series ⁹⁰⁻⁹²

Mental health conditions limited to:

- Mood disorders, including depression
- Schizophrenia spectrum disorders

Meta-Analysis/ Systematic Review ^{93,94}

Neurologic conditions limited to dementia‡ and Parkinson's Disease

Meta-Analysis/ Systematic Review ^{95-98, 208}
Cohort Study ³⁶

Obesity (BMI ≥ 30 kg/m² or $\geq 95^{\text{th}}$ percentile in children)

Meta-Analysis ¹⁰¹⁻¹⁰³
Systematic Review ^{75*}
Cohort ^{46,104-112,63,113-116*}

Physical inactivity

CDC Systematic Review [E]

Pregnancy and recent pregnancy	Meta-Analysis/ Systematic Review ^{75,117} Case Control ^{118,119} Case Series ¹²⁰⁻¹²² Cohort Study ¹²³⁻¹²⁶
Primary immunodeficiencies	CDC Systematic Review [F]
Smoking, current and former	Meta-Analysis ^{83,127,128-135}
Solid organ or blood stem cell transplantation	Meta-Analysis ¹⁰⁸ Case Series ¹³⁶⁻¹⁴⁷ Cohort ¹⁴⁸⁻¹⁵¹
Tuberculosis	CDC Systematic Review [H]
Use of corticosteroids or other immunosuppressive medications	Meta-Analysis/ Systematic Review ¹⁵² Cohort Study ¹⁵³ Cross-Sectional ¹⁵⁴ Case Series ¹⁵⁵⁻¹⁵⁷

Complete List of Disabilities from CDC's Systematic Review Process

- Attention-deficit/hyperactivity disorder (ADHD)
- Autism
- Cerebral palsy
- Charcot foot
- Chromosomal disorders
- Chromosome 17 and 19 deletion
- Chromosome 18q deletion
- Cognitive impairment
- Congenital hydrocephalus
- Congenital malformations
- Deafness/hearing loss
- Disability indicated by Barthel Index
- Down syndrome
- Fahr's syndrome
- Fragile X syndrome
- Gaucher disease
- Hand and foot disorders
- Learning disabilities
- Leber's hereditary optic neuropathy (LHON) or Autosomal dominant optic atrophy (ADOA)
- Leigh syndrome
- Limitations with self-care or activities of daily living
- Maternal inherited diabetes and deafness (MIDD)
- Mitochondrial encephalopathy, lactic acidosis, and stroke-like episodes (MELAS) and risk markers
- Mobility disability
- Movement disorders

- Multiple disability (referred to in research papers as "bedridden disability")
- Multisystem disease
- Myoclonic epilepsy with ragged red fibers (MERRF)
- Myotonic dystrophy
- Neurodevelopmental disorders
- Neuromuscular disorders
- Neuromyelitis optica spectrum disorder (NMOSD)
- Neuropathy, ataxia, and retinitis pigmentosa (NARP)
- Perinatal spastic hemiparesis
- Primary mitochondrial myopathy (PMM)
- Progressive supranuclear palsy
- Senior-Loken syndrome
- Severe and complex disability (referred to in research papers as "polyhandicap disability")
- Spina bifida and other nervous system anomalies
- Spinal cord injury
- Tourette syndrome
- Traumatic brain injury
- Visual impairment/blindness
- Wheelchair use

Suggestive Higher Risk

Suggestive higher risk is defined as an underlying medical condition or risk factor that did not have a published meta-analysis or systematic review or did not undergo the [CDC systematic review process](#). The evidence is supported by mostly cohort, case-control, or cross-sectional studies. (Systematic reviews are available for some conditions for children with underlying conditions.)

Condition	Evidence of Impact on COVID-19 Severity [Reference number]
Children with certain underlying conditions Read More: Information for Pediatric Healthcare Providers	Systematic Review ^{158,159} Cross-Sectional Study ^{99,160,161} Cohort Study ^{99,100,162-169} Case Series ^{170,171}
Epilepsy	Cohort Study ²⁰⁹
Hemophilia	Cohort Study ²¹⁰
Overweight (BMI ≥25 kg/m ² but <30 kg/m ²)	Cohort Study ¹¹¹ Case Series ¹¹⁰
Sickle cell disease	Cohort ¹⁷⁰⁻¹⁷³ Case Series ^{170,173-188}
Substance use disorders	Case-Control Study ¹⁸⁹⁻¹⁹¹ Cohort Study ^{192,193}

Mixed Evidence (inconclusive: no conclusions can be drawn from the evidence)

Mixed evidence is defined as an underlying medical condition or risk factor that has a published meta-analysis or systematic review or underwent the [CDC systematic review process](#). The meta-analysis or systematic review is inconclusive, either because the aggregated data on

the association between an underlying condition and severe COVID-19 outcomes are inconsistent in direction or there are insufficient (or limited) data on the association between an underlying condition and severe COVID-19 outcomes.

- Limited: The evidence consists of one study, or several small studies with no comparison group, limiting the conclusions that can be drawn.
- Inconsistent: The evidence suggests no clear direction of association, meaning no firm conclusions can be drawn.

Notice

- * Indicates presence of evidence for pregnant and non-pregnant women
- ‡ Underlying conditions for which there is evidence in pediatric patients
- ^ Risk may be further increased for people receiving dialysis

Condition	Evidence of Impact on COVID-19 Severity [Reference number]
Alpha 1 antitrypsin deficiency	Limited: CDC Systematic Review [I]
Bronchopulmonary dysplasia	Limited: CDC Systematic Review [J]
Hepatitis B	Inconsistent: CDC Systematic Review [B]
Hepatitis C	Limited: CDC Systematic Review [B]
Hypertension*	Inconsistent Meta-Analysis ^{83,194-197} Systematic Review ^{198, 75,*} Cohort Study ^{35,36,41,199-205} Case Series ²⁰⁶
Thalassemia	Limited: CDC Systematic Review [N]

Actions Healthcare Professionals Can Take

- Recommend vaccination with approved and authorized COVID-19 vaccines (updated 2024-2025 COVID-19 vaccine), which are safe and effective. Check out the [Interim Clinical Considerations for Use of COVID-19 Vaccines](#) as well as [Stay Up to Date with Your Vaccines](#) and [locations for COVID-19 vaccination for patients](#) for more information.
- Prescribe antivirals, which have been shown to significantly decrease the risk of hospitalization and death when treating patients with mild or moderate illness and risk factors for severe illness. Outcomes are improved if therapeutics are started within the first 5-7 days of symptom onset.
- Consider Pemivibart (Pemgarda™), a monoclonal antibody for COVID-19 [pre-exposure prophylaxis](#) in people who are moderately or severely immunocompromised and unlikely to mount an adequate immune response to COVID-19 vaccination and who meet the [FDA-authorized conditions for use](#). Pemivibart is an IV-infusion monoclonal antibody that is authorized for pre-exposure prevention of COVID-19 for individuals (12 years of age and older weighing at least 40 kg). Pemivibart may provide another layer of protection against COVID-19 in addition to vaccination and can be given at least 2 weeks after receiving a COVID-19 vaccine. Healthcare providers should consult the [Pemivibart EUA Fact Sheet](#) and [EUA Frequently Asked Questions](#) for the FDA-authorized conditions under which Pemivibart may be used. CDC is monitoring variants and how commonly they occur to understand if they might affect how well Pemivibart works. [The FDA will provide additional updates](#) to the EUA materials, as appropriate, if new information emerges. This is the only preventive option available for COVID-19 for the immunocompromised community, as described above, at the present time.
- Remind older patients and those with underlying medical conditions that [wearing a mask is an additional prevention strategy](#) they can choose to further protect themselves.
- Encourage patients to keep appointments for routine care and adhere to treatment regimens for their medical conditions.
- Consider use of telehealth when appropriate.
- Check out [additional information for your patients](#).

Considerations for Patients Within Racial and Ethnic Minority Groups

- Ask patients about their concerns about vaccines and therapy. Consider using an evidence-based and culturally sensitive approach, such as [motivational interviewing](#). Try to provide trusted sources of information and other resources.
- Encourage nucleic acid amplification tests (NAATs), including PCR tests, as well as early treatment for patients who are eligible.
- Facilitate access to culturally and linguistically appropriate resources.
- Reduce barriers to accessing current outpatient treatments.

CDC strongly encourages healthcare professionals, patients and their advocates, and health system administrators to regularly consult the [Infectious Diseases Society of America \(IDSA\) COVID-19 Treatment Guidelines](#).

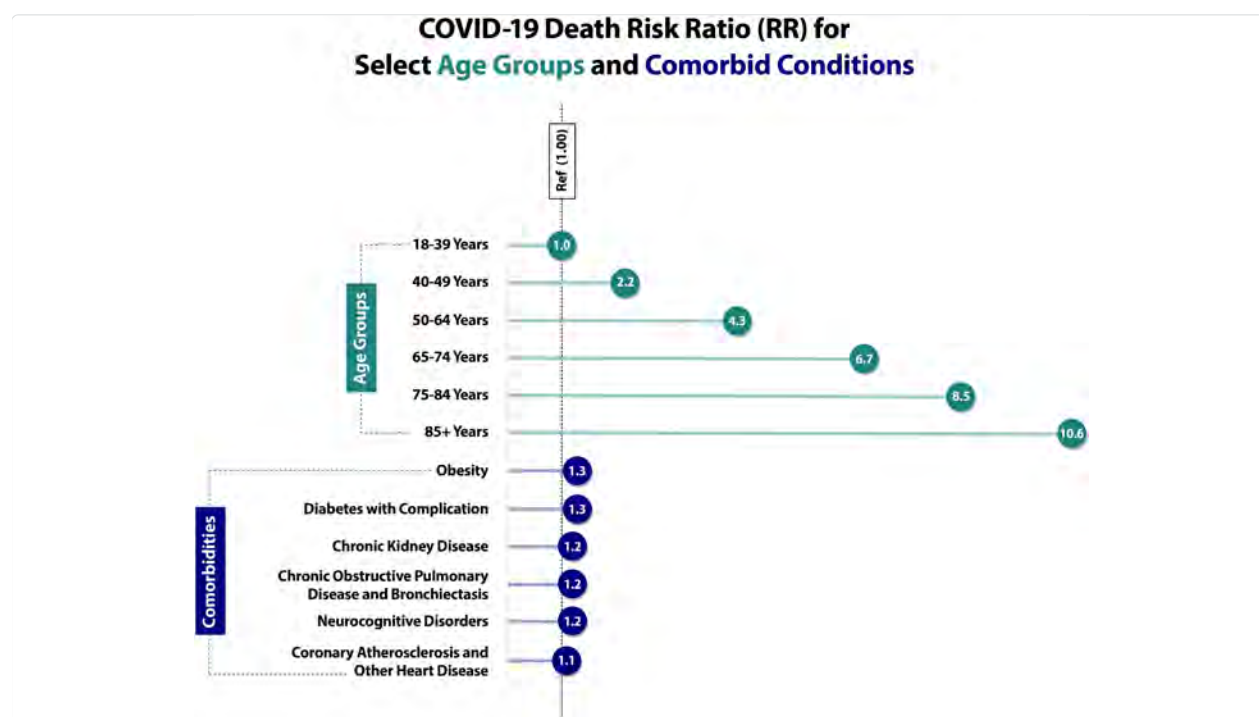
Key Findings from One Large Cross-Sectional Study

Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021

This [study](#) used data from the Premier Healthcare Database, which represents approximately 20% of all inpatient admissions in the United States since 2000. This cross-sectional study of 540,667 adults hospitalized with COVID-19 included both inpatients and hospital-based outpatients with laboratory-diagnosed COVID-19 from March 1, 2020, through March 31, 2021. The database included reports from 592 acute care hospitals in the United States. The study was designed to examine risk factors associated with severe outcomes of COVID-19 including admission to an ICU or stepdown unit, invasive mechanical ventilation, and death.

Main Findings:

- Certain underlying medical conditions were associated with an increased risk for severe COVID-19 illness in adults.
- Having multiple conditions was also associated with severe COVID-19 illness.
- Obesity, diabetes with complications, and anxiety and fear-related disorders had the strongest association with death.
- The number of frequent underlying medical conditions (present in $\geq 10.0\%$ of patients) increased with age.²⁰⁷

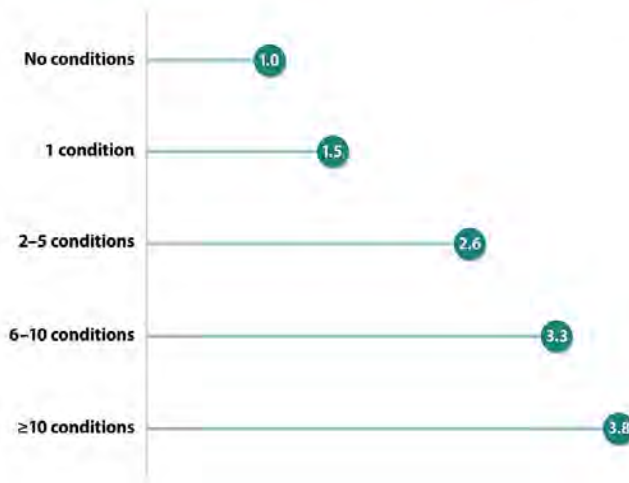


COVID-19 Death Risk Ratio (RR) for Select Age Groups and Comorbid Conditions.

Adapted from Sources:

- Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. To learn more, visit the *Preventing Chronic Disease* article: https://www.cdc.gov/pcd/issues/2021/21_0123.htm
- Pennington AF, Kompaniyets L, Summers AD, Danielson ML, Goodman AB, Chevinsky JR, Preston LE, Schieber LZ, Namulanda G, Courtney J, Strosnider HM, Boehmer TB, Mac Kenzie WR, Baggs J, Gundlapalli AV, Risk of Clinical Severity by Age and Race/Ethnicity Among Adults Hospitalized for COVID-19—United States, March–September 2020, *Open Forum Infectious Diseases*, Volume 8, Issue 2, February 2021. To learn more, visit: <https://doi.org/10.1093/ofid/ofaa638>

COVID-19 Death Risk Ratio (RR) Increases as the Number of Comorbid Conditions Increases



Death risk ratio (RR) increases as the number of underlying medical conditions increases among adults hospitalized with COVID-19.

Source: Kompaniyets L, Pennington AF, Goodman AB, Rosenblum HG, Belay B, Ko JY, et al. Underlying Medical Conditions and Severe Illness Among 540,667 Adults Hospitalized With COVID-19, March 2020–March 2021. To learn more, visit the *Preventing Chronic Disease* article: https://www.cdc.gov/pcd/issues/2021/21_0123.htm

More Information

- [Methods for the Underlying Conditions ICD-10 List \[PDF, 2 pages, 112K\]](#) [PDF](#)
- [COVID-19 Therapeutics](#)
- [Clinical Presentation](#)
- [COVID-19 Treatment in Outpatients](#)
- [United States COVID-19 Deaths, Emergency Department \(ED\) Visits, and Test Positivity by Geographic Area](#)
- [Demographic Trends of COVID-19 Deaths in the US Reported to NVSS](#)
- [Health Equity: Promoting Fair Access to Health](#)
- [COVID-19 Vaccination Clinical & Professional Resources](#)

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See CDC Systematic Review References

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SOURCES

CONTENT SOURCE:

National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

SOURCES

- * Indicates presence of evidence for pregnant and non-pregnant women
- ‡ Underlying conditions for which there is evidence in pediatric patients
- ^ Risk may be further increased for people receiving dialysis

**STATEWIDE STANDING ORDER AUTHORIZING
DISPENSING AND ADMINISTERING OF THE COVID-19
VACCINE TO ADULTS 18+ UNDER VIRGINIA CODE
54.1-3408(I)**

Date Issued: September 10, 2025

Purpose: This order is intended to supplement the authority that currently exists under state and federal law for pharmacists and pharmacy interns to administer U.S Food and Drug Administration (FDA) approved COVID-19 vaccines for 2025-2026 to people 18 years of age and over. This statewide standing order offers a mechanism to facilitate accessibility of COVID-19 vaccines that can lower the risk of severe illness, hospitalization or death caused by SARS-CoV2 virus by authorizing qualified and trained pharmacy personnel to administer certain vaccines as designated by the Commissioner of Health.

This order authorizes:

- Pharmacists actively licensed in Virginia who are in good standing to practice in Virginia per the Virginia Board of Pharmacy to dispense and administer FDA-approved COVID-19 vaccines;
- Pharmacy interns who have satisfied the training requirements of the PREP Act acting under the supervision of a pharmacist,

Eligible providers shall administer the COVID-19 vaccine in accordance with Virginia Code §54.1-3408 (I) as described below.

This order is effective on the date of prescriber signature and will expire when revoked or ceased, whichever comes sooner. This order shall be reviewed annually against best practices and may be revised or updated if new information about COVID-19 vaccines necessitates it.

The site must maintain a copy of the standing order if administering vaccine pursuant to the order. Please call the Office of the Commissioner at (804) 864-7001 with questions about the standing order.

Eligible Vaccine Recipients:

The following COVID-19 vaccines may be administered via intramuscular injection to eligible persons aged 18 years and older.

Product Selection, Criteria and Directions for Use in Adults*:

2025-2026 Formula Product Name	Age	1 st dose	2 nd dose	
		Injection Volume	Timing between doses	Injection Volume
MNEXSPIKE (COVID-19 Vaccine, mRNA) injectable suspension	18-64 with at least one underlying condition 65 years of age and older	0.2 mL	For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of MNEXSPIKE at least 3 months after the last dose of COVID-19 vaccine	0.2 mL
SPIKEVAX (COVID-19 Vaccine, mRNA) injectable suspension	18-64 with at least one underlying condition 65 years of age and older	0.5 mL	For individuals previously vaccinated with any COVID-19 vaccine, administer the dose ≥ 2 months after the last dose of COVID-19 vaccine	0.5 mL
COMIRNATY (COVID-19 Vaccine, mRNA) 30 mcg/0.3 mL injectable suspension prefilled syringe (packaging has gray cap/gray border)	18-64 with at least one underlying condition 65 years of age and older	0.3 mL	For individuals previously vaccinated with any COVID-19 vaccine, administer the dose at least 2 months after the last dose of COVID-19 vaccine	0.3 mL
NUVAXOVID (COVID-19 Vaccine, Adjuvanted) injectable suspension	18-64 with at least one underlying condition 65 years of age and older	0.5 mL	For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of NUVAXOVID at least 2 months after the last dose of COVID-19 vaccine	0.5 mL

*** Please note that the FDA indications for some of these products include pediatric populations. This standing order is limited to individuals 18 years and older. Please refer to manufacturer package inserts or the [U.S. FDA website](#) for additional information.**

Additional Criteria:

- COVID-19 vaccines and other vaccines may be administered at the same time. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For individuals 18 years and older, the deltoid muscle can be used for more than one intramuscular injection.
 - Label each syringe with the name and the dosage (amount) of the vaccine, lot number, the initials of the preparer, and the exact beyond-use time, if applicable.
 - Separate injection sites by 1 inch or more, if possible.
 - Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible.

Statewide Standing Order Authorizing Dispensing and Administering of the COVID19 Vaccine to Adults 18+ under Virginia Code 54.1-3408(I)

Created 9/10/2025

Procedures:

- Screen for any vaccine precautions and contraindications using an appropriate pre-vaccine questionnaire or Table 3 in the [CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States](#) before administering the vaccine.
- Provide the vaccine recipient with a copy of the Information for Recipients and Caregivers.
- Obtain informed consent of the patient or parent, guardian, or person standing in loco parentis.
- Educate about where, how, and when to obtain the additional COVID-19 vaccination as indicated.
- Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine.
- Ensure pharmacist accessibility, as defined by the PREP Act, to provide medication supervision of the vaccination site/service, to assess and evaluate individuals who present with precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.

Contraindications:

Do not administer any of the COVID-19 Vaccine, mRNA vaccines (MNEXSPIKE, SPIKEVAX, or COMIRNATY) to anyone with a known history of an immediate or severe allergic reaction (e.g., anaphylaxis) to any component of mRNA vaccine or to anyone who had a reaction to a previous dose of mRNA COVID-19 vaccine.

Do not administer the COVID-19 Vaccine Adjuvanted (NUVAXOVID) to anyone with a known history of an immediate or severe allergic reaction (e.g., anaphylaxis) to any component of NUVAXOVID or to anyone who had a severe allergic reaction (e.g., anaphylaxis) following a previous dose of a Novavax COVID-19 Vaccine, Adjuvanted.

Precautions:

- History of severe allergic reaction (e.g., anaphylaxis) to any other vaccine or injectable therapy.
- Self-reported moderate to severe acute illness.
- Clinical trials and post marketing data from use of authorized or approved mRNA/Adjuvanted COVID-19 vaccines have demonstrated increased risks of myocarditis and pericarditis following vaccination.
- Syncope (fainting) may occur in association with administration of injectable vaccines. Procedures should be in place to avoid injury from fainting.

Post-vaccination Observation and Emergency Protocol:

- In accordance with ACIP's General Best Practices Guidance for Immunization, all individuals receiving a vaccine should be observed for at least 15 minutes following vaccination. Persons with a history of anaphylaxis should be observed for 30 minutes.
- Vaccine providers shall be prepared to manage medical emergencies by having a written emergency medical protocol with policies and procedures, as well as appropriate equipment and medications (e.g. epinephrine), in places where vaccines are provided according to CDC

Statewide Standing Order Authorizing Dispensing and Administering of the COVID19 Vaccine to Adults 18+ under Virginia Code 54.1-3408(I)

Created 9/10/2025

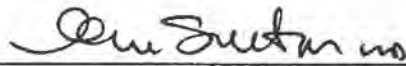
Clinical Considerations for Managing Anaphylaxis (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis>). Pharmacists may administer epinephrine in accordance with the Board of Pharmacy (BOP) [statewide protocol](https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/StatewideProtocols/) (<https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/StatewideProtocols/>).

- Report any vaccine administration errors (whether or not associated with an adverse event), serious adverse events (irrespective of attribution to vaccination), cases of Multisystem Inflammatory Syndrome in children and adults, or cases of COVID-19 that result in hospitalization or death following administration of the vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) via the VAERS online reporting tool (<https://vaers.hhs.gov/reportevent.html>) or by calling 1-800-822-7967.

Reporting and Follow-Up:

- Record COVID-19 vaccination in the pharmacy or medical record within 24 hours and ensure all required data elements are reported to the Virginia Immunization Information System (VIIS) within 7 days of vaccine administration.
- Vaccine recipients and/or their parent, guardian, or person standing in loco parentis must be provided with a personal vaccine record indicating the date of vaccination, product name/manufacture, lot number, name/location of administering pharmacy, and when the recipient needs to return for the second dose of any of the COVID-19 Vaccines, if indicated.
- Additional doses of the vaccine, if indicated, must be scheduled before the individual leaves the site.

Prescriber:



Karen Shelton, MD, FACOG
NPI Number: 1619926680
Virginia Medical License Number: 0101260180
Virginia Department of Health

Date:

09/10/2025

****DRAFT** VIRGINIA BOARD OF
PHARMACY**

Vaccine Statewide Protocol for Persons Ages Three (3) through Seventeen (17)

(Does not include influenza or COVID-19 vaccines)

Except for influenza and COVID-19 vaccines, consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) and the third enactment clause of [HB1323](#), a pharmacist may issue a prescription to initiate treatment with or administer a vaccine to a person age three (3) through seventeen (17) recommended at his or her age, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such vaccine. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine. Please note that this protocol does not authorize the administration of influenza or COVID-19 vaccines to persons ages three through seventeen. COVID-19 vaccines may be administered to this age group pursuant to the PREP Act until such authority expires. Influenza vaccines may be administered to this age group pursuant to the PREP Act until such authority expires or [§54.1-3408 \(W\)](#). The PREP Act is currently scheduled to expire on December 31, 2029. Under the PREP Act, COVID-19 and influenza vaccines must be administered according to CDC Immunization Schedule.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s) (e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual ages 3 through 17 whose immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule published by the CDC, and
- An individual ages 3 through 17 preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA

The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age or older than 17 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING

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

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. The pharmacist shall also provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

CHAPTER 790

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

[S 672]

Approved May 27, 2022

Be it enacted by the General Assembly of Virginia:

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

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

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

1. A provision for payment of medical assistance on behalf of individuals, up to the age of 21, placed in foster homes or private institutions by private, nonprofit agencies licensed as child-placing agencies by the Department of Social Services or placed through state and local subsidized adoptions to the extent permitted under federal statute;
2. A provision for determining eligibility for benefits for medically needy individuals which disregards from countable resources an amount not in excess of \$3,500 for the individual and an amount not in excess of \$3,500 for his spouse when such resources have been set aside to meet the burial expenses of the individual or his spouse. The amount disregarded shall be reduced by (i) the face value of life insurance on the life of an individual owned by the individual or his spouse if the cash surrender value of such policies has been excluded from countable resources and (ii) the amount of any other revocable or irrevocable trust, contract, or other arrangement specifically designated for the purpose of meeting the individual's or his spouse's burial expenses;
3. A requirement that, in determining eligibility, a home shall be disregarded. For those medically needy persons whose eligibility for medical assistance is required by federal law to be dependent on the budget methodology for Aid to Families with Dependent Children, a home means the house and lot used as the principal residence and all contiguous property. For all other persons, a home shall mean the house and lot used as the principal residence, as well as all contiguous property, as long as the value of the land, exclusive of the lot occupied by the house, does not exceed \$5,000. In any case in which the definition of home as provided here is more restrictive than that provided in the state plan for medical assistance services in Virginia as it was in effect on January 1, 1972, then a home means the house and lot used as the principal residence and all contiguous property essential to the operation of the home regardless of value;
4. A provision for payment of medical assistance on behalf of individuals up to the age of 21, who are Medicaid eligible, for medically necessary stays in acute care facilities in excess of 21 days per admission;
5. A provision for deducting from an institutionalized recipient's income an amount for the maintenance of the individual's spouse at home;
6. A provision for payment of medical assistance on behalf of pregnant women which provides for payment for inpatient postpartum treatment in accordance with the medical criteria outlined in the most current version of or an official update to the "Guidelines for Perinatal Care" prepared by the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists or the "Standards for Obstetric-Gynecologic Services" prepared by the American College of Obstetricians and Gynecologists. Payment shall be made for any postpartum home visit or visits for the mothers and the children which are within the time periods recommended by the attending physicians in accordance with and as indicated by such Guidelines or

Standards. For the purposes of this subdivision, such Guidelines or Standards shall include any changes thereto within six months of the publication of such Guidelines or Standards or any official amendment thereto;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

participant's long-term care. Components of the program, including the treatment of assets for Medicaid eligibility and estate recovery, shall be structured in accordance with federal law and applicable federal guidelines;

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

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

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

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

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

B. In preparing the plan, the Board shall:

1. Work cooperatively with the State Board of Health to ensure that quality patient care is provided and that the health, safety, security, rights and welfare of patients are ensured.
2. Initiate such cost containment or other measures as are set forth in the appropriation act.
3. Make, adopt, promulgate and enforce such regulations as may be necessary to carry out the provisions of this chapter.
4. Examine, before acting on a regulation to be published in the Virginia Register of Regulations pursuant to § **2.2-4007.05**, the potential fiscal impact of such regulation on local boards of social services. For regulations with potential fiscal impact, the Board shall share copies of the fiscal impact analysis with local boards of social services prior to submission to the Registrar. The fiscal impact analysis shall include the projected costs/savings to the local boards of social services to implement or comply with such regulation and, where applicable, sources of potential funds to implement or comply with such regulation.
5. Incorporate sanctions and remedies for certified nursing facilities established by state law, in accordance with 42 C.F.R. § 488.400 et seq. "Enforcement of Compliance for Long-Term Care Facilities With Deficiencies."

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

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

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

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

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

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

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

4. Refuse to enter into or renew an agreement or contract, or elect to terminate an existing agreement or contract, with a provider who is or has been a principal in a professional or other corporation when such corporation has been convicted of or otherwise pled guilty to any violation of § **32.1-314**, **32.1-315**, **32.1-316**, or **32.1-317**, or any other felony or has been excluded from participation in any federal program pursuant to 42 C.F.R. Part 1002.

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

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

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

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

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

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

H. The Department of Medical Assistance Services shall:

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

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

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

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

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

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

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

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

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

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

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

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

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;
2. Epinephrine;
3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;
4. Prenatal vitamins for which a prescription is required;
5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services;
6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;
7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention ~~or that have a current emergency use authorization from the U.S. Food and Drug Administration~~ and vaccines for COVID-19;
8. Tuberculin purified protein derivative for tuberculosis testing; ~~and~~
9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;
10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; and
11. Tests for COVID-19 and other coronaviruses.

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

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

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. *No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.).* If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, ~~upon request,~~ provide information regarding primary

health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

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

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

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

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

§ 54.1-3321. Registration of pharmacy technicians.

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

1. The entry of prescription information and drug history into a data system or other record keeping system;
2. The preparation of prescription labels or patient information;
3. The removal of the drug to be dispensed from inventory;
4. The counting, measuring, or compounding of the drug to be dispensed;
5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;
7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; ~~and~~
8. *Under the supervision of a pharmacist, meaning the supervising pharmacist is at the same physical location of the technician or pharmacy intern, and consistent with the requirements of § 54.1-3303.1, administration of the following drugs and devices to persons three years of age or older as set forth in regulations of the Board: vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and*
9. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

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

1. An application and fee specified in regulations of the Board;
2. (Effective July 1, 2022) Evidence that he has successfully completed a training program that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military; and
3. Evidence that he has successfully passed a national certification examination administered by the Pharmacy Technician Certification Board or the National Healthcareer Association.

C. The Board shall promulgate regulations establishing requirements for:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;
2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and
3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

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

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

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

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

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

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

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

Excerpt from page 99877 in the Federal Register

DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary 12th Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19

ACTION: Notice of amendment. **SUMMARY:** The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to extend the duration of the Declaration to December 31, 2029, and to republish the Declaration in full.

DATES: This amendment is effective as of January 1, 2025.

“I am now amending section XII of the Declaration to extend the time period of PREP Act coverage through December 31, 2029. COVID-19 continues to present a credible risk of a future public health emergency. COVID-19 continues to cause significant serious illness, morbidity, and mortality during outbreaks. The risk of domestic cases is high due to ongoing outbreaks that continue domestically and internationally in the year since the PHE for COVID-19 ended. Development of and stockpiling vaccines, therapeutics, devices, and diagnostics for COVID-19 continues to be needed for U.S. preparedness against the credible threat of a public health emergency due to outbreaks of COVID-19. Continued coverage under the PREP Act, as provided in this Declaration, is intended to prepare for and mitigate the credible risk presented by COVID-19. This includes extending the time period for PREP Act coverage for licensed pharmacists, pharmacy interns, and qualified technicians, which allows for continued access by the recipient Population to Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines and COVID-19 tests. As stated in prior amendments to this Declaration, licensed pharmacists, pharmacy interns and qualified pharmacy technicians are well positioned to provide continued access to Covered Countermeasures, particularly in certain areas or for certain populations that have too few primary-care providers or that are otherwise medically underserved. As of 2022, nearly 90 percent of Americans lived within five miles of a community pharmacy. During the COVID-19 pandemic, the majority of Americans have received their COVID-19 vaccines and tests from a pharmacy. In addition, continued access by the Population to seasonal influenza vaccines mitigates risks that seasonal influenza infections, in conjunction with COVID-19 infections, could overwhelm healthcare providers. As qualified persons, these licensed pharmacists, pharmacy interns, and qualified pharmacy technicians will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. To the extent that any State law would otherwise prohibit these healthcare professionals who are a “qualified person” from prescribing, dispensing, or administering Covered Countermeasures that are COVID-19 vaccines, seasonal influenza vaccines or COVID-19 tests, such law is preempted. Other conforming changes and technical corrections are made throughout the Declaration for consistency and clarity.”

*** DRAFT ***

VIRGINIA BOARD OF PHARMACY

Pharmacist Hormonal Contraceptive Statewide Protocol (Excluding Emergency Contraception)

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

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

PHARMACIST EDUCATION AND TRAINING

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

PATIENT INCLUSION CRITERIA

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

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

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

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

To determine patient eligibility, the pharmacist shall:

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

PROCESS FOR HANDLING INELIGIBLE PATIENTS

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

FURTHER CONDITIONS

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

DRUG INCLUSION CRITERIA

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

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

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER; COUNSELING

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

Adopted: 9/9/2020

Effective Date: 1/3/2021

Revised: 11/28/2023

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

VIRGINIA ROUTINE HORMONAL CONTRACEPTIVE SELF-SCREENING QUESTIONNAIRE

Name: _____ Today's Date: _____ Weight: _____

Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____

Healthcare Provider's Telephone, Fax, or Email: _____

What was the date of your last women's health clinical visit? _____

Any Allergies to Medications? Yes / No If yes, list them here: _____

Pregnancy Screen:

1.	Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	Yes ☐ No ☐
2.	Have you had a baby in the last 4 weeks?	Yes ☐ No ☐
3.	Did you have a miscarriage or abortion in the last 7 days?	____/____/____
4.	Did your last menstrual period start within the past 7 days?	Yes ☐ No ☐
5.	Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes ☐ No ☐
6.	Have you been using a reliable contraceptive method consistently and correctly?	Yes ☐ No ☐
<i>If you answered NO to ALL of the questions above, you may stop here and consult with the pharmacist. If you answered YES to at least one of the questions above, please proceed with completing this form.</i>		

Additional Information:

7.	Do you think you might be pregnant now?	Yes ☐ No ☐
8.	Have you used emergency contraception within the last 5 days?	Yes ☐ No ☐
9.	What was the first day of your last menstrual period?	____/____/____
10.	Have you ever been told by a medical professional not to take hormones?	Yes ☐ No ☐
11.	Have you ever taken birth control pills, or used a birth control patch, ring, or injection?	Yes ☐ No ☐
12.	Did you ever experience a bad reaction to using hormonal birth control?	Yes ☐ No ☐
13.	- If yes, what kind of reaction occurred?	
14.	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes ☐ No ☐
15.	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes ☐ No ☐
16.	- If yes, which one do you use? (List here)	
17.	Do you have a preferred method of birth control that you would like to use? (check box) ☐ A pill that you take daily ☐ A patch that you change weekly ☐ A vaginal ring that you change monthly ☐ An injection that you receive every 3 months	

Medical History

Smoking:

18.	Do you smoke cigarettes or vape nicotine?	Yes ☐ No ☐
19.	-If yes, number or equivalent number of cigarettes per day either smoked or vaped.	____/day

Postpartum (nonbreastfeeding women)/Breastfeeding:

20.	Have you given birth within 21 days? If yes, how long ago?	Yes ☐ No ☐
21.	Are you currently breastfeeding?	Yes ☐ No ☐

Diabetes:

22.	Do you have diabetes?	Yes ☐ No ☐
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Headaches:

23.	Do you get migraine headaches?	Yes ☐ No ☐
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24.	- If yes, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes ☐ No ☐
Hypertension, History of high blood pressure during pregnancy:		
25.	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes ☐ No ☐
Deep venous thrombosis (DVT)/Pulmonary embolism (PE), Ischemic heart disease, Known thrombogenic mutations, Multiple risk factors for atherosclerotic cardiovascular disease, Peripartum cardiomyopathy, Stroke, Valvular heart disease:		
26.	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes ☐ No ☐
27.	Have you ever had a blood clot?	Yes ☐ No ☐
28.	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes ☐ No ☐
29.	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes ☐ No ☐
History of bariatric surgery:		
30.	Have you had bariatric surgery or stomach reduction surgery?	Yes ☐ No ☐
Breast disease:		
31.	Do you have or have you ever had breast cancer?	Yes ☐ No ☐
Cirrhosis, Gallbladder disease, History of cholestasis, Liver tumors, Viral hepatitis:		
32.	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes ☐ No ☐
Rheumatoid arthritis, Systemic lupus erythematosus:		
33.	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes ☐ No ☐
Epilepsy, HIV, Tuberculosis, Drug Interactions (Antiretrovirals, Anticonvulsant, Antimicrobial therapy):		
34.	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes ☐ No ☐
35.	- If yes, list them here:	
Other information:		
36.	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes ☐ No ☐
37.	- If yes, list them here:	
38.	Will you be immobile for a long period? (e.g., flying on a long airplane trip, etc.)	Yes ☐ No ☐

Internal use only

☐ Verified DOB with valid photo ID BP Reading _____/_____

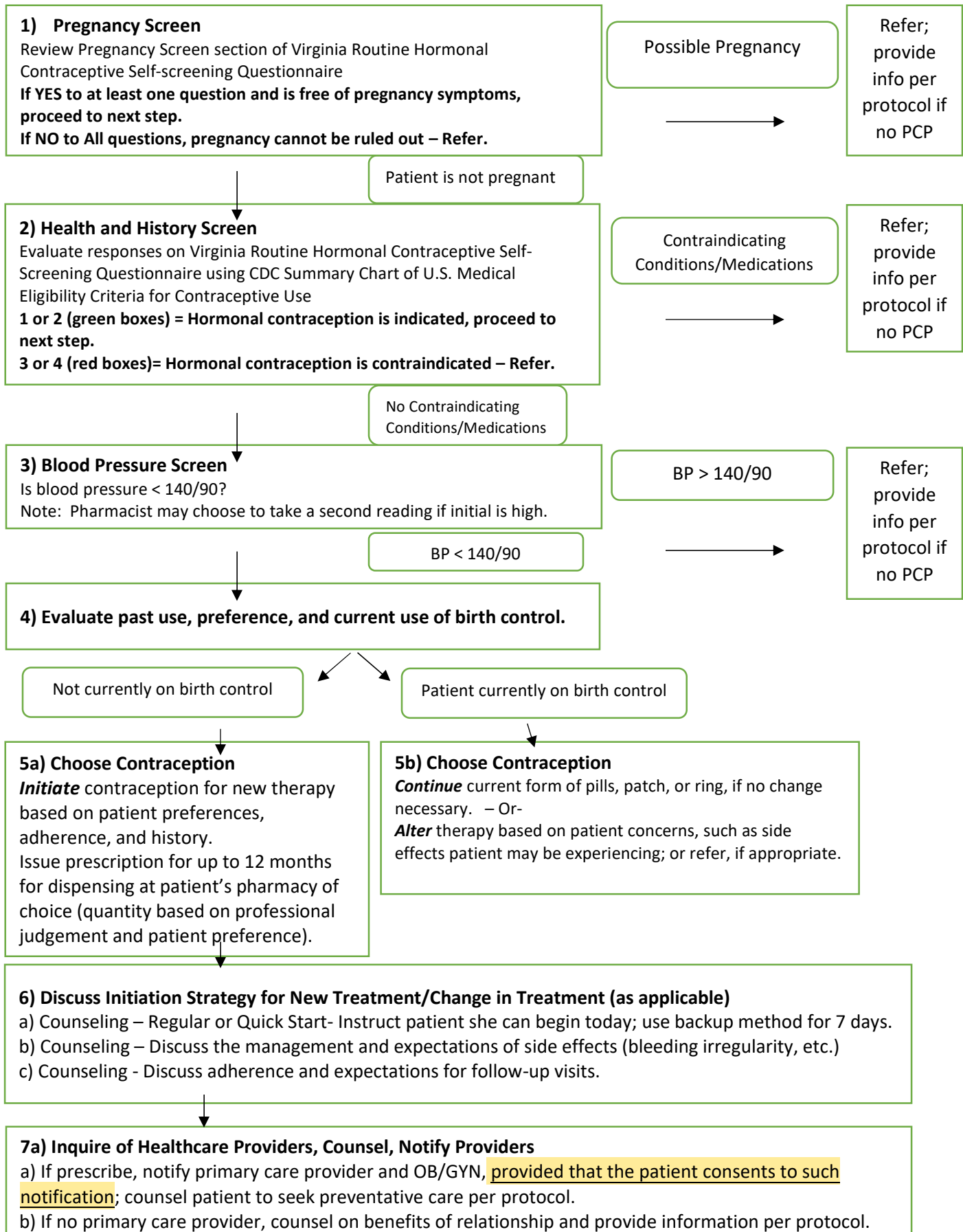
☐ Drug Prescribed: _____
 Sig: _____
 Pharmacist Name: _____
 Pharmacy Name and Address: _____
 Pharmacy Phone: _____

☐ Patient Referred

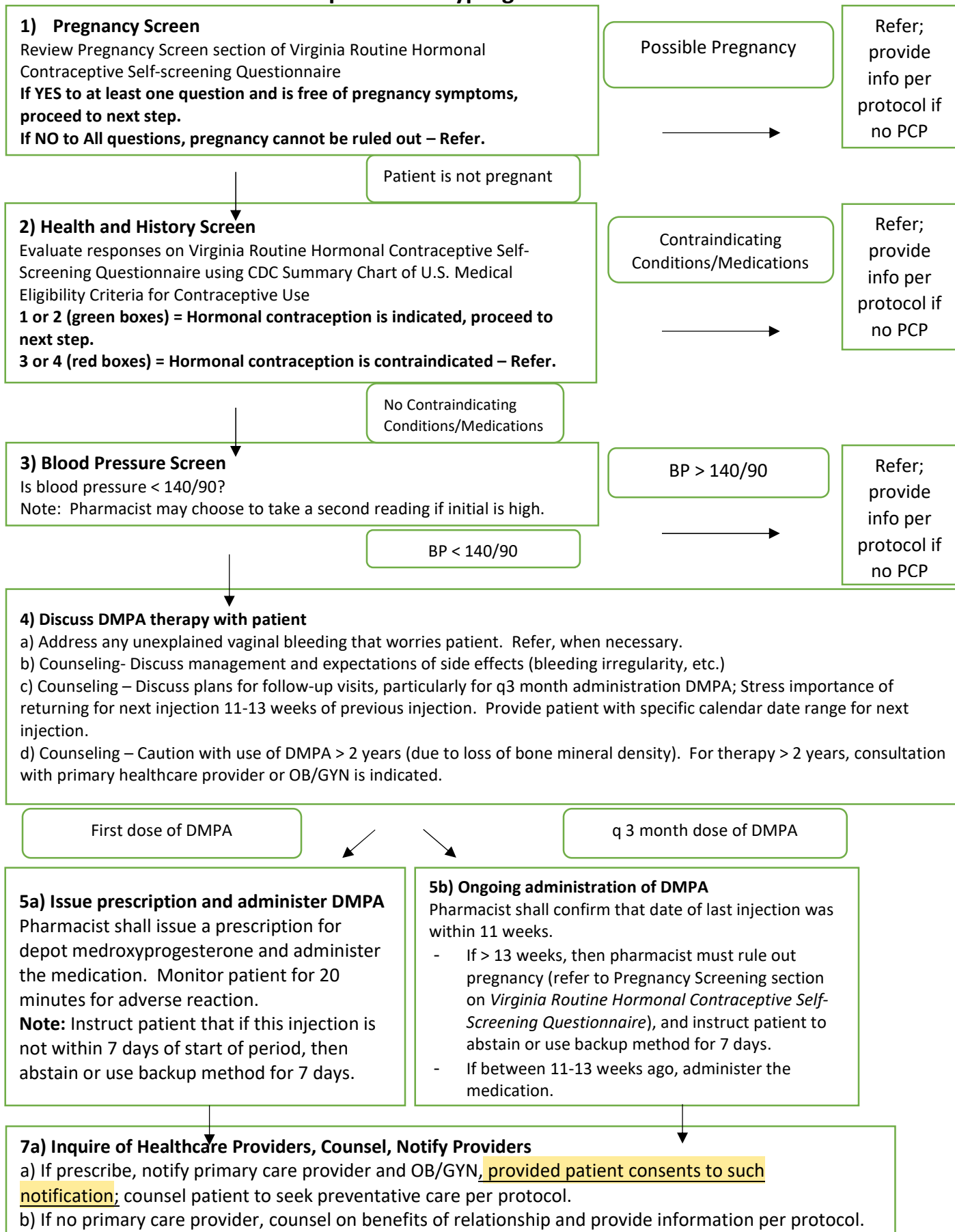
Reason(s): _____

Notes: _____

Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives



Virginia Algorithm for Pharmacists to Prescribe & Administer Depot Medroxyprogesterone Acetate



****DRAFT** VIRGINIA BOARD OF PHARMACY**

Pharmacist Naloxone or Other Opioid Antagonist Statewide Protocol

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

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

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone or any other opioid antagonist formulation approved by the FDA for overdose reversal under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

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

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

PATIENT EXCLUSION CRITERIA

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

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

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and counsel the patient or the patient's agent on how to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER

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

WHAT IS NALOXONE?

Naloxone is a medication designed to temporarily **block the effects of opioids**, and can reverse overdose.

- Naloxone only works if opioids are in the body, it has no effect on alcohol or other drugs
- It can take **1-3 minutes** to start working and may require more than one dose.
- Effects can **last 30-90 minutes**, this varies per person.
- Naloxone may cause an opioid dependent person to go into **withdrawal** (e.g. nausea, vomiting, agitation, muscle aches).

Naloxone Saves Lives.

To learn more about using naloxone attend a REVIVE! training event! These events are **free and available to anyone** wanting to learn how to save a life with naloxone.

A REVIVE! Opioid Overdose Response Kit is provided at each training free of charge and includes:

- Latex-free gloves
- Rescue breathing face mask
- Instruction Card
- A training completion card
- And stickers to document time of dosing



ADDRESS

PO Box 1797
Richmond, VA 23218

WEB

dbhds.virginia.gov search "revive"

REVIVE!

HOW TO RECOGNIZE AND RESPOND TO AN OPIOID OVERDOSE EMERGENCY WITH NALOXONE

An opioid overdose can happen to anyone taking opioids — whether they are taking medications prescribed or using them recreationally. Opioids can cause a person's **breathing to slow down or stop** — this is considered an overdose.



245

OPIOIDS

Opioids are a class of drugs that include prescription pain medications like:

- Hydrocodone
- Oxycodone
- Fentanyl
- Morphine
- Codeine
- Methadone
- Buprenorphine
- Tramadol

and also street drugs like heroin.

OVERDOSE

When a person consumes more opioids than their body can tolerate it can stop central nervous system functions such as breathing and heartbeat.

Someone may be overdosing if they are

- Unresponsive to yelling, pinching, or a sternum rub
- not breathing or having really slow/shallow breaths
- Having blue lips and/ or fingertips

REDUCE RISK

Some of the primary risk factors associated with overdose are:

- Mixing drugs
- Lowered Tolerance (haven't used opioids before or in a while)
- Using alone
- Age and Physical Health
- Mode of Transmission
- Previous non-fatal overdose

RESPOND

If you suspect someone has overdosed

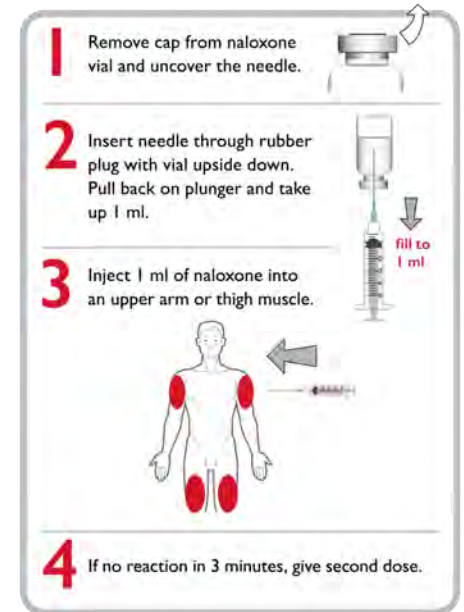
1. Check for responsiveness
2. Call 911
3. Give 2 Rescue Breaths
4. Give Naloxone
5. Begin Rescue Breathing

Naloxone expires, visit dbhds.virginia.gov to learn where you can get naloxone at no-cost.

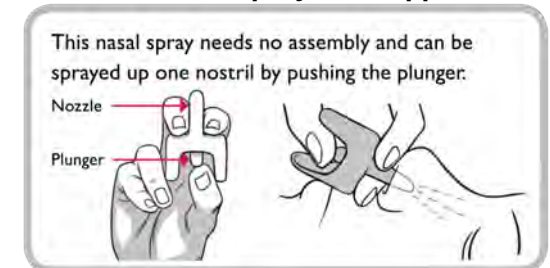
USING NALOXONE

Use Naloxone if you suspect someone is overdosing, even if you are unsure.

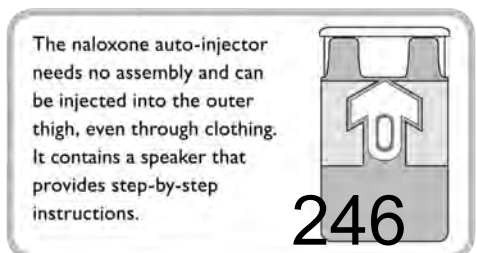
IM Injection (FDA Approved)



Narcan Nasal Spray (FDA Approved)



Auto-injector (FDA Approved)



****DRAFT** VIRGINIA BOARD OF PHARMACY**

Pharmacist Protocol for Testing and Initiating Treatment for Influenza

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for Influenza and, when diagnostically confirmed, initiate the dispensing of an antiviral to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antiviral therapy is readily available to treat acute influenza infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

A pharmacist shall exercise clinical judgement in assessing patients pursuant to this Protocol outside of the standard influenza season (approximately October 1 – April 30). **Resource:**

<https://www.cdc.gov/flu/weekly/>

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antiviral therapy under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute influenza. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection shall treat patients according to current CDC guidelines at <https://www.cdc.gov/flu/hcp/clinical-guidance/index.html>.

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and,
- Reported symptom onset < 48 hours before time of presentation.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including

- corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- A patient receiving hospice or home health services;
- A patient who has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or
 - Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO₂) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status

- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of flu-like signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's influenza status.

- If positive, the pharmacist may proceed to consideration for immediate antiviral therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, and consider influenza immunization) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions.

DRUG INCLUSION CRITERIA

The pharmacist may immediately initiate antiviral therapy only in selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

A. Oral oseltamivir (Tamiflu)

a. Contraindications

- Known hypersensitivity to oseltamivir or any component
- Patients 18 years and older with CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded from receiving Tamiflu. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record.

b. Dosing – all doses to be administered x 5 days

- Patients 18 years and older: 75 mg twice daily
- Patients 18 years and older with renal impairment
 - CrCl > 60 ml/min: no dosage adjustment necessary
 - CrCl > 30 to 60 ml/min: 30mg twice daily
 - CrCl > 10 to 30 ml/min: 30mg once daily

B. Oral baloxavir marboxil (Xofluza)

a. Contraindications

- Known hypersensitivity to baloxavir or any component
- Weight < 40 kg

b. Dosing – all doses to be administered as a single dose

- Weight-based

1. 40 kg to < 80 kg: 40 mg
2. 80 kg and above: 80 mg

C. Inhaled zanamivir (Relenza Diskhaler)

- a. Contraindications
 - i. Known hypersensitivity to zanamivir or any component
 - ii. Underlying respiratory disease or asthma
- b. Dosing – all doses to be administered twice daily x 5 days
 - i. 10 mg (two 5 mg inhalations)

If the patient qualifies for multiple therapies above, the pharmacist shall document the rationale for selecting the antiviral therapy dispensed. Documentation may include patient preference, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
 - Significant deterioration in condition or new evidence of clinical instability;
 - Onset of symptoms inconsistent with influenza or indicative of serious complications of influenza; or
 - Medication adverse effects severe enough to warrant discontinuation.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for influenza pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment,

testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- Influenza vaccination;
- Appropriate self-care, including symptom control, hygiene, and infection control measures;
- CDC guidelines that a patient with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile (100°F) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care.

NOTIFICATION OF PRIMARY CARE PROVIDER

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

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Influenza Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18 years of age or older?
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Do you require supplemental oxygen therapy?
☐ Yes ☐ No Have you taken an antiviral in the last 30 days?
☐ Yes ☐ No Do you have a pending test for your flu-like symptoms (COVID, strep, flu)?
☐ Yes ☐ No Have you tested positive for influenza in the previous four weeks?
When did your flu-like symptoms start? ☐ More than two days ago. ☐ 2 days ago, yesterday, or today.
Do you have any of the following symptoms (check all that apply)? ☐ Fever ☐ Nasal congestion ☐ Muscle/body aches ☐ Cough ☐ Sore Throat ☐ Other:
Do you have any of the following? ☐ History of allergic reactions to influenza treatment ☐ History of physiologic side effects from any previous influenza treatment
Have you received FluMist or a generic equivalent within the past two weeks? ☐ Yes ☐ No

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	Refer to PCP if determined clinically unstable in pharmacist professional judgment or any of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
☐ Yes ☐ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and
- Reported symptom onset < 48 hours before time of presentation.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Patient is receiving hospice or home health services;
- Patient has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or

- Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

- ☐ Positive for influenza (continue)
- ☐ Negative for influenza (refer to PCP + symptomatic treatment)

PATIENT ACTION

- ☐ Yes ☐ No Influenza Diagnosed
- ☐ Yes ☐ No Antiviral Treatment Prescribed
- ☐ Yes ☐ No Refer to PCP

Therapy Options		
Influenza Adult Treatment		
☐ Oral Oseltamivir (Tamiflu)	Dispense: ☐ 75mg #10; No refills ☐ Renal impairment CrCl > 30 to 60 ml/min: 30mg twice daily CrCl > 10 to 30 ml/min: 30mg once daily	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
☐ Inhaled Zanamivir (Relenza Diskhaler)	Dispense: ☐ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
☐ Oral Baloxavir Marboxil (Xofluza)	Dispense: ☐ 40mg x 1 ☐ 80mg x1 No refills	Take 1 tablet by mouth now

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number
--------------	----------------

SIGNATURE

DATE

Adopted: 9/24/2021
Effective: 12/22/2021
Revised: ~~11/28/2023~~

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL

PURPOSE

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

PHARMACIST EDUCATION AND TRAINING

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

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing¹ from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection² or from a comparable provider approved by the Virginia Board of Pharmacy

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

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

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing
- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations³: Sections 1 and 2

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

² CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at <https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf>
<https://www.cdc.gov/tb/hcp/education/core-curriculum-on->

Adopted: 9/24/2021
Effective: 12/22/2021
Revised: ~~11/28/2023~~

[tuberculosis.html](#)

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

[Testing and Treatment of Latent Tuberculosis Infection in the United States: A Clinical Guide for Health Care Providers and Public Health Programs](#).
(NTCA/NSTC, 202). Available at: [LTBI Clinical Recommendations](#)

Commented [SA(1)]: Was 'Formerly titled Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations — A Guide for Health Care Providers and Public Health Programs' but now with the most recent 3rd Edition, I believe is currently titled 'Testing and Treatment of Latent Tuberculosis Infection in the United States'. NSTC/NTCA Clinical Guide | November 2023

Adopted: 9/24/2021
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Revised: 11/28/2023

- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019⁴
- High Burden TB Country List, Virginia Department of Health⁵

INCLUSION CRITERIA

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

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

EXCLUSION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month⁶ (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a documented positive TST
- Any individual who is receiving an initial TST and will be receiving annual TB testing and thus is in need of two-step testing (refer to two step testing protocol)
- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

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

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

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

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

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

Commented [AB2]: History of BCG isn't technically exclusionary for using TST, as we understand it.

Commented [SA(3R2)]: While that is true, I seem to recollect that this was the stance adopted to avoid having the pharmacist getting too much into the weeds of this and refer for an IGRA (unless maybe they were comfortable to proceed & provide client with the necessary education on impact of BCG vaccine within various age groups, so to speak).

Commented [CJ4R2]: I agree and recommend leaving as written.

Commented [SA(5)]: Link would have to be changed to access the current 3rd edition. See above comment for footnote #3

Adopted: 9/24/2021
Effective: 12/22/2021
Revised: ~~11/28/2023~~

[ting/Tuberculin Skin Testing Information for Health Care Providers.pdf](#)

Adopted: 9/24/2021
Effective: 12/22/2021
Revised: 11/28/2023

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

MEDICATIONS

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

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

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

PROCEDURES FOR INITIATION OF TB SCREENING

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

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

PROCEDURES FOR MONITORING AND FOLLOW UP

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

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

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

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

DOCUMENTATION

Adopted: 9/24/2021
Effective: 12/22/2021
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Pharmacists will document via prescription or medical record each person who receives a TST under this protocol including:

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

NOTIFICATION AND REFERRAL

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

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

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which the patient is located.

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

VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM
(For Pharmacist Use When Screening Patient; Not intended to be a Self-Screening Document)

Name: _____ Today's Date: _____ Weight: _____
 Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____
 Healthcare Provider's Telephone, Fax, or Email: _____
 Any Allergies to Medications? *Yes / No* If yes, list here: _____

Are you required to have a Tuberculosis (TB) Risk Assessment or Tuberculin Skin Test (TST) for your job, school, or other mandatory reason? Yes ☐ No ☐
 If yes, specify reason? _____

If YES, ensure pharmacists may legally sign document certifying assessment or TST results for intended purpose. If pharmacist may not legally certify, refer patient to PCP. If NO, proceed with completing form.

Patient Authorization:

I hereby authorize the pharmacist to perform the TB Risk Assessment and administer the TST, if warranted. I agree that the results of this test may be shared with other health care providers. I acknowledge that I have received the Notice of Privacy Practices. I understand that: this information will be used by health care providers for care and not for statistical purposes only; this information will be kept confidential; medical records must be kept at a minimum of six years following the last patient encounter except for (i) records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative, or (ii) records that are required by contractual obligation or federal law to be maintained for a longer period of time.

I agree to return to the pharmacy located at _____
 to have the results of the test read by the pharmacist on this date _____.

I further authorize the pharmacist to notify the following of a positive TB Skin Test (choose one):

- ☐ Primary Care Physician: _____ (First & Last Name) _____ (Tel. #) _____
☐ Local Free Clinic ☐ Local Federally-Qualified Healthcare Center

Patient Printed Name: _____ Date: _____
 Patient Signature: _____ Date: _____

If patient does not agree to Patient Authorization section, refer patient to PCP.

Screening for TB Symptoms:

1.	Do you have coughing that has lasted for more than 3 weeks?	Yes ☐ No ☐
2.	Are you coughing up blood or mucous?	Yes ☐ No ☐
3.	Do you have a fever? Temperature reading: _____	Yes ☐ No ☐
4.	Have you experienced unintentional weight loss?	Yes ☐ No ☐
5.	Do you have a loss of appetite? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐
6.	Are you experiencing night sweats? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐
7.	Do you have fatigue? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐

If patient answered YES to at least one of the questions above (taking 5, 6, and 7 in context), stop here and refer patient to PCP. If patient answered NO to all of the questions above, proceed with completing this form.

Screening for TB History:

8.	Have you ever been treated for TB Disease/Latent Tuberculosis Infection (LTBI)?	Yes ☐ No ☐
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Appendix A

9.	Have you ever had a documented prior positive test for TB infection? If yes, date of positive test (if known): _____ Type of Test: ☐ TST/IGRA ☐ TST Reading: _____ mm If yes to prior positive test, did you have a chest radiograph performed after the positive test? CXR date (if known): _____ Results: ☐ Normal ☐ Abnormal If chest radiograph was normal after positive test, did you receive LTBI treatment?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
If YES to prior positive TB test, those seeking testing for administrative purposes must have documentation of the past prior positive TB test otherwise testing will still be required for work clearance. If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP. If YES to prior positive TB test and YES to subsequent NORMAL chest radiograph, no repeat TB testing is indicated if asymptomatic; refer for LTBI treatment if previously untreated. If NO prior positive TB test, proceed with completing this form.		
Screening for TB Infection Risk		
10.	Have you had close contact to someone with known or suspected active TB disease at any time? Name _____ of source case: _____	Yes ☐ No ☐
If YES, report to local health department. TST may still be performed. If NO, proceed with completing this form.		
Screening for High Burden TB Countries:		
11.	Were you born in a country outside of the United States? If yes, which country? _____	Yes ☐ No ☐
12.	Have you traveled or resided in a country outside of the United States for 3 months or longer? If yes, which country? _____	Yes ☐ No ☐
13.	Have you traveled or resided in a country outside of the United States for the purpose of receiving medical treatment? If yes, which country? _____	Yes ☐ No ☐
Refer to current VDH High Burden TB Countries list. If YES and born in or traveled to/resided in country on list $\geq$ 3 months, refer to BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, TST may still be performed. If NO or country did not appear on list, proceed with completing this form.		
Screening for BCG		
14.	Were you ever administered the BCG vaccination?	Yes ☐ No ☐
If YES, refer. If NO, proceed with completing form.		
Assessing Other Risks for Acquiring LTBI		
15.	Do you reside or work in a high TB risk congregate setting (e.g., correctional facility, nursing home, and long-term care facilities for elderly, mentally ill, or persons living with AIDS)?	Yes ☐ No ☐
16.	Are you a healthcare worker who serves high-risk clients? NOTE: Stop and refer patient to local health department if screening is part of an ongoing contact investigation within the facility approved by the local health department.	Yes ☐ No ☐
17.	Have you experienced homelessness within the past two years?	Yes ☐ No ☐
18.	Do you inject drugs for recreational use or use crack cocaine?	Yes ☐ No ☐
19.	Do you have a regular health care provider? Have you received medical care within the last two years? If NO to both questions, patient is considered medically underserved.	Yes ☐ No ☐ Yes ☐ No ☐
If YES to any of the questions (#15-18) or if the patient is medically underserved, and screening is NOT part of an ongoing contact investigation within a facility approved by the local health department, a TST is indicated. If NO to questions #15-18 and patient is not medically underserved, proceed with completing form.		
Assessing Risk for Developing TB Disease if Infected		
20.	Have you been diagnosed with HIV infection?	Yes ☐ No ☐

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Appendix A

21.	Are you at risk for HIV infection? If YES, recommend an HIV test. Administer TST even if patient refuses HIV test or consider referral for IGRA testing.	Yes ☐	No ☐
22.	Were you recently infected with Mycobacterium tuberculosis?	Yes ☐	No ☐
23.	Do you have any of the following medical conditions:		
	- Low body weight due to chronic malabsorption syndromes?	Yes ☐	No ☐
	- Lung disease silicosis caused by breathing in tiny bits of silica?	Yes ☐	No ☐
	- Diabetes?	Yes ☐	No ☐
	- End stage renal disease or on hemodialysis?	Yes ☐	No ☐
	- Head or neck cancer?	Yes ☐	No ☐
	- Leukemia?	Yes ☐	No ☐
	- Lymphoma?	Yes ☐	No ☐
	- Hematologic or reticuloendothelial disease?	Yes ☐	No ☐
24.	Have you ever had any of the following procedures:		
	- Gastrectomy?	Yes ☐	No ☐
	- Intestinal bypass?	Yes ☐	No ☐
	- Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	Yes ☐	No ☐
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone $\geq$ 15mg/day for $\geq$ 1 month) or other immunosuppressive medication?	Yes ☐	No ☐
If YES to any of the questions in this section, TST test is indicated. If YES to HIV positive questions or on immunosuppressive therapy, consider referral for IGRA testing.			
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.			

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Report of Tuberculosis Screening

Name: _____ Date of Birth: _____ Date: _____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by (PRINT OR TYPE):

Name of Pharmacist: _____

Name of Pharmacy: _____ Tel. #: _____

Pharmacy Address: _____

TB Screening and/or Testing ConclusionsI. No Symptoms or Risks Identified on TB Risk Assessment

☐ A tuberculin skin test (TST) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need annual testing.

☐ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If one of these two statements applies, select the appropriate statement and skip to section IV and select statement "A".

If neither statement applies, go to section II.

If in a health care setting that requires a test for TB infection but no symptoms are present, go to Section III.

II. Symptoms Consistent with Potential Tuberculosis are Present

Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Advise of isolation precautions. Proceed to section IV and select statement "B". If there are no symptoms consistent with TB, go to section III.

III. Testing for TB Infection via Tuberculin Skin Test (record both tests if a 2-step TST was required)

#1 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____

Pharmacist Name: _____

Date read: _____ Time: _____ Results: _____ mm Interpretation: Negative ☐ Positive ☐

Pharmacist Name: _____

#2 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____

Pharmacist Name: _____

Date read: _____ Time: _____ Results: _____ mm Interpretation: Negative ☐ Positive ☐

Pharmacist Name: _____

If test(s) above are negative, proceed to section IV and select statement "A".

If test(s) above are positive, proceed to section IV and select statement "B".

IV. TB Screening/Testing Conclusion

☐ A. Based on the TB Screening and/or TST, the individual listed above does not demonstrate a risk of having tuberculosis in a communicable form.

☐ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual was counseled and referred to (check all that apply):

☐ Primary Care Provider (Name): _____ (Tel.) _____

☐ Local Health Department (Name): _____ (Tel.) _____

☐ Provided Contact Information for Primary Health Care Providers

This individual should be treated by a PCP for:

☐ Evaluation for Active TB Disease Based on Symptoms (pharmacist must immediately call local health department);

☐ Prior Positive Test with No Subsequent Normal Chest Radiograph;

☐ Prior Positive Test with Normal Chest Radiograph, but LTBI Previously Untreated;

☐ IGRA since Individual Born in High Burden TB Country;

☐ IGRA since Individual has Received BCG;

☐ IGRA since Individual is Immunocompromised or on Immunosuppressive Therapy;

☐ Positive TST Result.

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Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date _____ Trainer (QC by) _____ Trainee (TST placed by) _____	
Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable	
1. Preliminary	
_____ Uses appropriate hand hygiene methods before starting.	_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Screens patient for contraindications (severe adverse reactions to previous TST). [*]	_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ Uses well-lit area.	_____ Advances needle until entire bevel is under the first layer of skin.
	_____ Releases stretched skin.
	_____ Injects entire dose slowly.
	_____ Forms wheal, as liquid is injected.
2. Syringe[†] filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen[§]	
_____ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen. [¶]	_____ Removes needle without pressing area.
_____ Checks label and expiration date on vial.	_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
	_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ Marks opening date on multidose vial.	_____ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____ mm).
_____ Fills immediately after vial removed from refrigeration.	_____ If blood or fluid is present, blots site lightly with gauze or cotton ball.
_____ Cleans vial stopper with antiseptic swab.	_____ Discards used gauze or cotton ball according to local standard precautions.
_____ Twists needle onto syringe to ensure tight fit.	_____ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
_____ Removes needle guard.	_____ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).
_____ Inserts needle into the vial.	_____ Uses appropriate hand hygiene methods after placing TST.
_____ Draws slightly over 0.1 mL of 5 TU PPD into syringe.	
_____ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.	
_____ Removes needle from vial.	
_____ Returns antigen vial to the refrigerator immediately after filling.	
3. TST administration site selected and cleaned	
_____ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site. ^{**}	
_____ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.	
_____ Cleans the site with antiseptic swab using circular motion from center to outside.	
_____ Allows site to dry thoroughly before administering antigen.	
4. Needle inserted properly to administer antigen	
_____ Rests arm on firm, well-lit surface.	
_____ Stretches skin slightly. ^{††}	
5. Explanation to the client regarding care instructions for the injection site	
	_____ The wheal (bump) is normal and will remain about 10 minutes.
	_____ Do not touch wheal; avoid scratching.
	_____ Avoid pressure or bandage on injection site.
	_____ Rare local discomfort and irritation does not require treatment.
	_____ May wash with soap and water (without pressure) after 1 hour.
	_____ No lotions or liquids on site, except for light washing, as above.
	_____ Keep appointment for reading.

^{*} Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

[†] Use a 1/4–1/2-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

[§] Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000;161:1376–95.

[¶] Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid-containing vaccines instead of tuberculosis skin tests. *MMWR* 2004;53:662–4.

^{**} If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.

SOURCE: National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

^{††} Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (Continued) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ Trainer (QC by) _____ Trainee (TST placed by) _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

- _____ Uses appropriate hand hygiene methods before starting.
- _____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
- _____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
- _____ Uses well-lit area.
- _____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

- _____ Palpates with arm bent at elbow at a 90° angle.
- _____ Lightly sweeps 2-inch diameter from injection site in four directions.
- _____ Uses zigzag featherlike touch.
- _____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

- _____ Holds palm over injection site.
- _____ Cleanse site with antiseptic swab using circular motion from center to outside.
- _____ Uses fingertips to find margins of the induration.
- _____ Marks the induration by placing small dots on both sides of the induration.
- _____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.

_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

- _____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
- _____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

- _____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
- _____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; <http://www.fda.gov/medwatch> report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.

† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).

§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

Appendix D: Interpretation of the Tuberculin Skin Test; Effective 12/22/2021

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction¹

≥5 mm Induration	≥10 mm Induration	≥15 mm Induration
Considered positive in the following persons: - Persons living with the human immunodeficiency virus (HIV) - Recent contacts of a person with Tuberculosis (TB) disease - Persons with a chest radiography (CXR) findings suggestive of previous TB disease - Patients with organ transplants - Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists)	Considered positive in the following persons: - Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB - Persons with substance use disorders - Mycobacteriology laboratory personnel - Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities - Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions - Persons <90% of ideal body weight - Children aged <5 years - Infants, children, and adolescents exposed to adults in high-risk categories	Considered positive in any person, including ducing persons with no known risk factors for TB.

Commented [SA(6)]: Is this a typo and rather meant 'including'?

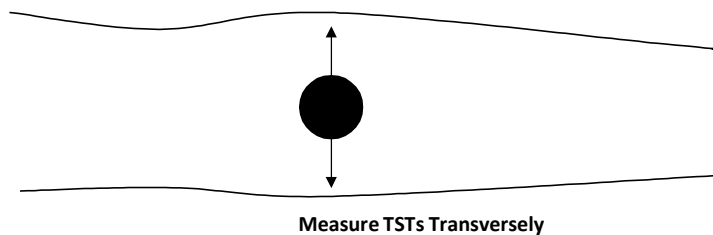
Commented [CJ7R6]: yes

*All tests should be interpreted based on patient risk and test characteristics.

A negative TST result does not exclude LTBI or active TB disease.

¹ Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: <https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration>

Appendix D: Interpretation of the Tuberculin Skin Test; Effective 12/22/2021



CDC LTBI: A Guide for Primary Health Care Providers

<https://www.cdc.gov/tb/publications/ltpi/pdf/LTBIbooklet508.pdf>

<https://www.cdc.gov/tb/hcp/education/latent-tb-infection-guide-primary-care-providers.html>

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VIRGINIA BOARD OF PHARMACY

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

PURPOSE

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

PHARMACIST EDUCATION AND TRAINING

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

- The Centers for Disease Control and Prevention Guidelines for Targeted Tuberculin Testing¹ from a provider accredited by the Accreditation Council for Pharmacy Education
- The Centers for Disease Control and Prevention Core Curriculum on Tuberculosis - Chapter 2: Testing for Tuberculosis Infection² or from a comparable provider approved by the Virginia Board of Pharmacy

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

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

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

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

² CDC Core Curriculum on Tuberculosis: What the Clinician Should Know. Available at <https://www.cdc.gov/tb/education/corecurr/pdf/CoreCurriculumTB-508.pdf>
<https://www.cdc.gov/tb/hcp/education/core-curriculum-on-tuberculosis.html>

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- Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations³: Sections 1 and 2
- Tuberculosis Screening, Testing and Treatment of U.S. Healthcare Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019⁴
- High Burden TB Country List, Virginia Department of Health⁵

INCLUSION CRITERIA

Pharmacists acting under this protocol are authorized to initiate the dispensing, administration, and interpretation of TSTs to adults aged ≥ 18 years who are receiving initial TB skin testing and may continue to receive an annual TST for employment purposes. The 2020 CDC Guidelines for Screening, Testing and Treatment of Healthcare Personnel no longer include a recommendation for serial screening for the majority of healthcare personnel after the initial screening, unless they fall into a particular high risk group (e.g., pulmonologists) or there is an exposure or on-going transmission at the healthcare facility⁶.

EXCLUSION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site
- Live vaccination administered within the last month⁷ (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST

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

Testing and Treatment of Latent Tuberculosis Infection in the United States: A Clinical Guide for Health Care Providers and Public Health Programs (NTCA/NTSC, 2021). Available at: [LTBI Clinical Recommendations](#)

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

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

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

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

https://www.cdc.gov/tb/publications/factsheets/testing/Tuberculin_Skin_Testing_Information_for_Health_Care_Providers.pdf

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

Commented [AB1]: History of BCG isn't technically exclusionary for using TST, as we understand it.

Commented [CJ2R1]: Recommend keeping. See comments in one-step protocol.

CONSIDERATIONS

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

MEDICATIONS

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

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

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

PROCEDURES FOR INITIATION OF TB SCREENING

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

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

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

PROCEDURES FOR MONITORING AND FOLLOW UP

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

Interpretation and classification of TST results is determined by diameter of induration and consideration of risk factors as outlined in ATS/CDC Guideline¹ (Appendix D). If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), patients must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions.

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

COUNSELING REQUIREMENTS

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Individuals receiving TST will receive counseling regarding:

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

DOCUMENTATION

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

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

NOTIFICATION AND REFERRAL

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

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

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

VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM
(For Pharmacist Use When Screening Patient; Not intended to be a Self-Screening Document)

Name: _____ Today's Date: _____ Weight: _____
 Date of Birth: _____ Age: _____ Healthcare Provider's Name: _____
 Healthcare Provider's Telephone, Fax, or Email: _____
 Any Allergies to Medications? *Yes / No* If yes, list here: _____

Are you required to have a Tuberculosis (TB) Risk Assessment or Tuberculin Skin Test (TST) for your job, school, or other mandatory reason? Yes ☐ No ☐
 If yes, specify reason? _____

If YES, ensure pharmacists may legally sign document certifying assessment or TST results for intended purpose. If pharmacist may not legally certify, refer patient to PCP. If NO, proceed with completing form.

Patient Authorization:

I hereby authorize the pharmacist to perform the TB Risk Assessment and administer the TST, if warranted. I agree that the results of this test may be shared with other health care providers. I acknowledge that I have received the Notice of Privacy Practices. I understand that: this information will be used by health care providers for care and not for statistical purposes only; this information will be kept confidential; medical records must be kept at a minimum of six years following the last patient encounter except for (i) records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative, or (ii) records that are required by contractual obligation or federal law to be maintained for a longer period of time.

I agree to return to the pharmacy located at _____
 to have the results of the test read by the pharmacist on this date _____.

I further authorize the pharmacist to notify the following of a positive TB Skin Test (choose one):

☐ Primary Care Physician: _____ (First & Last Name) _____ (Tel. #) _____
☐ Local Free Clinic ☐ Local Federally-Qualified Healthcare Center

Patient Printed Name: _____ Date: _____
 Patient Signature: _____ Date: _____

If patient does not agree to Patient Authorization section, refer patient to PCP.

Screening for TB Symptoms:

1.	Do you have coughing that has lasted for more than 3 weeks?	Yes ☐ No ☐
2.	Are you coughing up blood or mucous?	Yes ☐ No ☐
3.	Do you have a fever? Temperature reading: _____	Yes ☐ No ☐
4.	Have you experienced unintentional weight loss?	Yes ☐ No ☐
5.	Do you have a loss of appetite? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐
6.	Are you experiencing night sweats? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐
7.	Do you have fatigue? <i>(evaluate symptoms 5, 6, and 7 in context)</i>	Yes ☐ No ☐

If patient answered YES to at least one of the questions above (taking 5, 6, and 7 in context), stop here and refer patient to PCP. If patient answered NO to all of the questions above, proceed with completing this form.

Screening for TB History:

8.	Have you ever been treated for TB Disease/Latent Tuberculosis Infection (LTBI)?	Yes ☐ No ☐
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Appendix A

9.	Have you ever had a documented prior positive test for TB infection? If yes, date of positive test (if known): _____ Type of Test: ☐ TST/IGRA ☐ TST Reading: _____ mm If yes to prior positive test, did you have a chest radiograph performed after the positive test? CXR date (if known): _____ Results: ☐ Normal ☐ Abnormal If chest radiograph was normal after positive test, did you receive LTBI treatment?	Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐
If YES to prior positive TB test, those seeking testing for administrative purposes must have documentation of the past prior positive TB test otherwise testing will still be required for work clearance. If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP. If YES to prior positive TB test and YES to subsequent NORMAL chest radiograph, no repeat TB testing is indicated if asymptomatic; refer for LTBI treatment if previously untreated. If NO prior positive TB test, proceed with completing this form.		
Screening for TB Infection Risk		
10.	Have you had close contact to someone with known or suspected active TB disease at any time? Name _____ of source case: _____	Yes ☐ No ☐
If YES, report to local health department. TST may still be performed. If NO, proceed with completing this form.		
Screening for High Burden TB Countries:		
11.	Were you born in a country outside of the United States? If yes, which country? _____	Yes ☐ No ☐
12.	Have you traveled or resided in a country outside of the United States for 3 months or longer? If yes, which country? _____	Yes ☐ No ☐
13.	Have you traveled or resided in a country outside of the United States for the purpose of receiving medical treatment? If yes, which country? _____	Yes ☐ No ☐
Refer to current VDH High Burden TB Countries list. If YES and born in or traveled to/resided in country on list ≥ 3 months, refer to BCG vaccination status. If BCG vaccinated, refer for IGRA. For others, TST may still be performed. If NO or country did not appear on list, proceed with completing this form.		
Screening for BCG		
14.	Were you ever administered the BCG vaccination?	Yes ☐ No ☐
If YES, refer. If NO, proceed with completing form.		
Assessing Other Risks for Acquiring LTBI		
15.	Do you reside or work in a high TB risk congregate setting (e.g., correctional facility, nursing home, and long-term care facilities for elderly, mentally ill, or persons living with AIDS)?	Yes ☐ No ☐
16.	Are you a healthcare worker who serves high-risk clients? NOTE: Stop and refer patient to local health department if screening is part of an ongoing contact investigation within the facility approved by the local health department.	Yes ☐ No ☐
17.	Have you experienced homelessness within the past two years?	Yes ☐ No ☐
18.	Do you inject drugs for recreational use or use crack cocaine?	Yes ☐ No ☐
19.	Do you have a regular health care provider? Have you received medical care within the last two years? If NO to both questions, patient is considered medically underserved.	Yes ☐ No ☐ Yes ☐ No ☐
If YES to any of the questions (#15-18) or if the patient is medically underserved, and screening is NOT part of an ongoing contact investigation within a facility approved by the local health department, a TST is indicated. If NO to questions #15-18 and patient is not medically underserved, proceed with completing form.		
Assessing Risk for Developing TB Disease if Infected		
20.	Have you been diagnosed with HIV infection?	Yes ☐ No ☐

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Appendix A

21.	Are you at risk for HIV infection? If YES, recommend an HIV test. Administer TST even if patient refuses HIV test or consider referral for IGRA testing.	Yes ☐	No ☐
22.	Were you recently infected with Mycobacterium tuberculosis?	Yes ☐	No ☐
23.	Do you have any of the following medical conditions:		
	- Low body weight due to chronic malabsorption syndromes?	Yes ☐	No ☐
	- Lung disease silicosis caused by breathing in tiny bits of silica?	Yes ☐	No ☐
	- Diabetes?	Yes ☐	No ☐
	- End stage renal disease or on hemodialysis?	Yes ☐	No ☐
	- Head or neck cancer?	Yes ☐	No ☐
	- Leukemia?	Yes ☐	No ☐
	- Lymphoma?	Yes ☐	No ☐
	- Hematologic or reticuloendothelial disease?	Yes ☐	No ☐
24.	Have you ever had any of the following procedures:		
	- Gastrectomy?	Yes ☐	No ☐
	- Intestinal bypass?	Yes ☐	No ☐
	- Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	Yes ☐	No ☐
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone $\geq$ 15mg/day for $\geq$ 1 month) or other immunosuppressive medication?	Yes ☐	No ☐
If YES to any of the questions in this section, TST test is indicated. If YES to HIV positive questions or on immunosuppressive therapy, consider referereferral for IGRA testing.			
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.			

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Report of Tuberculosis Screening

Name: _____ Date of Birth: _____ Date: _____

TO WHOM IT MAY CONCERN: The above individual has been evaluated by (PRINT OR TYPE):

Name of Pharmacist: _____

Name of Pharmacy: _____ Tel. #: _____

Pharmacy Address: _____

TB Screening and/or Testing ConclusionsI. No Symptoms or Risks Identified on TB Risk Assessment

☐ A tuberculin skin test (TST) is not indicated at this time due to the absence of symptoms suggestive of active TB, no risk factors identified for infection or for developing active TB if infected, and no known recent contact with active TB. Health care workers employed in a low risk facility according to CDC "Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005" do not need annual testing.

☐ The individual has a history of TB infection. Follow-up chest x-ray is not indicated at this time due to the absence of symptoms suggestive of active TB.

If one of these two statements applies, select the appropriate statement and skip to section IV and select statement "A".

If neither statement applies, go to section II.

If in a health care setting that requires a test for TB infection but no symptoms are present, go to Section III.

II. Symptoms Consistent with Potential Tuberculosis are Present

Call the local health department to refer the person for further TB evaluation immediately. This notification is necessary even when the individual prefers to pursue an evaluation privately. Advise of isolation precautions. Proceed to section IV and select statement "B". If there are no symptoms consistent with TB, go to section III.

III. Testing for TB Infection via Tuberculin Skin Test (record both tests if a 2-step TST was required)

#1 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____

Pharmacist Name: _____

Date read: _____ Time: _____ Results: _____ mm Interpretation: Negative ☐ Positive ☐

Pharmacist Name: _____

#2 TST Lot: _____ Date Administered: _____ Time: _____ Site: _____

Pharmacist Name: _____

Date read: _____ Time: _____ Results: _____ mm Interpretation: Negative ☐ Positive ☐

Pharmacist Name: _____

If test(s) above are negative, proceed to section IV and select statement "A".

If test(s) above are positive, proceed to section IV and select statement "B".

IV. TB Screening/Testing Conclusion

☐ A. Based on the TB Screening and/or TST, the individual listed above does not demonstrate a risk of having tuberculosis in a communicable form.

☐ B. Active tuberculosis cannot be ruled out in the individual listed above. The individual was counseled and referred to (check all that apply):

☐ Primary Care Provider (Name): _____ (Tel.) _____

☐ Local Health Department (Name): _____ (Tel.) _____

☐ Provided Contact Information for Primary Health Care Providers

This individual should be treated by a PCP for:

☐ Evaluation for Active TB Disease Based on Symptoms (*pharmacist must immediately call local health department*);

☐ Prior Positive Test with No Subsequent Normal Chest Radiograph;

☐ Prior Positive Test with Normal Chest Radiograph, but LTBI Previously Untreated;

☐ IGRA since Individual Born in High Burden TB Country;

☐ IGRA since Individual has Received BCG;

☐ IGRA since Individual is Immunocompromised or on Immunosuppressive Therapy;

☐ Positive TST Result.

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Appendix F. Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Placing Tuberculin Skin Tests (TSTs) — Mantoux Method

Date	Trainer (QC by)	Trainee (TST placed by)
Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable		
1. Preliminary		
☐ Uses appropriate hand hygiene methods before starting.	☐ Holds needle bevel-up and tip at 5°–15° angle to skin.	☐ Inserts needle in first layer of skin with tip visible beneath skin.
☐ Screens patient for contraindications (severe adverse reactions to previous TST). [*]	☐ Advances needle until entire bevel is under the first layer of skin.	☐ Releases stretched skin.
☐ Uses well-lit area.	☐ Injects entire dose slowly.	☐ Forms wheal, as liquid is injected.
2. Syringe[†] filled with exactly 0.1 mL of 5 tuberculin units (TU) purified protein derivative (PPD) antigen[§]		
☐ Removes antigen vial from refrigeration and confirms that it is 5 TU PPD antigen.	☐ Removes needle without pressing area.	☐ Activates safety feature of device per manufacturer's recommendations, if applicable.
☐ Checks label and expiration date on vial.	☐ Places used needle and syringe immediately in puncture-resistant container without recapping needle.	
☐ Marks opening date on multidose vial.	☐ Immediately measures wheal to ensure 6–10 mm in diameter (Actual wheal measurement _____ mm).	☐ If blood or fluid is present, blots site lightly with gauze or cotton ball.
☐ Fills immediately after vial removed from refrigeration.	☐ Discards used gauze or cotton ball according to local standard precautions.	☐ If the TST is administered incorrectly (too deeply or too shallow) and the wheal is inadequate (<6 mm), a new TST should be placed immediately. Applying the second TST on the other arm or in a different area of the same arm (at least 2 inches from the first site) is preferable so that the TST result will be easier to read.
☐ Cleans vial stopper with antiseptic swab.	☐ Documents all information required by the setting (e.g., date and time of TST placement, person who placed TST, location of injection site and lot number of tuberculin).	
☐ Twists needle onto syringe to ensure tight fit.	☐ Uses appropriate hand hygiene methods after placing TST.	
☐ Removes needle guard.		
☐ Inserts needle into the vial.		
☐ Draws slightly over 0.1 mL of 5 TU PPD into syringe.		
☐ Removes excess volume or air bubbles to exactly 0.1 mL of 5 TU PPD while needle remains in vial to avoid wasting of antigen.		
☐ Removes needle from vial.		
☐ Returns antigen vial to the refrigerator immediately after filling.		
3. TST administration site selected and cleaned		
☐ Selects upper third of forearm with palm up ≥2 inches from elbow, wrist, or other injection site. ^{**}		
☐ Selects site free from veins, lesions, heavy hair, bruises, scars, and muscle ridge.		
☐ Cleans the site with antiseptic swab using circular motion from center to outside.		
☐ Allows site to dry thoroughly before administering antigen.		
4. Needle inserted properly to administer antigen		
☐ Rests arm on firm, well-lit surface.		
☐ Stretches skin slightly. ^{††}		
5. Explanation to the client regarding care instructions for the injection site		
	☐ The wheal (bump) is normal and will remain about 10 minutes.	
	☐ Do not touch wheal; avoid scratching.	
	☐ Avoid pressure or bandage on injection site.	
	☐ Rare local discomfort and irritation does not require treatment.	
	☐ May wash with soap and water (without pressure) after 1 hour.	
	☐ No lotions or liquids on site, except for light washing, as above.	
	☐ Keep appointment for reading.	

^{*} Severe adverse reactions to the TST are rare but include ulceration, necrosis, vesiculation, or bullae at the test site, or anaphylactic shock, which is substantially rare. These reactions are the only contraindications to having a TST administered.

[†] Use a 1/4–1/2-inch 27-gauge needle or finer, disposable tuberculin (preferably a safety-type) syringe.

[§] Prefilling syringes is not recommended. Tuberculin is absorbed in varying amounts by glass and plastics. To minimize reduction in potency, tuberculin should be administered as soon after the syringe has been filled as possible. Following these procedures will also help avoid contamination. Test doses should always be removed from the vial under strictly aseptic conditions, and the remaining solution should remain refrigerated (not frozen). Tuberculin should be stored in the dark as much as possible and exposure to strong light should be avoided. **SOURCE:** American Thoracic Society, CDC, Infectious Disease Society of America. Diagnostic standards and classification of tuberculosis in adults and children. *Am J Respir Crit Care Med* 2000;161:1376–95.

^{||} Preventing tuberculin antigen and vaccine (e.g., Td toxoid) misadministration is important. Measures should include physical separation of refrigerated products, careful visual inspection and reading of labels, preparation of PPD for patient use only at time of testing, and improved record keeping of lot numbers of antigens, vaccines, and other injectable products. **SOURCE:** CDC. Inadvertent intradermal administration of tetanus toxoid-containing vaccines instead of tuberculosis skin tests. *MMWR* 2004;53:662–4.

^{**} If neither arm is available or acceptable for testing, the back of the shoulder is a good alternate TST administration site.

SOURCE: National Tuberculosis Controllers Association, National Tuberculosis Nurse Consultant Coalition. Tuberculosis nursing: a comprehensive guide to patient care. Smyrna, GA: National Tuberculosis Controllers Association; 1997.

^{††} Stretch skin by placing nondominant hand of health-care worker (HCW) on patient's forearm below the needle insertion point and then applying traction in the opposite direction of the needle insertion. Be careful not to place the nondominant hand of the HCW opposite the administration needle if the patient is likely to move during the procedure, which might cause an accidental needle-stick injury to the HCWs. In children and others who are likely to move during the procedure, certain trainers prefer stretching the skin in the opposite direction of the needle insertion by placing the nondominant hand of the HCW under the patient's forearm. This method should not be used for persons with poor skin turgor.

Appendix F. (Continued) Quality control (QC) procedural observation checklists

Quality Control (QC) Procedural Observation Checklist for Reading Tuberculin Skin Test (TST) Results — Palpation Method

Date _____ Trainer (QC by) _____ Trainee (TST placed by) _____

Scoring: ✓ or Y = Yes X or N = No NA = Not Applicable

1. Preliminary

- _____ Uses appropriate hand hygiene methods before starting.
- _____ Keeps fingernails shorter than fingertips to avoid misreading TST result.
- _____ Keeps TST reading materials at hand (eyeliner pencil or ballpoint pen,* and ruler).
- _____ Uses well-lit area.
- _____ Inspects for the site of the injection.

2. Palpate — finding margin ridges (if any)

- _____ Palpates with arm bent at elbow at a 90° angle.
- _____ Lightly sweeps 2-inch diameter from injection site in four directions.
- _____ Uses zigzag featherlike touch.
- _____ Repeats palpation with arm bent at elbow at a 45° angle to determine presence or absence of induration.

If induration is present, continue with these steps†:

3. Placing marks

- _____ Holds palm over injection site.
- _____ Cleanse site with antiseptic swab using circular motion from center to outside.
- _____ Uses fingertips to find margins of the induration.
- _____ Marks the induration by placing small dots on both sides of the induration.
- _____ Inspects dots, repeats finger movements toward indurated margin, and adjusts dots if needed.

_____ Marks dots transverse (perpendicular) to long axis of forearm.

4. Placing and reading ruler

- _____ Places the "0" ruler line inside the edge of the left dot. Reads the ruler line inside right dot edge (uses lower measurement if between two gradations on millimeter scale) (Figure 1).
- _____ Uses appropriate hand hygiene methods after reading TST result.

5. Documenting results

- _____ Records all TST results in millimeters, even those classified as negative. Does not record only as "positive" or "negative." Records the absence of induration as "0 mm."
- _____ Correctly records results in mm; only a single measured induration in mm should be recorded.
Trainee's measurement _____ mm.
Trainer's (gold standard) measurement _____ mm.
Trainee's result within 2 mm of gold standard reading?§
Yes _____ No _____

NOTE: In rare instances, the reaction might be severe (vesiculation, ulceration, or necrosis of the skin). Report severe adverse events to the FDA MedWatch Adverse Events Reporting System (AERS), telephone: 800-FDA-1088; fax: 800-FDA-0178; <http://www.fda.gov/medwatch> report form 3500, Physicians' Desk Reference.

* A fine-tipped eyeliner pencil or ballpoint pen can be used as a marker. An eyeliner pencil is useful for TST training and for blinded independent duplicate readings (BIDRs) because the dots are easy to remove with a dot of lubricant (e.g., baby oil). Alternative TST result reading methods have been described, including the pen method.

† If induration is not present, record the TST result as 0 mm and go to the end of this form (Documenting results).

§ For example, if the TST trainer reads the TST result (the gold standard reading) as 11 mm, the trainee's TST reading should be between 9–13 mm to be considered correct.

Appendix D: Interpretation of the Tuberculin Skin Test; Effective ~~12/22/2021~~

The TST reading should be based on measurement of induration, not erythema, using a Mantoux skin test ruler. The diameter of induration should be measured transversely to the long axis of the forearm and recorded in millimeters. Record no induration as zero (0) millimeters.

Classification of the Tuberculin Skin Test Reaction¹

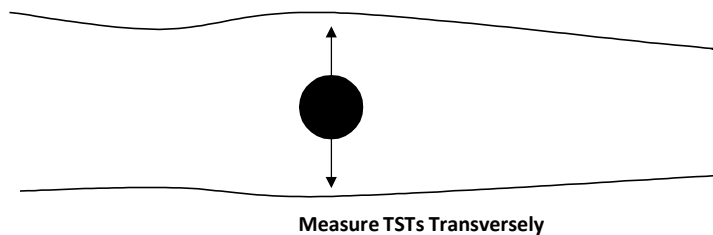
≥5 mm Induration	≥10 mm Induration	≥15 mm Induration
Considered positive in the following persons: - Persons living with the human immunodeficiency virus (HIV) - Recent contacts of a person with Tuberculosis (TB) disease - Persons with a chest radiography (CXR) findings suggestive of previous TB disease - Patients with organ transplants - Persons who are immunosuppressed for other reasons (e.g., prolonged therapy with corticosteroids equivalent of ≥15 mg per day of prednisone for 1 month or longer or those taking tumor necrosis factor-alpha [TNF-alpha] antagonists)	Considered positive in the following persons: - Persons born in countries where TB disease is common including Mexico, the Philippines, Vietnam, India, China, Haiti, and Guatemala, or other countries with high rates of TB - Persons with substance use disorders - Mycobacteriology laboratory personnel - Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities - Persons with certain medical conditions that place them at high risk for TB, such as silicosis, diabetes mellitus, severe kidney disease, certain types of cancer, and certain intestinal conditions - Persons <90% of ideal body weight - Children aged <5 years - Infants, children, and adolescents exposed to adults in high-risk categories	Considered positive in any person, including dueing persons with no known risk factors for TB.

*All tests should be interpreted based on patient risk and test characteristics.

A negative TST result does not exclude LTBI or active TB disease.

¹ Testing and Treatment of Latent Tuberculosis Infection in the United States: Clinical Recommendations, Appendix 1: Interpretation of Test Results.(NTCA/NTSC, 2021). Available at: <https://survey.alchemer.com/s3/6183608/2021-LTBI-Testing-Treatment-Publication-Registration>

Appendix D: Interpretation of the Tuberculin Skin Test; Effective ~~12/22/2021~~



CDC LTBI: A Guide for Primary Health Care Providers

<https://www.cdc.gov/tb/publications/ltpi/pdf/LTBIbooklet508.pdf>

<https://www.cdc.gov/tb/hcp/education/latent-tb-infection-guide-primary-care-providers.html>

Figure 1: The TST Booster Phenomenon

As the years pass, the person's ability to react to tuberculin lessens. Occurs mainly in previously infected older adults whose ability to react to tuberculin has decreased over time. These people should still be considered for LTBI treatment after ruling out TB disease, particularly if they have risk factors for progression to disease.

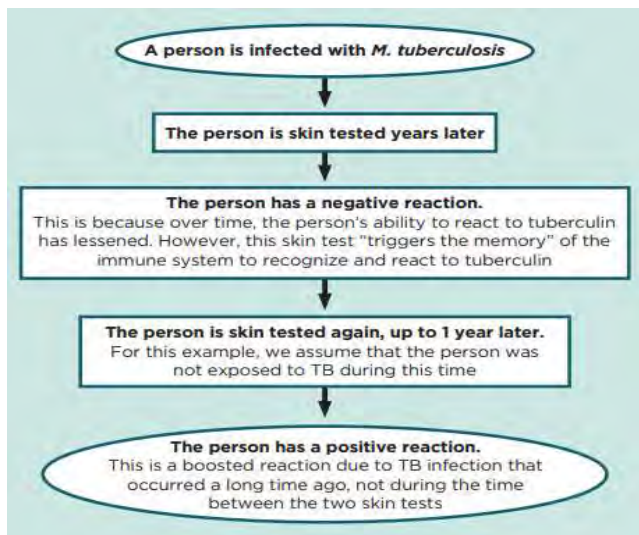
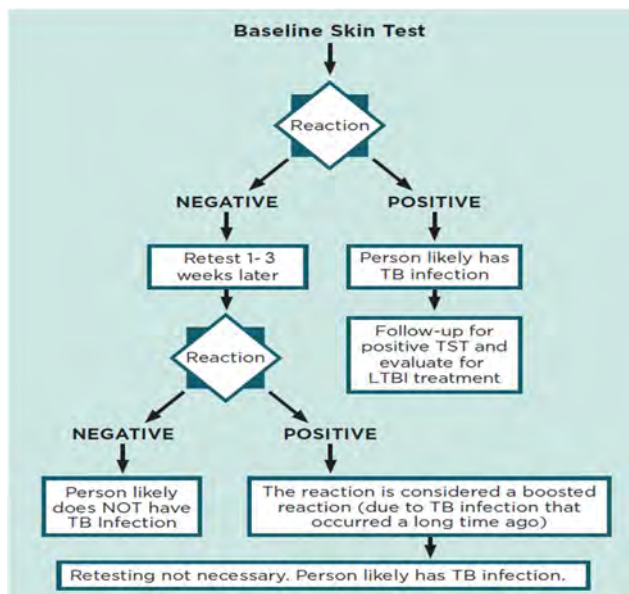


Figure 2: Two-Step TST Testing

Two-step testing is a strategy used to reduce the likelihood that a boosted reaction will be misinterpreted as a recent infection (Figure 2). Two-step testing should be used for the initial skin testing of persons who will be retested periodically. If the reaction to the first TST is classified as negative, a second TST should be repeated 1 to 3 weeks later. A positive reaction to the second TST likely represents a boosted reaction. Based on this second test result, the person should be classified as previously infected. This would not be considered a skin test conversion or a new TB infection; however, the patient may still be a candidate for LTBI treatment. If the second skin test result is also negative, the person should be classified as having a negative baseline TST result. **If either the first or second test result is positive, the individual should be referred for follow-up and evaluation for LTBI treatment.**



VIRGINIA BOARD OF PHARMACY

Pharmacist Epinephrine Statewide Protocol

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

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

PHARMACIST EDUCATION AND TRAINING

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

PATIENT INCLUSION CRITERIA

Patients eligible for epinephrine under this protocol:

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

COUNSELING

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

RECORDKEEPING

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

NOTIFICATION OF PRIMARY CARE PROVIDER

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

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Acute Group A Streptococcus Bacteria Infection

Pursuant to [Virginia Code](#) § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for acute Group A streptococcal (GAS) pharyngitis and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute GAS pharyngitis infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Infectious Disease Society of America (IDSA) and the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute GAS pharyngitis. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat acute GAS pharyngitis infection shall treat patients according to current [IDSA](#) and [CDC guidelines](#).

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and,
- Reported symptom onset < 96 hours before time of ~~presentation~~ assessment.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state, e.g., ~~(~~hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS~~);~~;
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced

- glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- Known hypersensitivity to penicillin or cephalosporins and absence of susceptibility results or known resistance to macrolides and clindamycin
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- A patient who has taken antibiotics for sore throat or upper respiratory infection in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
 - Muffled voice;
 - Drooling;
 - Stridor;
 - Respiratory distress;
 - "Sniffing" or "tripod" positions;
 - Fever and rigors;
 - Severe unilateral sore throat;
 - Bulging of the pharyngeal wall/floor or soft palate;
 - Trismus;
 - Crepitus;
 - Stiff neck; or
 - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or
 - Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's acute GAS pharyngitis status.

- If positive, the pharmacist may proceed to consideration for immediate antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver pursuant to the Counseling section of this Protocol or refer the patient, if clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

DRUG INCLUSION CRITERIA

The pharmacist may initiate one the following medication regimens based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Selection of antibiotic regimen will follow the ordered preference listed below. A lower-ranked regimen will only be prescribed if the patient or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen, or if the drug is not commercially available or appears on the [FDA drug shortages list](#). The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction.

If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

- A. First-line treatment
 - a. Amoxicillin
 - i. Contraindication: Penicillin allergy
 - ii. Dosing: 500 mg PO twice daily x 10 days, or
1,000 mg PO once daily x 10 days
 - b. Penicillin
 - i. Contraindication: Penicillin allergy
 - ii. Dosing
 - 1. Penicillin V, oral – 500mg PO twice daily x 10 days, or
250 mg PO four times daily x 10 days
 - 2. Penicillin G benzathine – 1.2million units IM, single dose, to be administered by the pharmacist.
- B. Second-line treatment
 - a. Cephalexin
 - i. Contraindications
 - 1. Cephalosporin allergy
 - 2. Severe penicillin allergy
 - ii. Dosing: 500 mg PO twice daily x 10 days
 - b. Cefadroxil
 - i. Contraindications
 - 1. Cephalosporin allergy
 - 2. Severe penicillin allergy
 - ii. Dosing: 1g PO daily x 10 days
- C. Third-line treatment (*Note: Potential resistance exists for both clindamycin and azithromycin. Clindamycin, Azithromycin and Clarithromycin should not be used unless there is documented susceptibility. Clindamycin is the preferred third-line treatment.*)
 - a. Clindamycin
 - i. Contraindication: Clindamycin allergy
 - ii. Dosing: 300 mg PO three times daily x 10 days
 - b. Azithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 500 mg PO once daily x 5 days
- D. Fourth-line treatment
 - a. Clarithromycin
 - i. Contraindication: Macrolide allergy
 - ii. Dosing: 250 mg PO twice daily x 10 days
- E. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
 - a. Acetaminophen PO according to over-the-counter ~~OTC~~ dosing recommendations; and
 - b. Ibuprofen PO according to OTC dosing recommendations.

RECORDKEEPING

In any case where amoxicillin is not the selected regimen, the pharmacist shall document the rationale for selecting the antibiotic dispensed. Documentation may include medication sensitivity, cost, and shared clinical decision-making.

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for acute GAS pharyngitis pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- If CLIA-waived test results are negative, counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home until for at least 24 hours have passed since last fever without the use of fever-reducing medications~~after fever subsides~~, hygiene/infection control measures, drink plenty of fluids, treat symptoms as needed, etc.) or refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.
- If CLIA-waived test results are positive, counsel on CDC guidelines (<https://www.cdc.gov/group-a-strep/hcp/clinical-guidance/strep-throat.html>) that a patient with a confirmed diagnosis of acute GAS pharyngitis should stay home from work or school until they are afebrile for at least 24 hours after starting antibiotic therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care such as from a primary care provider or urgent/emergent treatment facility if symptoms worsen or do not improve within 48 hours.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of

establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Acute Group A Streptococcal Pharyngitis Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Prescription-only Rx , over-the-counter OTC , herbal, topical, pain, or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

☐ Yes ☐ No Are you 18 years of age or older?
☐ Yes ☐ No Are you pregnant or breastfeeding?
☐ <u>Yes</u> ☐ <u>No</u> <u>Are you receiving hospice or home health services?</u>
☐ Yes ☐ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
☐ Yes ☐ No Do you have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis?
☐ Yes ☐ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxicillin, cephalexin, clarithromycin, or clindamycin?
☐ Yes ☐ No Do you have a pending test for your symptoms (COVID- <u>19</u> , strep, flu)?
☐ Yes ☐ No Have you had a tonsillectomy in the previous 30 days?
☐ Yes ☐ No Have you taken antibiotics in the last 30 days? If yes, why?
When did your symptoms start? ☐ <u>More than four days</u> <u>Four or more days</u> ago. ☐ Fewer than four days ago
Do you have any of the following symptoms (check all that apply)? ☐ Fever ☐ Sore throat ☐ Pain swallowing ☐ Swollen/tender cervical lymph nodes ☐ Inflamed or swollen tonsils or uvula ☐ Other:

– PHARMACY STAFF ONLY –

**PATIENT
ASSESSMENT**

Physical Assessment (record values)	Refer to PCP if determined clinically unstable in pharmacist professional judgment or any of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO ₂) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
☐ Yes ☐ No Acute altered mental status	Yes
Severe Symptoms of Respiratory Distress	Muffled voice; Drooling; Stridor; Respiratory distress; "Sniffing" or "tripod" positions; Fever and rigors; Severe unilateral sore throat; Bulging of the pharyngeal wall/floor or soft palate; Trismus; Crepitus; Stiff neck; or History of penetrating trauma to oropharynx.
Overt Viral Features	Conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and
- Reported symptom onset < 96 hours before time of ~~presentation~~ assessment.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state, e.g., ~~(~~hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS~~);~~

- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Patient has taken antibiotics for sore throat or upper respiratory infection in the last 30 days.
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
 - Muffled voice;
 - Drooling;
 - Stridor;
 - Respiratory distress;
 - "Sniffing" or "tripod" positions;
 - Fever and rigors;
 - Severe unilateral sore throat;
 - Bulging of the pharyngeal wall/floor or soft palate;
 - Trismus;
 - Crepitus;
 - Stiff neck; or
 - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
 - Two or more of the following criteria:
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >90 beats/min;
 - Respiratory rate >20 breaths/min;
 - Temperature < 96.8 degrees Fahrenheit; or
 - Temperature > 100.4 degrees Fahrenheit; or
 - Any one of the following criteria:
 - Acute altered mental status;
 - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
 - Pulse >125 beats/min;
 - Respiratory rate >30 breaths/min;
 - Oxygen saturation (SpO₂) < 90% via pulse oximetry; or
 - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

- ☐ Positive for acute GAS pharyngitis (continue)
- ☐ Negative for acute GAS pharyngitis (refer to PCP as clinically appropriate + symptomatic treatment)

PATIENT ACTION

- ☐ Yes ☐ No Acute GAS pharyngitis Diagnosed
- ☐ Yes ☐ No Antibiotic Treatment Prescribed
- ☐ Yes ☐ No Refer to PCP

Therapy Options (Refer to Drug Inclusions section of Protocol for drug order preference)		
Acute GAS Pharyngitis Adult Treatment		
Documentation of Rationale for Treatment Selection (if required):		
☐ Oral Amoxicillin	Dispense: ☐ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days; or
<u>☐ Oral Amoxicillin</u>	<u>Dispense: ☐ 500mg</u> <u>#20 No refills</u>	<u>Sig: Take 2 (two) (1000mg) by mouth once daily for 10 days</u>
☐ Oral Penicillin V	Dispense: ☐ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
<u>☐ Oral Penicillin V</u>	<u>Dispense: ☐ 250mg</u> <u>#40 No refills</u>	<u>Sig: Take 1 (one) (250mg) by mouth four times daily for 10 days</u>
☐ IM Penicillin G benzathine	Dispense: ☐ 1.2million units IM, single dose No refills	To be administered by the pharmacist
☐ Oral Cephalexin	Dispense: ☐ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
☐ Oral Cefadroxil	Dispense: ☐ 1g #10 No refills	Sig: Take 1 (one) (1g) by mouth daily for 10 days
<u>☐ Oral Clindamycin</u>	<u>Dispense: ☐ 300mg</u> <u>#30 No refills</u>	<u>Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days</u>
☐ Oral Azithromycin	Dispense: ☐ 500mg #5 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days
☐ Oral Clindamycin	Dispense: ☐ 300mg #30 No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days
☐ Oral Clarithromycin	Dispense: ☐ 250mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number
--------------	----------------

SIGNATURE

DATE

Licensing Report

Virginia Department of
Health Professions
Current Count of Licenses
Quarterly Summary
Quarter 4- Fiscal Year 2025

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

*** Veterinary Establishments are now grouped together, as the board works on designating existing establishments as "Ambulatory" or "Stationary", instead of "Full Service" or "Restricted Service".

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

BOARD	Occupation	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	CURRENT Q4 2025
Optometry	Optometrist	78	85	65	65	65	49	50	51	51	46	46	46	46	41
	Optometrist-Volunteer Registration	-	-	-	-	-	-	1	-	-	-	-	-	-	-
	Professional Designation	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	TPA Certified Optometrist	1,749	1,708	1,758	1,784	1,808	1,777	1,820	1,852	1,879	1,819	1,842	1,867	1,883	1,824
	Total	1,827	1,773	1,823	1,849	1,873	1,826	1,871	1,903	1,930	1,865	1,888	1,913	1,929	1,865
Pharmacy	Business CSR	1,399	1,463	1,507	1,529	1,423	1,465	1,508	1,533	1,417	1,498	1,509	1,702	1,640	1,723
	CE Courses	9	9	9	9	9	9	9	9	9	9	9	9	9	-
	EMS Designated Location	-	-	-	-	-	-	-	-	-	-	-	-	-	683
	Humane Society	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Limited Use Facility Dispensing	-	-	-	1	2	3	3	3	4	4	6	6	6	7
	Limited Use Pharmacy Technician	7	7	7	7	7	7	7	7	6	6	5	5	4	4
	Limited Use Practitioner Dispensing	1	2	2	3	3	3	4	6	8	8	12	12	16	18
	Medical Equipment Supplier	209	217	223	226	213	220	226	224	205	212	216	224	208	215
	Non-Resident Manufacturer	206	213	218	224	217	226	231	236	229	232	245	248	233	236
	Non-Resident Medical Equipment Supplier	331	354	361	369	346	355	367	379	345	367	380	390	367	373
	Non-resident Outsourcing Facility	30	29	32	33	35	33	32	31	31	33	33	37	36	38
	Non-resident Pharmacy	682	698	910	911	924	923	934	943	962	973	982	977	997	907
	Non-Resident Wholesale Distributor	624	634	643	641	610	624	635	641	612	624	633	637	621	642
	Non-restricted Manufacturer	31	32	34	34	35	35	35	35	32	34	36	36	36	36
	Non-Resident Third Party Logistics Prov.	181	181	194	206	207	219	229	238	234	241	247	254	252	259
	Non-resident Warehouse	98	99	105	115	109	114	123	130	127	142	154	167	171	183
	Outsourcing Facility	-	-	-	-	1	1	1	1	1	1	1	1	1	1
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	15,858	16,079	16,414	16,619	16,064	16,273	16,606	16,796	16,147	16,357	16,663	16,897	16,452	16,686
	Pharmacist-Volunteer Registration	-	-	-	-	-	1	-	-	-	-	-	-	-	-
	Pharmacy	1,773	1,768	1,765	1,765	1,762	1,755	1,751	1,738	1,744	1,737	1,726	1,726	1,727	1,698
	Pharmacy Intern	1,247	1,312	1,267	1,352	1,166	1,235	1,213	1,274	1,074	1,125	1,110	1,144	969	1,041
	Pharmacy Technician	12,421	12,924	13,622	13,875	12,312	12,871	13,310	13,640	12,275	12,607	13,437	13,925	12,933	13,520
	Pharmacy Technician Trainee	5,930	6,258	6,977	8,041	8,581	8,178	8,190	8,063	8,065	8,014	8,234	8,016	7,785	7,864

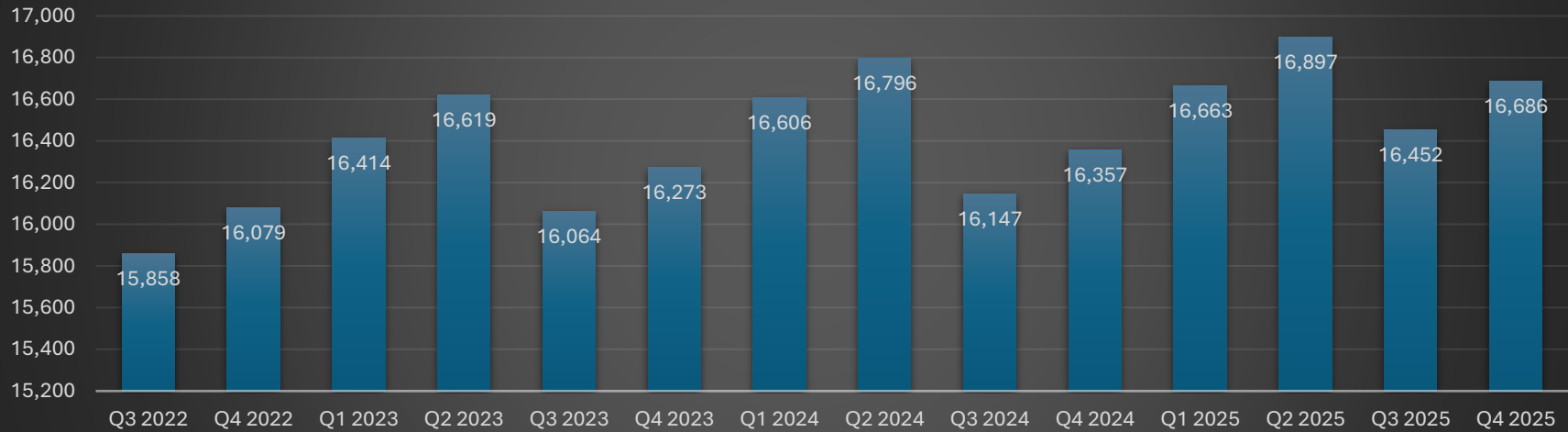
Current Licensure Count

Fiscal Year 2025 - Quarter 4

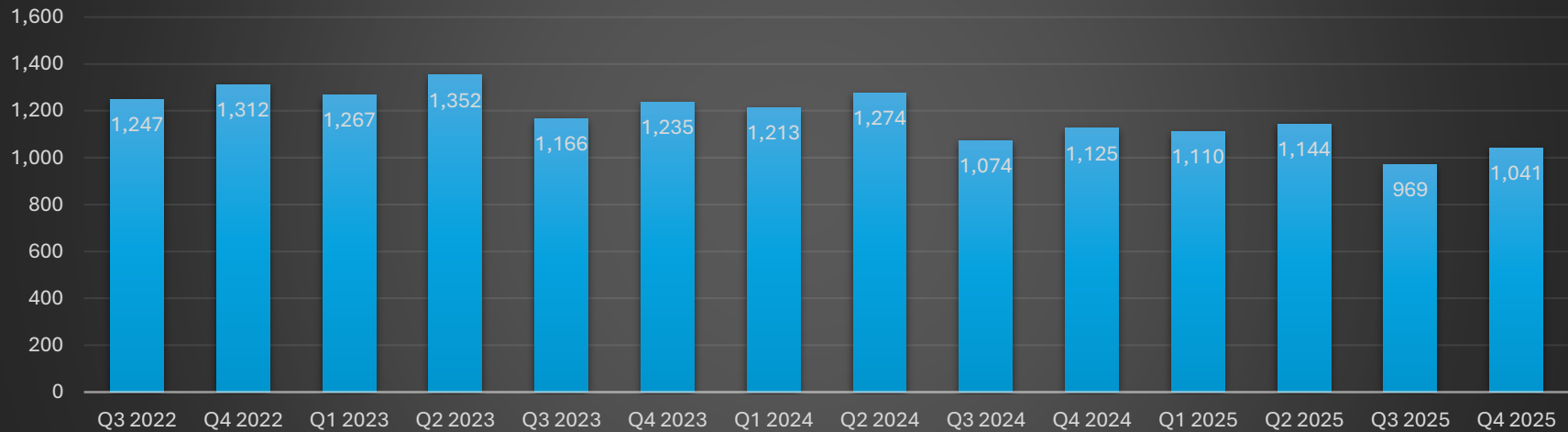
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Licensing Report

Pharmacist Current License Count

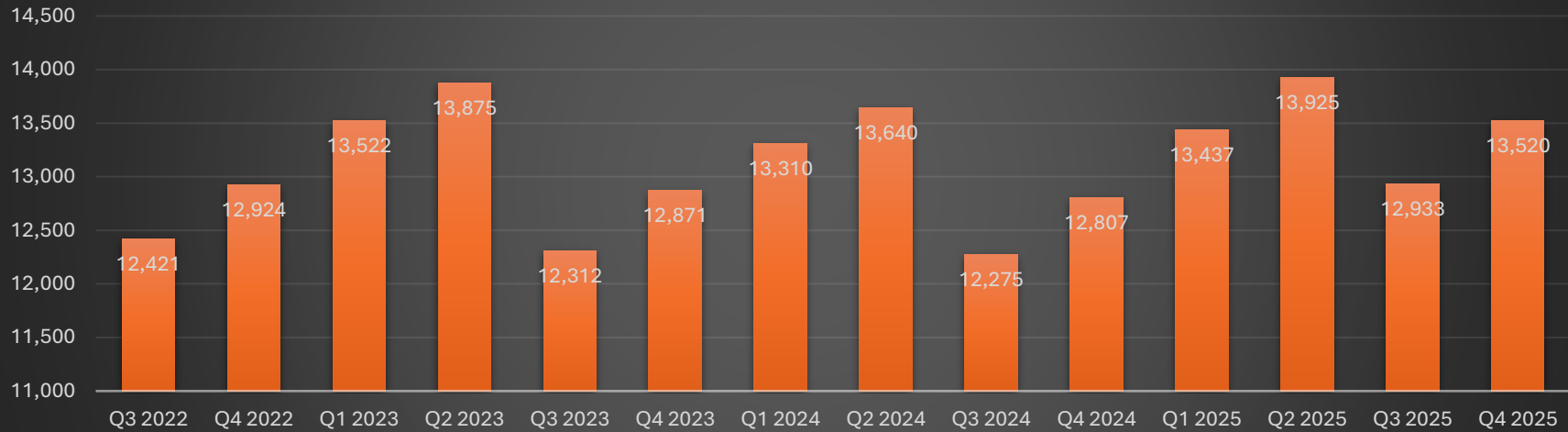


Pharmacy Intern Current License Count

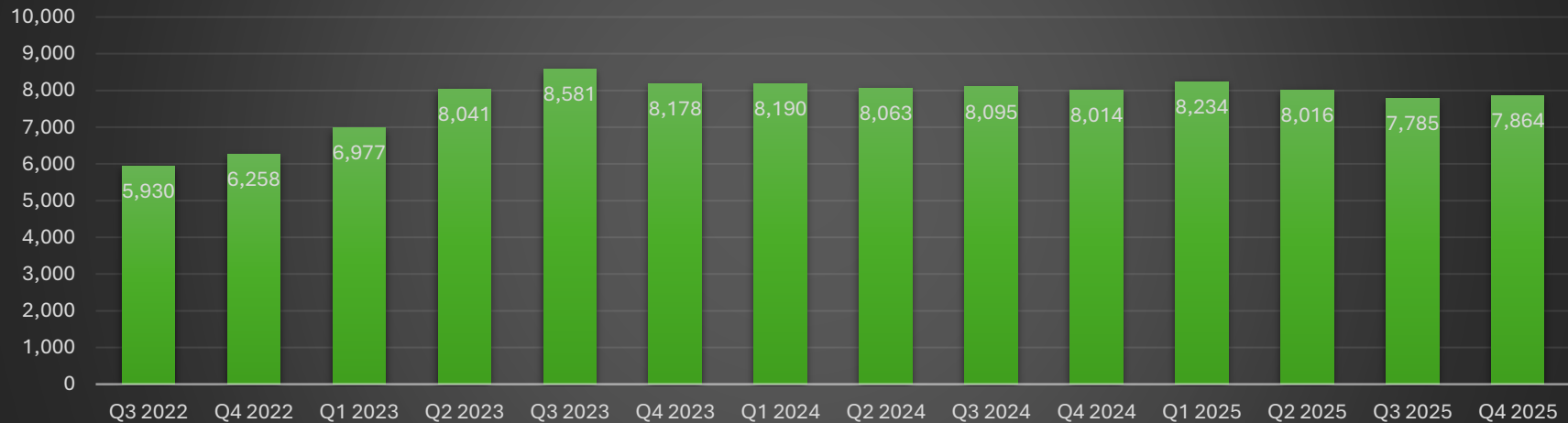


Licensing Report

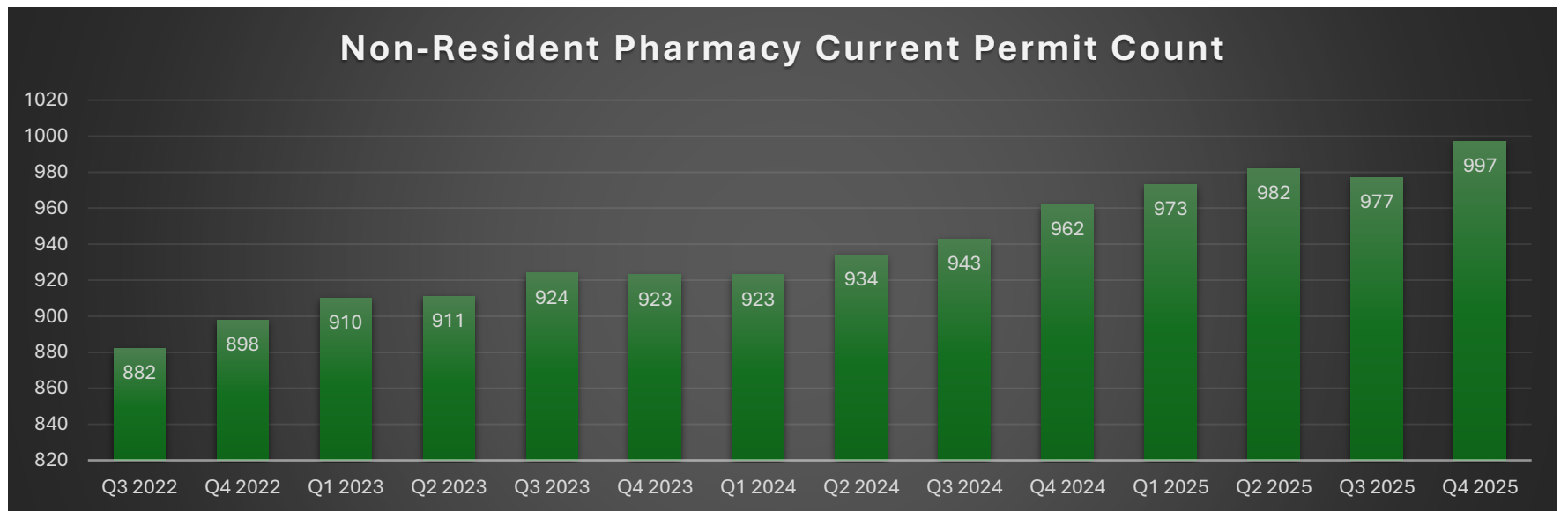
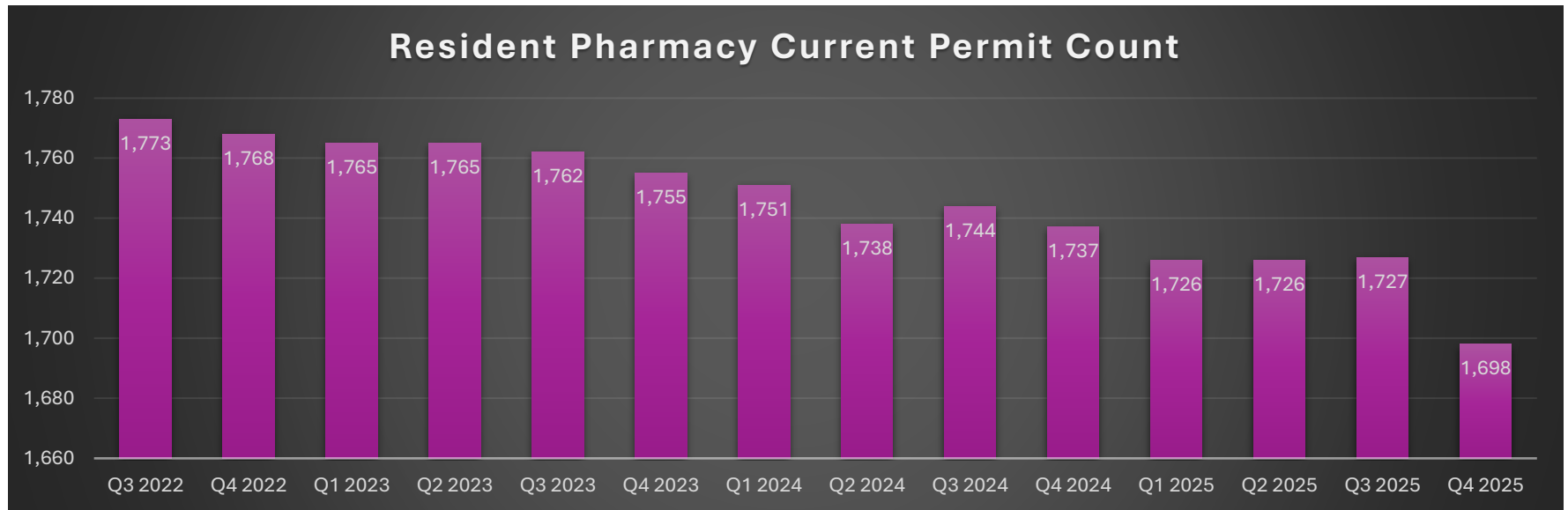
Pharmacy Technician Current License Count



Pharmacy Technician Trainee Current License Count



Licensing Report



Licensing Report



Virginia Department of Health Professions

New License Count

Quarterly Summary

Quarter 4- Fiscal Year 2025

Licenses issued by board and occupation during 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

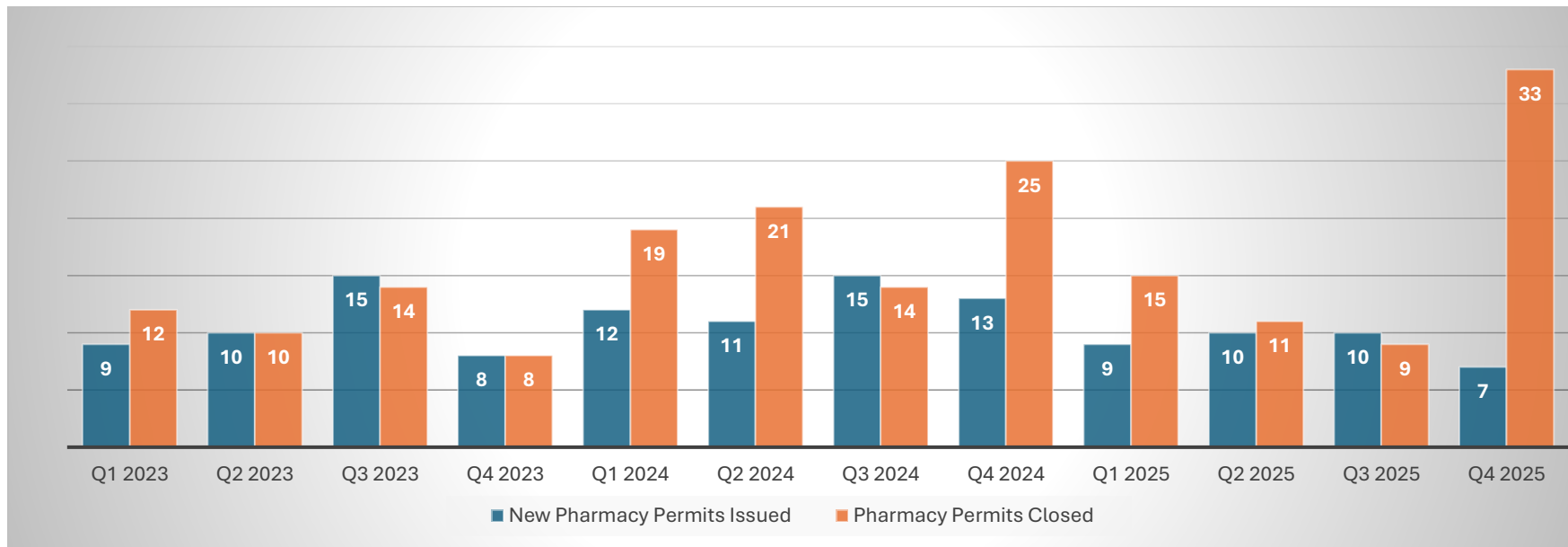
		Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	CURRENT Q4 2025
Pharmacy	Non-resident Outsourcing Facility	-	2	2	1	1	-	-	-	-	3	2	5	2	1
	Non-resident Pharmacy	22	28	23	17	28	18	24	21	25	28	30	20	15	29
	Non-resident Wholesale Distributor	10	4	11	4	9	10	14	9	8	9	15	7	13	18
	Non-restricted Manufacturer	1	1	2	-	2	-	-	-	-	1	2	-	-	-
	Outsourcing Facility	-	-	-	-	1	-	-	-	-	-	-	-	-	-
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	161	194	327	164	152	184	317	168	136	185	296	183	176	220
	Pharmacist-Volunteer Registration	1	-	1	2	-	1	4	-	-	-	-	-	-	-
	Non-resident Third Party Logistics Prov.	4	2	12	13	12	11	11	11	5	8	7	13	9	7
	Non-resident Warehouse	5	1	6	9	3	4	9	6	8	13	13	15	12	11
	Pharmacy Intern	115	86	88	126	132	83	85	104	88	69	76	86	83	85
	Pharmacy	12	10	9	10	15	8	12	11	15	13	9	10	10	7
	Pharmacy Technician	407	445	528	292	383	463	376	270	412	445	562	427	458	503
	Pharmacy Technician Training Program	2	2	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacy Technician Trainee	1,456	692	1,072	1,186	983	971	966	1,103	999	903	1,125	958	970	1,023
	Physician Selling Controlled Substances	20	24	27	40	30	13	31	28	18	7	48	28	17	38
	Physician Selling Drugs Location	4	5	3	3	3	4	3	4	3	3	6	8	5	5
	Pilot Programs	1	2	1	-	-	2	-	2	1	3	-	1	-	2
	Repackaging Training Program	-	-	-	-	-	-	-	-	-	-	-	-	-	-

New Licenses Issued

Quarter 4- Fiscal Year 2025

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Licensing Report



Virginia Board of Pharmacy
September 30, 2025
Licenses Issued

	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	5/1/25 - 7/31/25	License Count 9/12/2025
Business CSR	47	49	114	74	69	55	1,759
CE Courses	0	0	0	0	0	0	0
EMS Designated Locations			403	199	75	44	709
Limited Use Pharmacy Technician	0	0	0	0	0	0	4
Medical Equipment Supplier	3	8	6	1	3	4	219
Non-restricted Manufacturer	0	2	1	0	0	0	36
Outsourcing Facility	0	0	0	0	0	0	1
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	164	212	262	177	187	251	16,958
Pharmacist Volunteer Registration	0	0	0	0	0	0	0
Pharmacy	18	7	11	5	12	9	1,678
Pharmacy Intern	79	52	72	121	77	55	1,025
Pharmacy Technician	407	461	527	427	477	623	14,118
Pharmacy Technician Trainee	864	964	1,175	900	941	1,141	7,678
Physician Selling Controlled Substances	15	18	46	17	37	22	614
Limited Use Practitioner Dispensing	2	1	1	4	3	1	19
Nonresident Manufacturer	5	4	13	1	5	1	239
Nonresident Medical Equipment Supplier	9	16	9	8	10	5	381
Nonresident Outsourcing Facility	3	1	2	4	2	1	39
Nonresident Pharmacy	26	27	33	12	27	25	1,001
Nonresident Third Party Logistics Provider	6	8	12	7	11	4	260
Nonresident Warehouser	9	15	9	17	11	14	187
Nonresident Wholesale Distributor	9	12	12	7	17	19	654
Physician Selling Drugs Location	1	8	3	9	5	5	134
Pilot Programs	4	0	1	0	2	0	6
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	30
Third Party Logistics Provider	0	0	0	0	1	0	6
Warehouser	1	2	1	2	0	4	126
Limited Use Facility Dispensing	0	1	1	1	0	1	7
Wholesale Distributor	1	2	1	3	1	0	61
Total	1,673	1,870	2,715	1,996	1,973	2,284	47,951

September 30, 2025 - Full Board of Pharmacy Meeting

Quarterly Inspection Completed Review by License Type – Date Range: 4/01/2025 – 6/30/2025

Insp Status	License Type	Change of Location	Compliance	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	6		53		1	3	71	134
	Third Party Logistics Provider								0
	Limited-Use Facility Dispensing			1					1
	Medical Equipment Supplier	3		5			1	6	15
	Non-restricted Manufacturer								0
	Pharmacy	5	7	9		8	33	232	294
	Physician Selling Drugs Location			4				12	16
	Pilot Programs								0
	Warehouser	2		2		1		6	11
	Wholesale Distributor								0
Completed Total		16	7	74	0	10	37	327	471
Completed Virtual	Business CSR	3		19		1	1		24
	Warehouser							1	1
	Pharmacy						8		8
Completed Virtual Total		3	0	19	0	1	9	1	33
Grand Total		19	7	93	0	11	46	328	504

September 30, 2025 - Full Board of Pharmacy Meeting

Routine Pharmacy Inspections – Date Range: 4/01/2025 – 6/30/2025

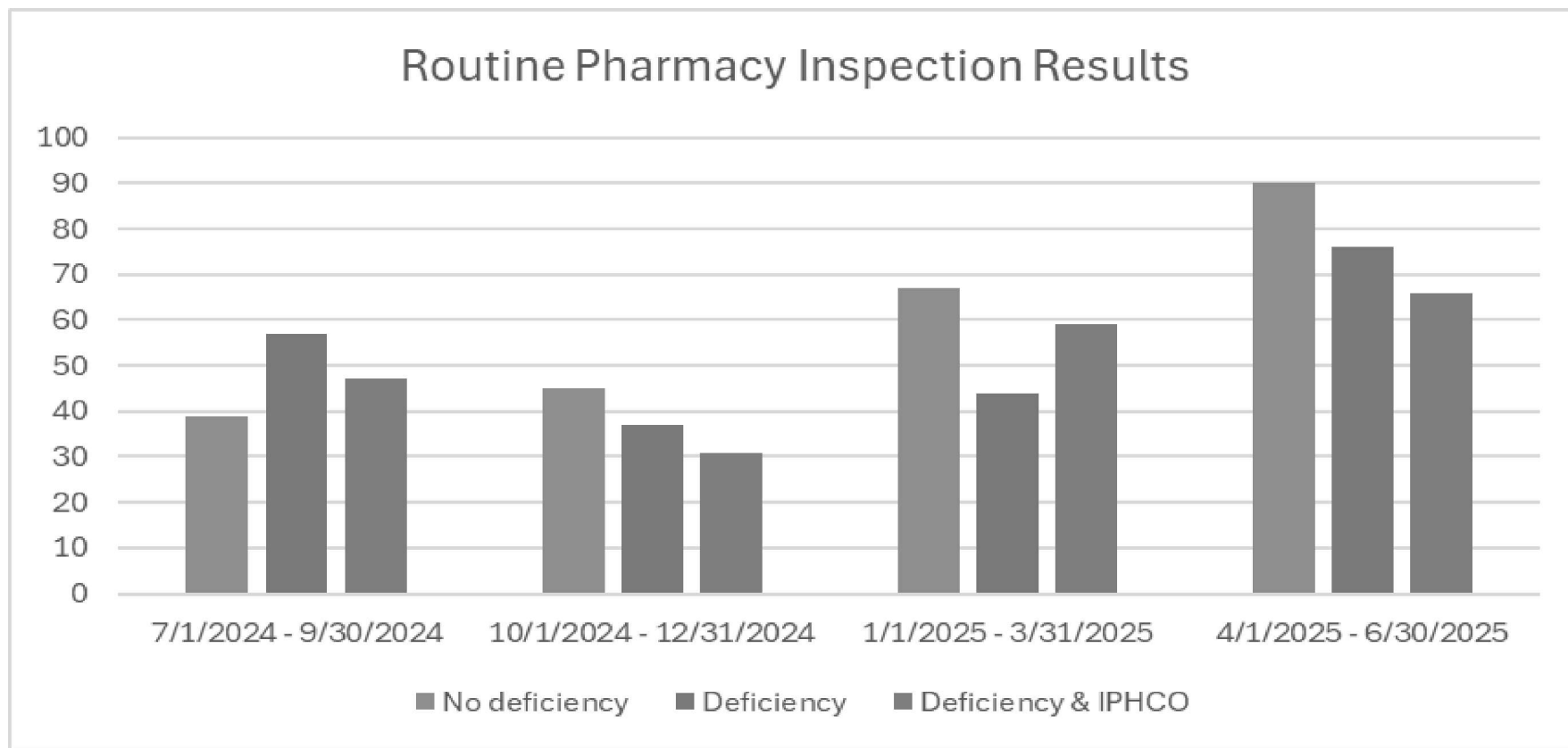
Top 5 cited deficiencies

Description	Number of times cited
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2.	23
130a. Compounded products not properly labeled.	20
124. Labels do not include all required information.	17
130. Required compounding/dispensing/distribution records not complete and properly maintained.	17
127. Repackaging records and labeling not kept as required or in compliance.	16

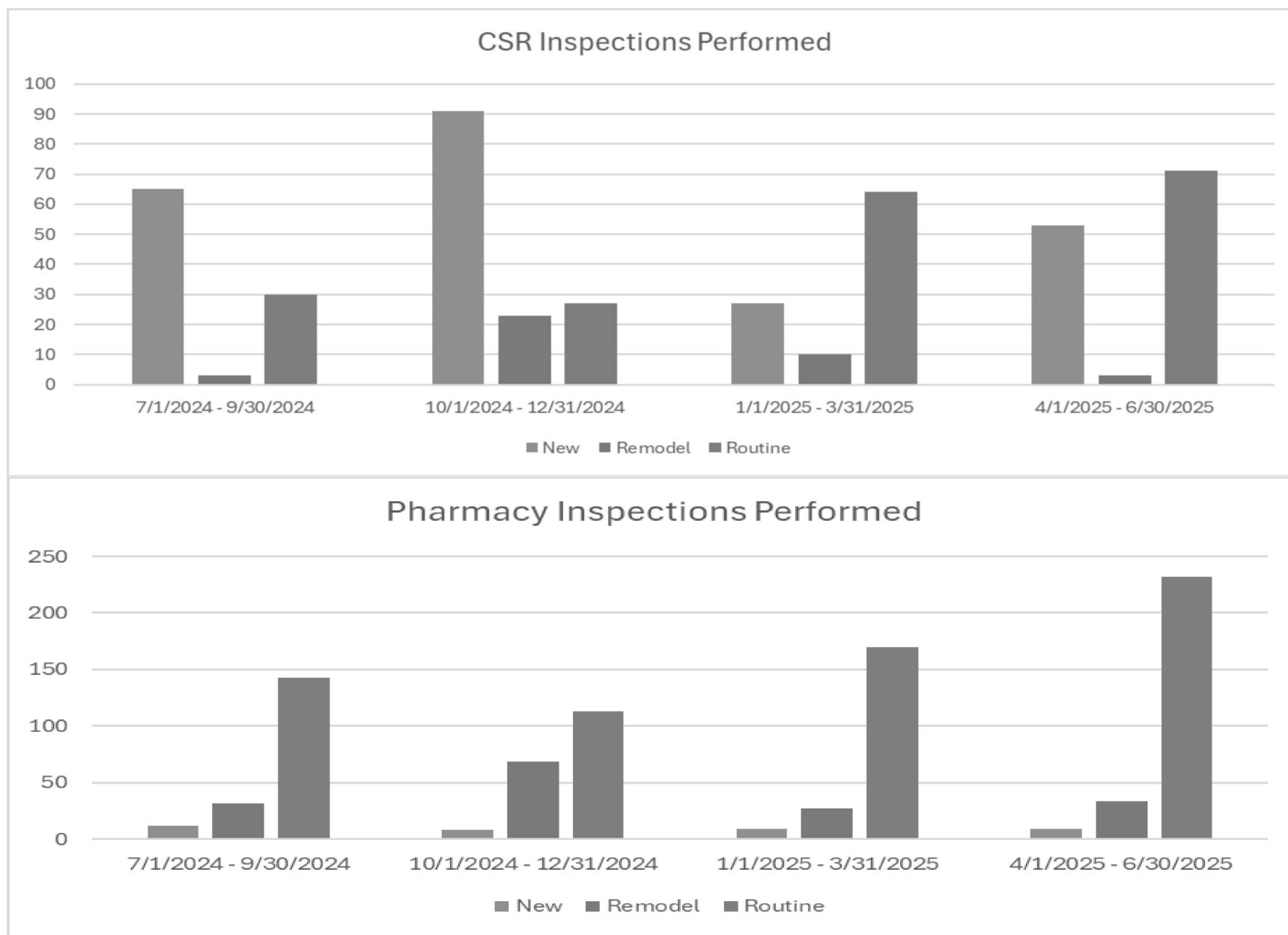
Routine Inspection Results - 4/01/2025 – 6/30/2025

License Type	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	28		40	68
Limited-Use Facility Dispensing	0		0	0
Wholesale Distributor	0		0	0
Medical Equipment Supplier	5		0	5
Pharmacy	76	66	90	232
Physician Selling Drugs Location	2		8	10
Warehouser	1		5	6
Grand Total	112	66	143	321

September 30, 2025 - Full Board of Pharmacy Meeting



September 30, 2025 - Full Board of Pharmacy Meeting



Cases Received, Open & Closed

Agency Summary

Quarter 4 – 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

	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	CURRENT Q4 2025
Number of Cases Received	1,621	1,556	1,481	1,773	1,898	2,050	1,961	2,054	1,881	1,941	1,876	1,929	2,244
Number of Cases Open	4,246	4,174	4,392	4,672	4,783	4,792	5,079	5,174	5,107	5,183	5,114	5,186	5,568
Number of Cases Closed	1,533	1,754	1,586	1,857	1,952	2,075	1,674	2,036	1,934	1,832	1,949	1,854	1,878



Virginia Department of Health Professions

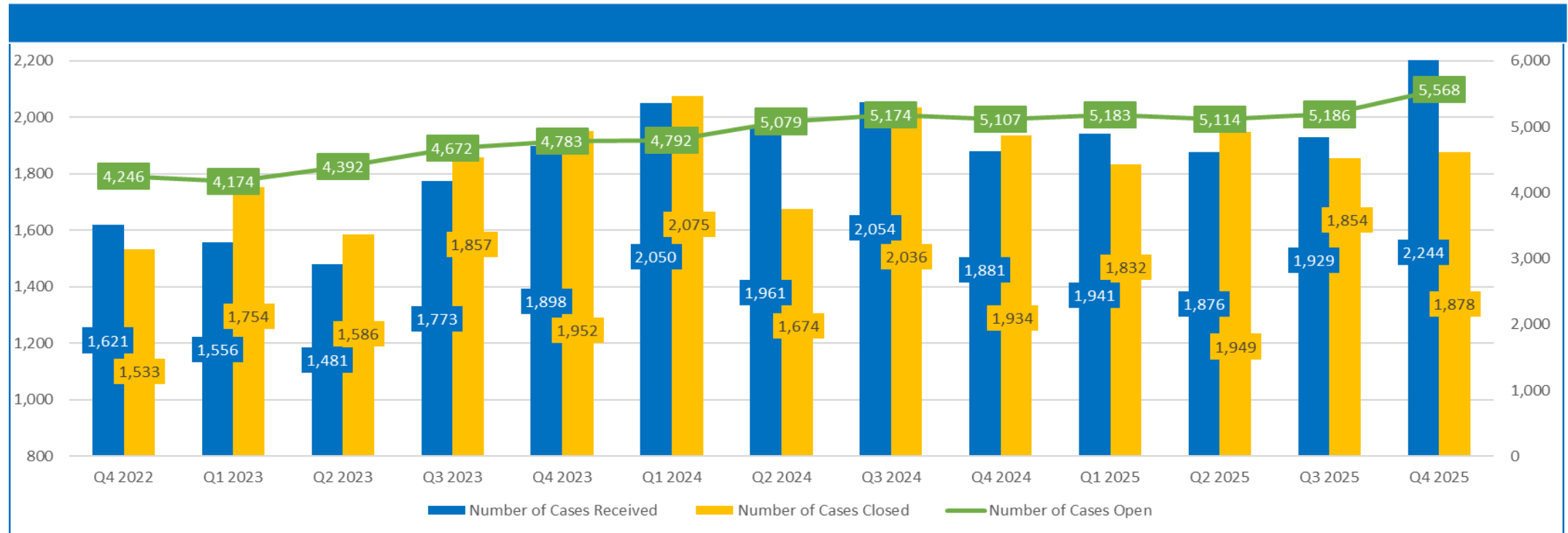
Cases Received, Open & Closed

Agency Summary

Quarter 4 – Fiscal Year 2025

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

Quarter Date Ranges	
Quarter 1	July 1 - September 30
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Quarter 4	April 1 - June 30



Cases Received, Open & Closed

Agency Summary

Quarter 4 – Fiscal Year 2025

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

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

														CURRENT
		Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	Q4 2025
Pharmacy	Number of Cases Received	185	215	210	204	249	206	179	204	172	174	167	200	229
	Number of Cases Open	409	416	437	384	442	390	372	383	348	321	310	341	372
	Number of Cases Closed	181	228	214	288	220	257	199	195	210	200	179	174	207
Physical Therapy	Number of Cases Received	3	15	13	10	4	10	27	10	9	18	15	16	15
	Number of Cases Open	39	35	34	36	35	31	55	52	33	39	46	48	55
	Number of Cases Closed	10	21	18	8	5	14	4	15	29	12	9	15	8
Psychology	Number of Cases Received	34	20	18	22	31	39	35	32	45	46	41	28	37
	Number of Cases Open	162	163	169	174	172	167	157	154	159	170	167	154	150
	Number of Cases Closed	22	26	16	24	49	44	43	37	40	35	43	42	50

Cases Received, Open & Closed

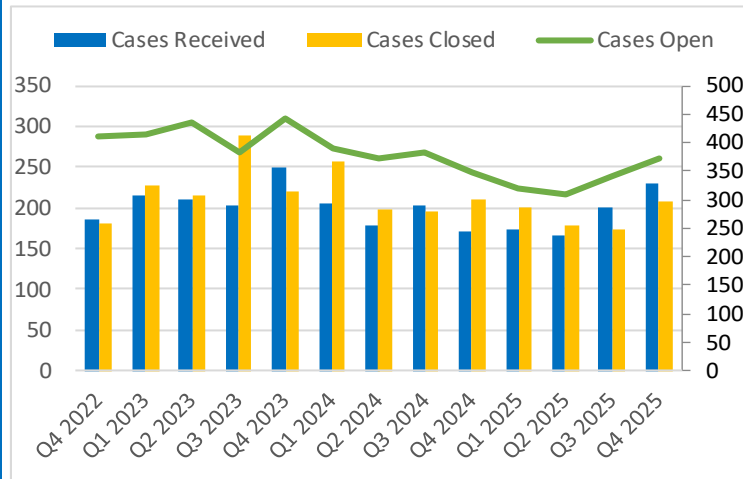
Agency Summary

Quarter 4 – Fiscal Year 2025

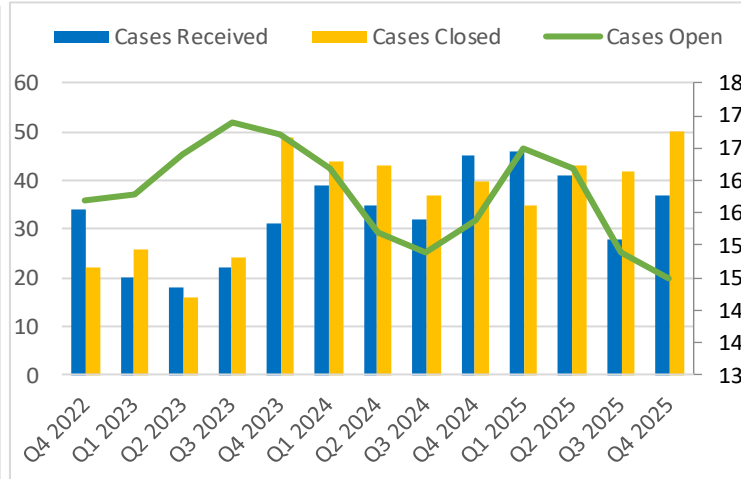
The “Received, Open, Closed” table below shows the number of received and closed cases during the quarters specified and a “snapshot” of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
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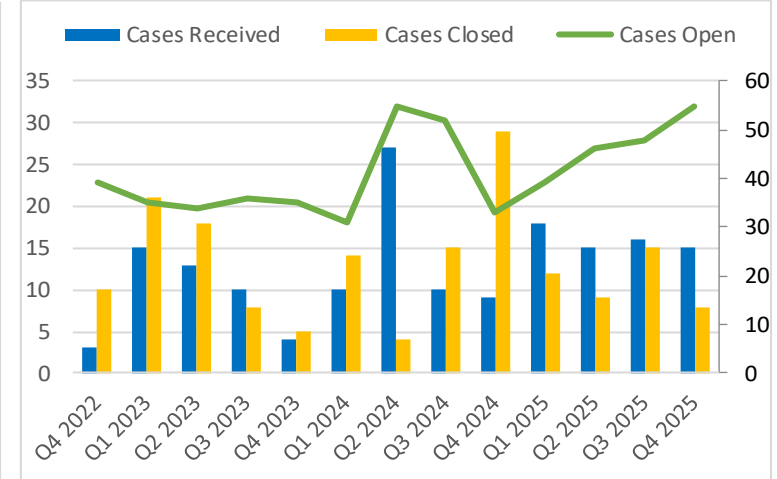
Pharmacy



Psychology



Physical Therapy



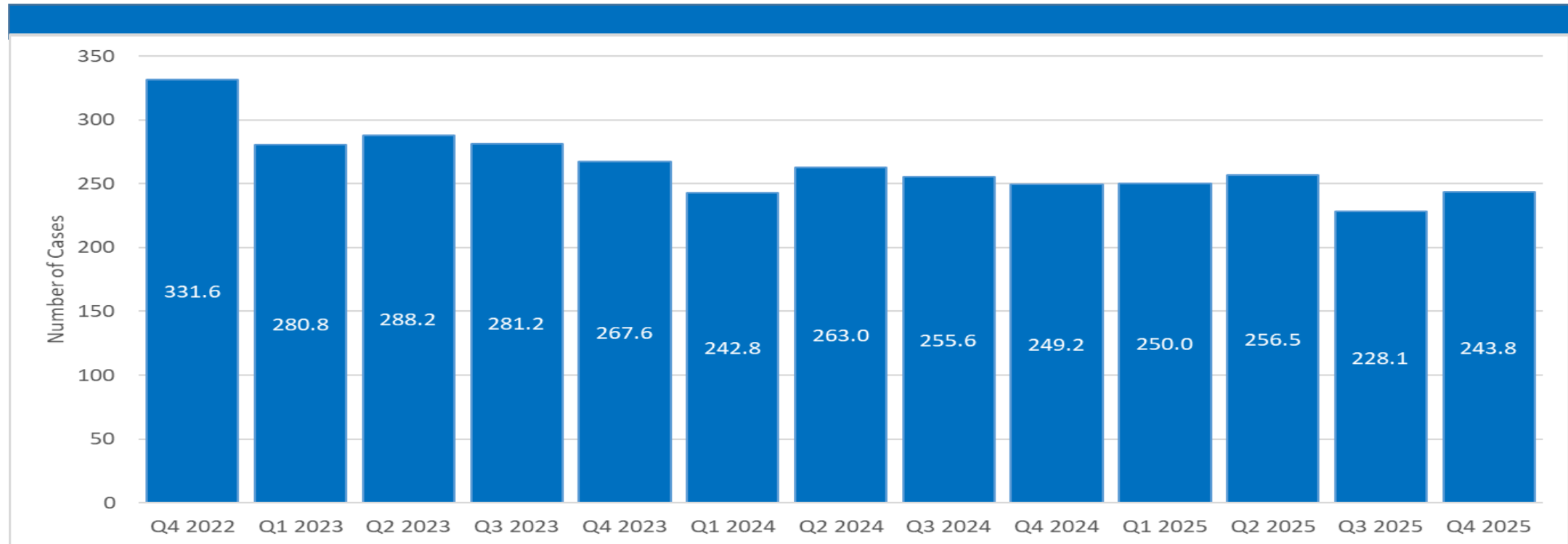


Virginia Department of Health Professions

Average Age of Cases Closed Quarterly Summary

Quarter 4- Fiscal Year 2025

The average age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter specified.





Virginia Department of Health Professions

Average Age of Cases Closed Quarterly Summary Quarter 4- Fiscal Year 2025

The average age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter specified.

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

BOARD													CURRENT
	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	Q2 2024	Q3 2024	Q4 2024	Q1 2025	Q2 2025	Q3 2025	Q4 2025
Audiology	231.0	309.4	291.0	216.7	278.0	137.6	179.8	325.7	390.6	163.3	310.7	194.5	554.0
Counseling	187.1	250.0	219.8	232.7	228.7	220.2	295.7	227.4	229.3	215.9	164.3	283.6	305.0
Dentistry	410.7	343.8	226.4	258.8	308.6	292.1	272.5	261.4	230.3	314.0	331.0	307.2	291.6
Funeral Directing	445.0	342.1	382.1	310.9	361.4	284.8	477.4	384.4	515.3	253.1	507.1	314.2	174.2
Long-Term Care Administrators	554.8	415.4	362.4	506.9	266.7	387.7	386.9	366.8	332.3	286.2	499.2	297.9	382.8
Medicine	233.6	256.3	275.0	186.9	203.7	169.2	190.8	166.7	157.8	192.5	162.4	129.4	137.4
Nurse aide	427.3	454.8	476.3	460.3	351.3	329.3	401.8	316.3	299.8	290.3	352.9	237.4	333.2
Nursing	494.1	380.6	384.7	430.9	380.7	329.5	306.5	335.5	349.3	355.0	302.9	306.4	340.5
Optometry	91.1	221.9	240.7	183.5	104.0	170.6	387.3	112.9	179.5	161.9	363.9	202.9	107.5
Pharmacy	130.7	124.3	147.6	197.5	104.6	135.8	164.7	221.2	134.4	155.3	164.0	119.6	134.0
Physical Therapy	436.4	238.2	405.8	202.7	580.3	366.6	106.3	390.0	292.0	440.1	492.5	132.1	536.7
Psychology	127.5	455.1	460.1	381.6	537.2	617.0	659.0	422.9	282.6	187.1	425.4	573.9	314.9
Social Work	136.5	130.9	63.7	204.3	95.9	211.3	51.8	282.5	446.3	226.0	170.2	477.9	299.2
Veterinary Medicine	298.6	205.9	209.6	214.6	207.0	173.5	274.7	236.7	271.8	255.6	368.3	252.0	285.2
Agency total	331.6	280.8	288.2	281.2	267.6	242.8	263.0	255.6	249.2	250.0	256.5	228.1	243.8

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q4 2021 - Q4 2025

Arne W. Owens

Director

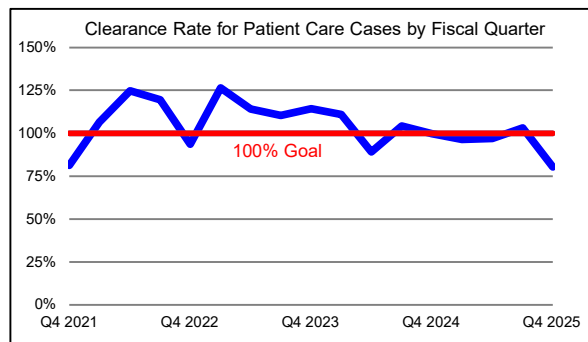
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."

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.

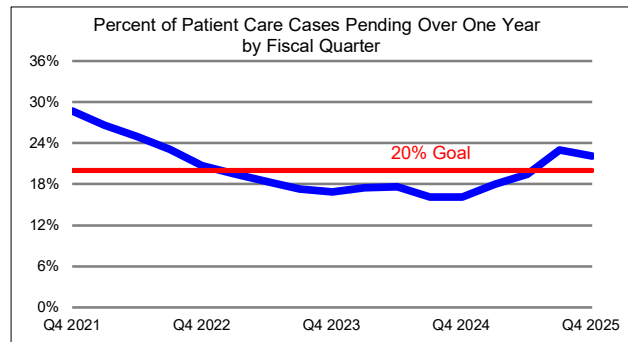
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 80%, with 1,453 patient care cases received and 1,168 closed.



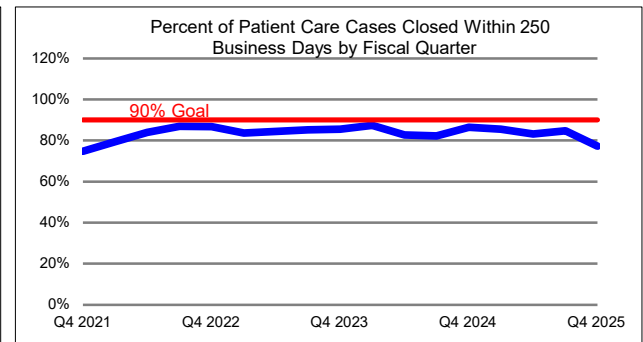
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

The current quarter shows 22% patient care cases pending over 250 business days, with 883 of the 3,995 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 77% patient care cases pending over 250 business days, with 861 of the 1,114 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: 63%

442 Cases Received

278 Cases Closed

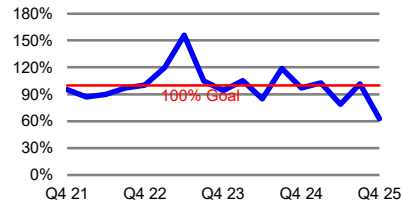
Pending Caseload: 7%

60 cases out of 802 are pending over 250 Days

Time to Disposition: 94%

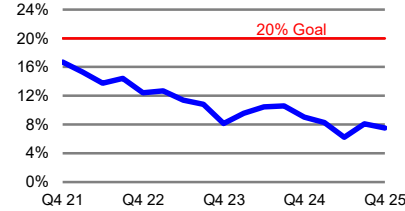
256 cases out of 271 were closed within 250 Days

Clearance Rate

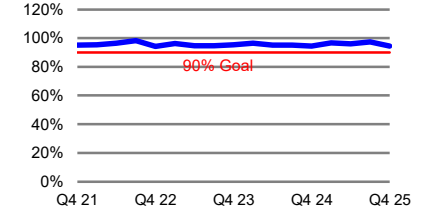


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition



Dentistry

Clearance Rate: 66%

115 Cases Received

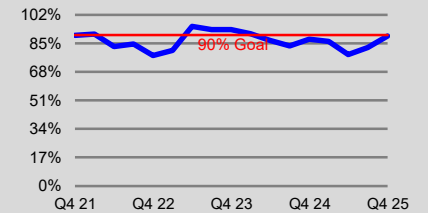
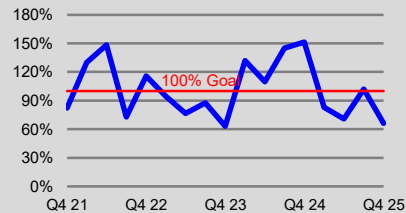
76 Cases Closed

Pending Caseload: 14%

54 cases out of 376 are pending over 250 Days

Time to Disposition: 89%

67 cases out of 75 were closed within 250 Days



Pharmacy

Clearance Rate: 96%

91 Cases Received

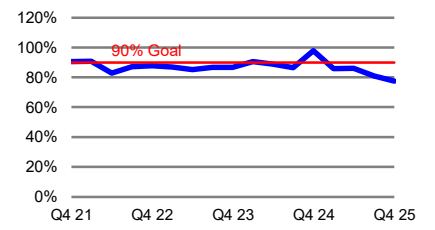
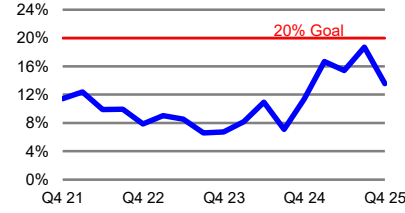
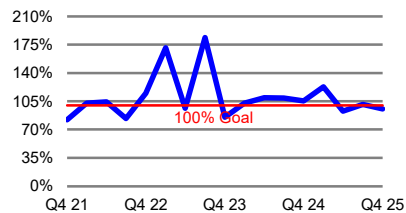
87 Cases Closed

Pending Caseload: 14%

27 cases out of 199 are pending over 250 Days

Time to Disposition: 78%

66 cases out of 85 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, Q4 2021 - Q4 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.

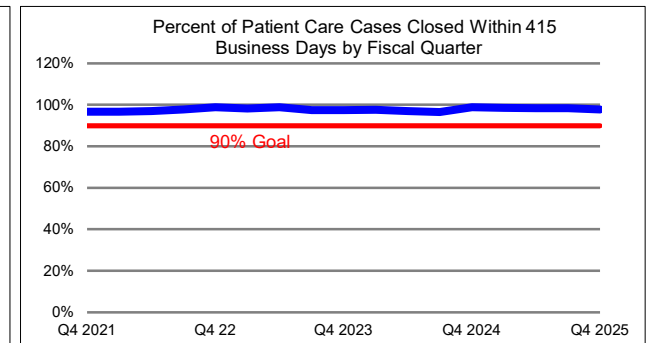
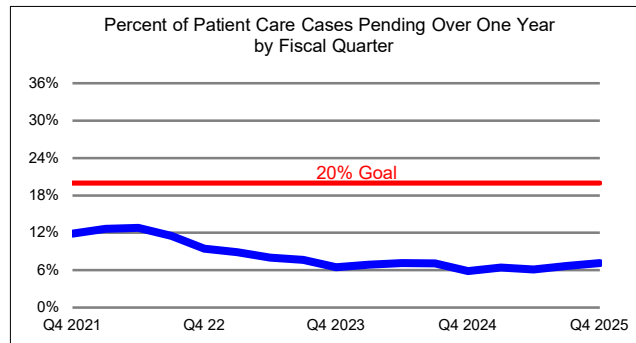
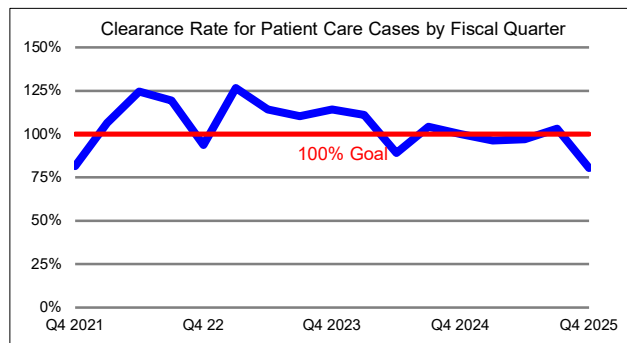
Age of Pending Caseload - the percent of open patient care cases over 415 business days old. This measure tracks the backlog of patient care cases older than 415 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

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's clearance rate is 80%, with 1,453 patient care cases received and 1,168 closed.

The current quarter shows 7% patient care cases pending over 415 business days, with 284 of the 3,995 patient care cases pending over 415 business days.

The current quarter shows 98% of patient care cases being resolved within 415 business days, with 1,089 of the 1,114 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: 63%

442 Cases Received

278 Cases Closed

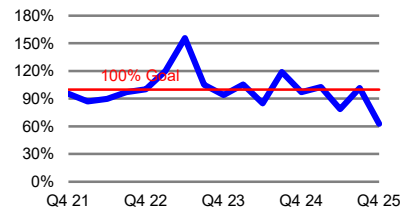
Pending Caseload Over 415 Days: 2%

18 cases out of 802 are pending over 415 Days

Time to Disposition Within 415 Days: 100%

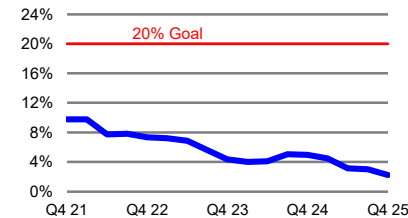
270 cases out of 271 were closed within 415 Days

Clearance Rate

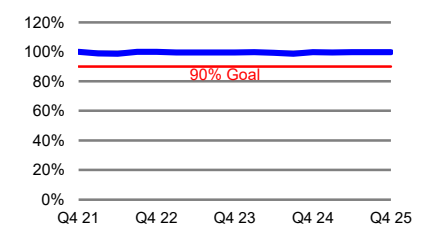


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition



Dentistry

Clearance Rate: 66%

115 Cases Received

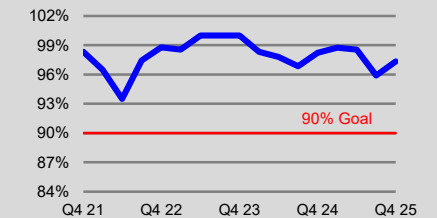
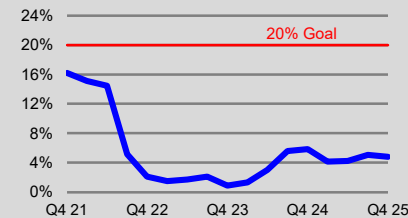
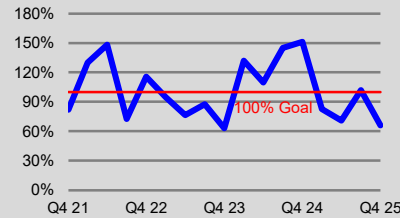
76 Cases Closed

Pending Caseload Over 415 Days: 5%

18 cases out of 376 are pending over 415 Days

Time to Disposition Within 415 Days: 97%

73 cases out of 75 were closed within 415 Days



Pharmacy

Clearance Rate: 96%

91 Cases Received

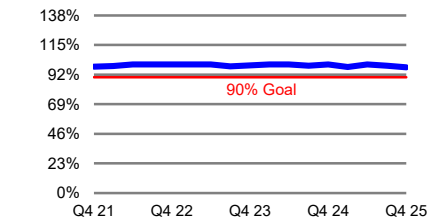
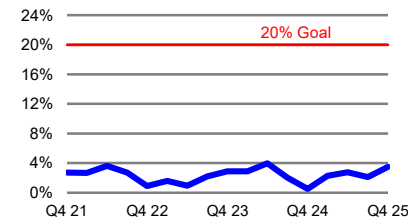
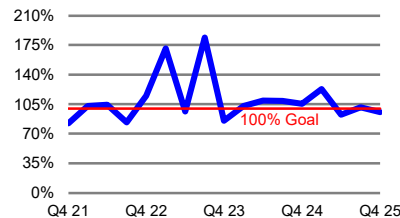
87 Cases Closed

Pending Caseload Over 415 Days: 4%

7 cases out of 199 are pending over 415 Days

Time to Disposition Within 415 Days: 98%

83 cases out of 85 were closed within 415 Days

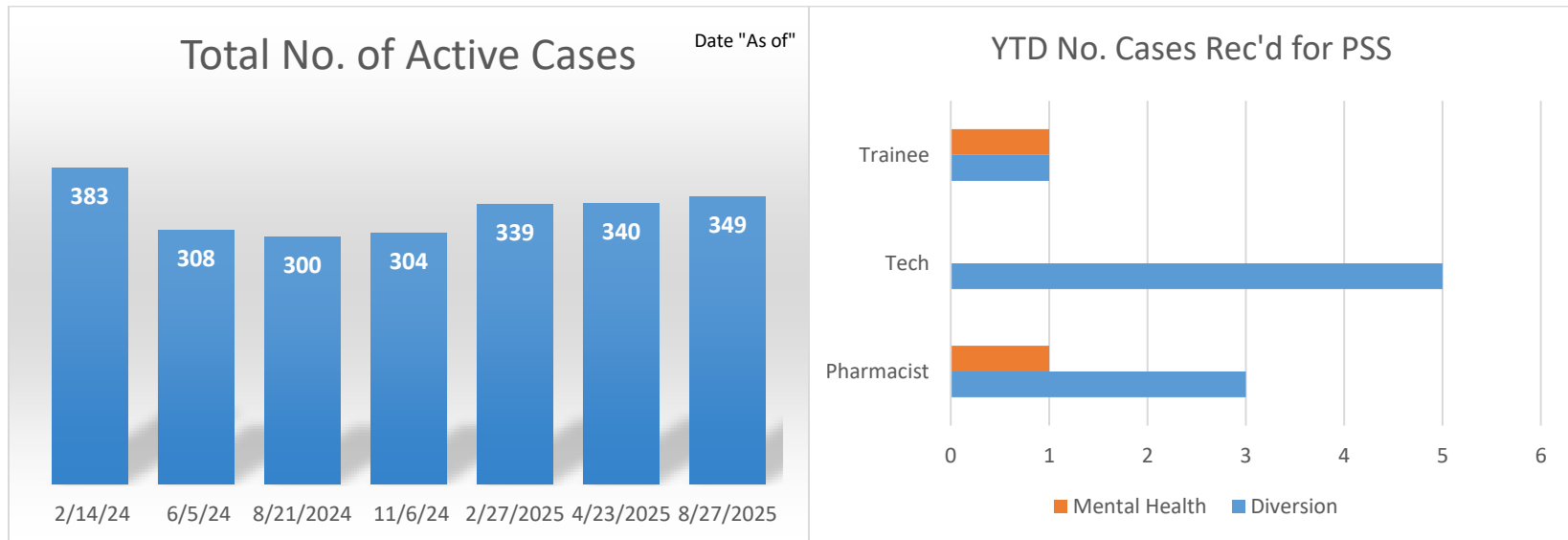


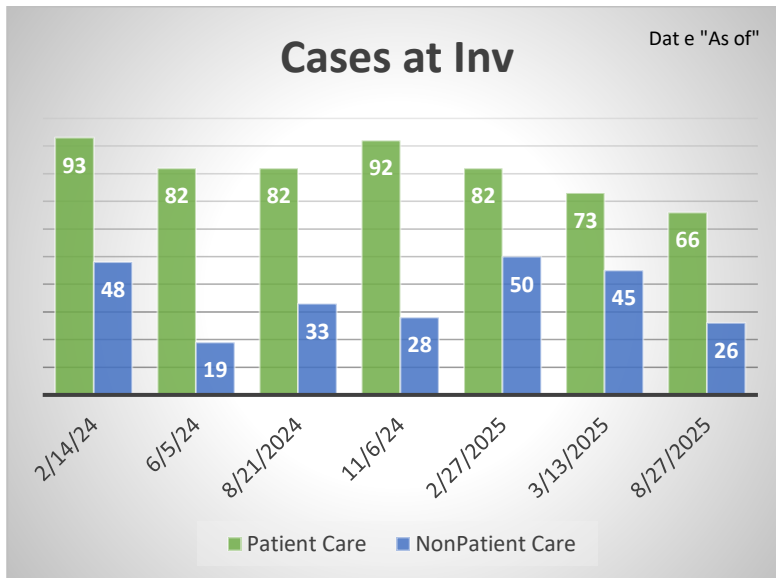
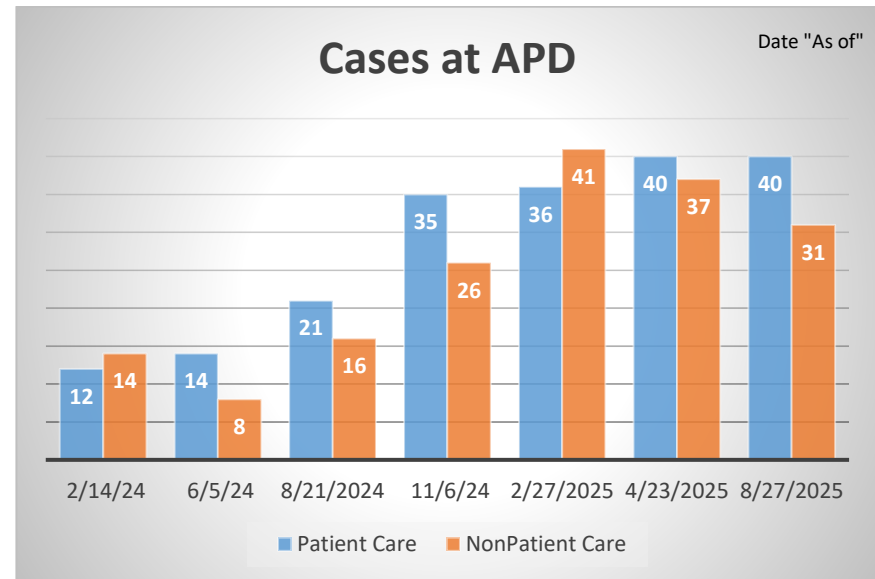
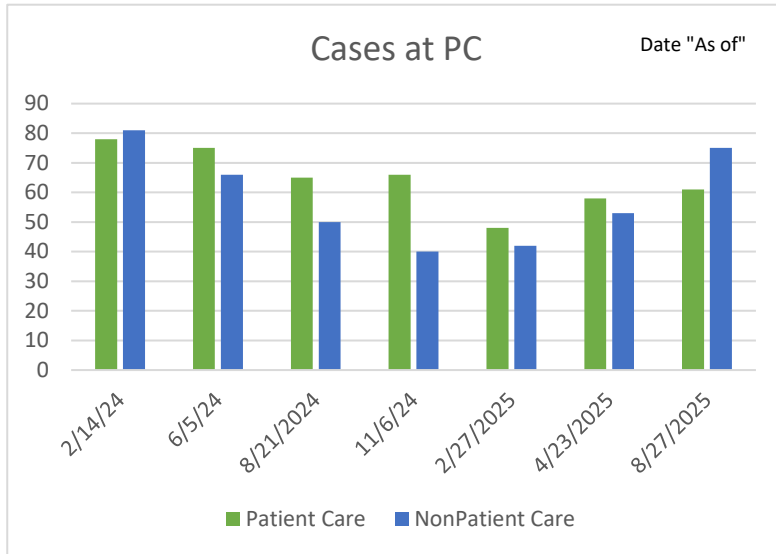
Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.
Note: If no cases are received and some cases are closed, we assign 100% as clearance rate

Discipline Program Report

Open Cases as of 8/27/25:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	OAG	TOTALS
Patient Care Cases	61	40	66	2	9	0	0	3	0	181
Non-Patient Care Cases	75	31	26	5	8	1	22	0	0	168
									TOTAL:	349





Upcoming Disciplinary Proceedings		
October 9, 2025	Agency Subordinate	IFC
October 15, 2025	Yuan/Richards-Spruill	Innovative Pilot
October 21, 2025	All Members	Formal Hearings
November 6, 2025	Agency Subordinate	IFC
November 18, 2025	All Members	Formal Hearings
November 20, 2025	Ratliff/Kale	IFC
December 9, 2025	Kocot/Dowdy	Pilot SCC
December 10, 2025	All Members	FBM and Formal Hearings
December 11, 2025	Dowdy/Hoffer	IFC

Executive Director's Report – September 30, 2025

Staff:

- ❖ Vacant disciplinary administrative assistant position

In-person or Virtual Meetings Attended Since May Board Meeting:

- ❖ FDA Interstate Compounding Meeting – June 4-5
- ❖ Monthly Interagency Standing Meeting
- ❖ Forensic Science Board Meeting – July (O'Halloran)
- ❖ Clinical Psychologist Prescribing Meetings SB 752 – July and August
- ❖ New Board Member Orientation Meeting for Tim Robertson – July (Juran, Shinaberry, Logan, and O'Halloran)
- ❖ Discussions regarding JCHC Pharmacy Desert Study
- ❖ School Health Services Committee, Subcommittee to Study SB 1303
- ❖ NABP Monthly Executive Officers' Call
- ❖ Therapeutic Interchange Work Group Meeting – August
- ❖ NABP Task Force to Study Drugs Lost in Transit – Chairman – August
- ❖ Monthly Planning Meetings for NABP/AACP Districts 1 & 2 Meeting
- ❖ Joint Subcommittee for Health and Human Resources Oversight – August

Upcoming In-person or Virtual Meetings:

- ❖ Monthly Interagency Standing Meeting
- ❖ Forensic Science Board Meeting – October
- ❖ Monthly Planning Meetings for NABP/AACP Districts 1 & 2 Meeting
- ❖ Discussions regarding JCHC Pharmacy Desert Study
- ❖ NABP Monthly Executive Officers' Call
- ❖ NABP/AACP Districts 1 & 2 Meeting – October 15-17
- ❖ NABP .Pharmacy Executive Board Meeting - October
- ❖ NABP Executive Officer, Legal Counsel, Compliance Officer, and Board Member Forums – October 27-31
- ❖ Regulation Committee Meeting – November 5
- ❖ Full Board Meeting – December 10

Presentations Given Since May Board Meeting:

- ❖ Virginia Pharmacy Association, Board of Pharmacy Law Update – August
- ❖ Appalachia College of Pharmacy, Board of Pharmacy Update – August
- ❖ VCU School of Pharmacy, Board of Pharmacy Update – August

Upcoming Presentations:

- ❖ Shenandoah School of Pharmacy, Board of Pharmacy Update – TBD
- ❖ Hampton University School of Pharmacy, Board of Pharmacy Update – TBD
- ❖ Virginia Society of Health-Systems Pharmacists Fall Seminar, November 7