COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Full Board Meeting
March 28, 2024
9AM

TOPIC	PAGES
Call to Order of Public Hearing: Dale St.Clair, PharmD, Chairman	
• Welcome & Introductions	
Public Hearing:	
• Placing Certain Chemicals into Schedule I	**90**
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Dale St.Clair, PharmD, Chairman	
• Approval of Agenda	
Approval of Previous Board Meeting Minutes:	**3-23**
• December 6, 2023, Full Board Meeting	
• December 6, 2023, Public Hearing	
• January 29, 2024, Telephone Conference Call	
• February 5, 2024, Telephone Conference Call	
• February 7, 2024, Formal Hearing	
• February 14, 2024, Telephone Conference Call	
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: Arne Owens	
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh	
• Chart of Regulatory Actions	**24-27**
• 2024 Legislative Report	**28-43**
• Consideration to amend EMS-related regulations	**44-78**
• Adoption of exempt final regulation to place certain chemicals into Schedule I	**79-90**
• Adoption of proposed regulations for the 2023 pharmacists initiating treatment action	**91-96**
• Amend Guidance Document110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*	**97-114**
• Amend Guidance Document 110-33 *Pharmacy Interns as Pharmacy Technicians, Pharmacy Technician Ratio*	**115-117**
• Amend Guidance Document 110-35 *Guidance on Virginia Prescription Requirements*	**118-128**
• Repeal Guidance 110-39 *Guidance for Continuous Hours Worked by Pharmacists and Breaks*	**129-136**

New Business:

- Amend TB One-Step and Two-Step statewide protocols **137-167**
- Amend HIV PrEP statewide protocol **Handout**
- Presentation and adoption of 2023 Pharmacist and Pharmacy Technicians Workforce Survey Reports, Barbara Hodgdon, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division **168-228**

Reports:

- Chairman's Report –Dale St.Clair, PharmD **Verbal**
- Report on Board of Health Professions – Sarah Melton, PharmD **Verbal**
- Report on Licensure of Individuals and Facilities – Beth O'Halloran, RPh/Ryan Logan, RPh **229-232**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **233-236**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **237-243**
- Report on Transition of Pharmaceutical Processor Program – Annette Kelley, M.S., C.S.A.C. **244-245**
- Executive Director's Report – Caroline D. Juran, RPh **246**

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

Adjourn

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Wednesday, December 6, 2023

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

CALL TO ORDER:	A full board meeting was called to order at 9:12AM.
PRESIDING:	Dale St Clair, PharmD, Chairman
MEMBERS PRESENT:	Cheri Garvin, RPh Larry Kocot, JD Ling Yuan, PharmD Wendy Nash, PharmD Patricia Richards-Spruill, RPh Kristopher Ratliff, DPh Shannon Dowdy, PharmD Michelle Hoffer, JD
MEMBERS ABSENT:	Sarah Melton, PharmD
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director Ryan Logan, Deputy Executive Director Ellen B. Shinaberry, PharmD, Deputy Executive Director Annette Kelley, Deputy Executive Director Sorayah Haden, Executive Assistant Arne Owens, DHP Agency Director James Jenkins, RN, Agency Deputy Director Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs James Rutkowski, Senior Assistant Attorney General Shannon Harris, Administrative and Office Specialist III
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	David M. Flammia Wendy Nash Tim Robertson
QUORUM:	With 9 members present, a quorum was established.
APPROVAL OF AGENDA:	The chairman indicated a subsequently amended agenda had been provided as a

handout which included one additional topic at the end of the Legislative/Regulatory/Guidance section to Amend Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*. A handout related to this topic was also provided. Hearing no additional items, the Chairman stated the amended agenda was accepted as presented and the Board proceeded.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

Hearing no corrections or additions, the Chairman indicated the minutes for the meetings held between September 26, 2023 and November 8, 2023 were approved as presented.

PUBLIC COMMENT:

Jamie Fisher, Executive Director, Virginia Pharmacy Association (VPhA), provided a public comment expressing VPhA's support of the pharmacy working conditions regulations and progress. VPhA is working with the Department of Medical Assistance Services regarding reimbursement fees. VPhA believes current reimbursement fees will negatively impact patient care by creating pharmacy deserts in vulnerable areas. She is hearing that some pharmacies may feel financially forced to no longer accept Medicaid. Ms. Fisher also stated increasing the pharmacist to pharmacy technician ratio will not help. Nothing precludes the pharmacy from currently scheduling an additional pharmacist who could then supervise up to an additional 4 pharmacy technicians. She announced that VPhA's annual meeting is scheduled for March 7-10 in Roanoke. A handout summarizing the public comment was provided to the Board.

DHP DIRECTOR'S REPORT:

Mr. Owens provided the Director's Report including a welcome to the new board members, Shannon Dowdy, PharmD and Michelle Hoffer, JD. Mr. Owens reported multiple business processes improvements were taking place throughout the agency with a current focus on licensing. New energy-efficient lighting has been installed throughout the building and parking lot. The proposed budget has been submitted and the official numbers will be presented to the upcoming General Assembly. The agency is still waiting to receive the final decision regarding legislative proposals submitted by DHP to the Governor for consideration. Healthcare workforce remains a top priority. Jim Jenkins is a co-lead on the Right Help, Right Now initiative. DHP is engaging with other agencies regarding reimbursement and will provide updates. Mr. Owens thanked the board and the Pharmaceutical Processor Program staff for their hard work with regulating medical cannabis for the past several years. Staff is preparing for the transition of the program to the Virginia Cannabis Control Authority as of 1/1/24.

LEGISLATIVE/ REGULATORY/GUIDANCE

CHART OF REGULATORY

Ms. Barrett briefly reviewed the chart of regulatory actions in the agenda

ACTIONS

packet and provided updated information that has taken place since the preparation of the chart as indicated on Regulatory Town Hall.

ADOPTION OF PROPOSED REGULATIONS FOR PHARMACY WORKING CONDITIONS

The Board reviewed and discussed the draft proposed regulations, Chapter 628 of the 2022 General Assembly Session, and the public comments captured in Attachment 1 of the agenda packet regarding the proposed regulations for Pharmacy Working Conditions. Ms. Barrett systematically reviewed the public comments with the Board and provided opportunity for the Board to affirm or provide direction for any requested regulatory changes. During its discussion, several members expressed concern for patient access to pharmacies and that low reimbursement rates are a contributing factor to poor working conditions.

MOTION:

The Board voted unanimously to adopt the proposed regulations for pharmacy working conditions (18VAC110-20-110 and 18VAC110-20-113) as presented and amended as follows:

- **18VAC110-20-113(C): Amend "all aspects" to "any aspects";**
- **18VAC110-20-113(D): At the end of the first sentence, insert "…or a form containing information identical to that in the form developed by the board, which may be electronic.";**
- **18VAC110-20-113(D)(1): At the end of the sentence, insert "…within 48 hours of request.";**
- **18VAC110-20-113 (D)(3), prior to "result in workplace discipline", insert "or board". (Motion by Garvin, Seconded by Dowdy)**

ACTION ITEM:

The Board directed staff to review *Staffing Requests or Concerns* forms during routine pharmacy inspections to educate and encourage use of the form, receive feedback on the form, demonstrate that the Board takes this issue seriously, and to monitor for compliance with the emergency regulations. Staff should seek additional guidance from the board, if needed, regarding the opening of cases.

CONSIDER RECOMMENDATION OF HB 2147 (PRESCRIPTION TRANSLATION SERVICES) WORKGROUP

The Board reviewed and discussed HB 2147. Meeting minutes in the agenda packet from the previous HB 2147 Workgroup Meeting held on September 28, 2023 were used as a reference.

MOTION:

The Board voted unanimously to approve the HB 2147 Work Group's recommendation to inform pharmacies and pharmacy personnel of certain federal laws prohibiting discrimination, advising they seek legal advice regarding applicability to their practice, and to share the task force report once approved for publication.

REPEAL OF GUIDANCE

DOCUMENTS RELATED TO THE MEDICAL CANNABIS PROGRAM

The Board reviewed and discussed the repeal of guidance documents related to the medical cannabis program in preparation of the transfer to the Virginia Cannabis Control Authority on January 1, 2024.

MOTION:

The Board voted unanimously to repeal Guidance Documents 110-14, 110-20, 110-40, 110-45, 110-48, and 110-51 related to the Medical Cannabis Program, effective January 1, 2024. (Motion by Ratliff, seconded by Garvin)

REPEAL OF CHAPTER 60 DUE TO THE TRANSFER OF THE MEDICAL CANNABIS PROGRAM

The Board reviewed and discussed the repeal of Chapter 60, *Regulations Governing Pharmaceutical Processors*, in preparation of the transfer to the Virginia Cannabis Control Authority on January 1, 2024.

MOTION

The Board voted unanimously to repeal Chapter 60, *Regulations Governing Pharmaceutical Processors*, by exempt action effective January 1, 2024 due to the transfer of the Medical Cannabis Program to the Virginia Cannabis Control Authority. (motion by Richards-Spruill, seconded by Kocot)

COMPLETION OF PERODIC REVIEW OF PUBLIC PARTICIPATION GUIDELINES CONTAINED IN 18VAC110-11

The Board discussed and reviewed the public comments received during the public comment period regarding the Public Participation Guidelines. It was noted that agencies are required to conduct periodic reviews of regulatory chapters every four years. Although this particular chapter is only changed when the Department of Planning and Budget provides new model language, the Board was still required to conduct a periodic review. It was advised that the Board should not initiate any changes, but retain as is until DPB amends the model regulations. The issue addressed in the public comment does not require a regulatory change and does not require a change to the public participation guidelines.

MOTION

The Board voted unanimously to retain 18VAC110-11 as presented. (motion by Dowdy, seconded by Hoffer)

ADOPTION OF EXEMPT REGULATIONS – ADDITION OF DRUG TO SCHEDULE IV PURSUANT TO FEDERAL CHANGES

The Board discussed the adoption of the exempt regulations pertaining to the addition of drug to Schedule IV pursuant to federal changes. The Board reviewed excerpts of the DEA scheduling change published October 31, 2023 and draft amendments to 18VAC110-20-323.

MOTION

The Board voted unanimously to adopt the exempt regulatory change to 18VAC110-20-323 to place zuranolone into Schedule IV pursuant to recent federal scheduling action changes and subsection E of Va. Code 54.1-3443. (Motion by Ratliff, Seconded by Yuan)

ADOPTION OF EXEMPT REGULATIONS – ADDITION

The Board discussed the adoption of exempt regulations pertaining to the

OF CHEMICALS TO SCHEDULE I

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

MOTION

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

- **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-(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. (motion by Garvin, seconded by Dowdy)**

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

The Board reviewed and discussed the relevant USP FAQs in the handout and the draft amendment of Guidance Document 110-9, *Pharmacy Inspection Deficiency Monetary Penalty Guide*.

MOTION

The Board voted unanimously to amend Guidance Document 110-9 as presented and as follows:

- **Amend deficiency # 25d to read "No documentation of results of the evaluation to determine cause of failure for a person who failed a media-fill test or gloved fingertip and thumb sampling"; the monetary penalty is changed to read "5000 if performing Category 3, 500 if performing Category 1 and 2"; and,**
- **Repeal deficiency 26a. (motion by Garvin, seconded by Nash)**

NEW BUSINESS:

PESENTATION ON USE OF AGENCY SUBORDINATE

Ms. Barrett reviewed the PowerPoint slides in the agenda packet entitled "Overview of the Agency Subordinate Process". The presentation consisted of defining a subordinate and its role to the board, the current informal conference process, the agency subordinate process, and the benefits of using a subordinate. The overview was provided to familiarize the Board with the process as staff hopes to utilize an agency subordinate in 2024 to assist with the increased caseload.

OLD BUSINESS:

CITING OF DEFICIENCES 13-16 WITHIN GUIDANCE DOCUMENT 110-9

The Board discussed the citing of deficiencies 13-16 within Guidance Document 110-9. On May 23, 2023, the Regulation Committee requested staff to identify how often these deficiencies were cited during quarters ending June 2023 and September 2023. No action was taken.

REASSESS NEED FOR POSSIBLE RETREAT

The Chairman reviewed suggested topics that were provided to staff by several members as requested during the September board meeting.

ACTION ITEM:

The Chairman will work with the executive director to review the list of suggested topics, identify possible topics for the March 2024 board meeting, and provide an update on any other topics. Staff will research the Notice of Intended Regulatory Action resulting from the 2021 periodic review which is under Administrative Review to ensure the Board can receive public comment and act on any overlapping topics.

STAFF RESEARCH ON EXISTING PHARMACY LOCATIONS MAPS

In response to the Board's request during the September meeting, Ms. Juran reported that the National Association of Chain Drug Stores does not have current geo-mapping of pharmacy locations that it could provide to the Board and that any information would be limited to chain pharmacies. NABP does not have current geo-mapping to provide either, but it did connect us with the National Community Pharmacists Association (NCPA) based on past research on this subject with the University of Southern California. Ms. Juran reported she was awaiting additional information from NCPA.

REPORTS:

CHAIRMAN'S REPORT

Dale St. Clair, PharmD, provided the Chairman's report including a welcome to the newest board member, Michelle Hoffer, JD. Recognition was given to William Lee, PharmD, former Board Member, for his service on the Board. He indicated that Dr. Lee could not attend the meeting to receive his appreciation plaque, but that it had been mailed to him upon his request. Dr. St. Clair attended the NABP Member Forum in Chicago during the prior week. He served as a panelist and thought the meeting was very informative. Dr. St. Clair extended his thanks and appreciation to Board staff for their consistent had work throughout the year.

ACTION ITEM:

Dr. St. Clair indicated he would like the board to discuss pharmacy technician educational training requirements at the March 2024 board meeting.

BOARD OF HEALTH PROFESSIONS

No report was provided.

REPORT ON LICENSURE

Ryan Logan, RPh, Deputy Executive Director presented the Licensing Report which included data from May 2022 through November 2023. As of

November 1, 2023, the Virginia Board of Pharmacy licensure count for Q1 2024 is 47,526, up from 45,203 in Q1 2023. It was noted that in-state pharmacy permits in Q1 2024 equaled 1,751, down from Q1 2023 which equaled 1,765. Nonresident pharmacy registrations were up at 923, from 910 the previous Q1 2023. Pharmacy technician registrations were at 13,310, down slightly from previous Q1 2023 at 13,522, but that pharmacy technician trainee registrations were at 8,190, up from previous Q1 2023 at 6,977. Pharmacist licenses were at 16,606, up slightly from previous Q1 2023 at 16,414.

REPORT ON INSPECTION PROGRAM

Ms. Juran presented the Inspections Report, in absence of Ms. Morton, which included data from July 2023 through September 30, 2023. The Enforcement Division conducted 464 inspections between 7/1/23 and 9/30/23, 217 of which were of pharmacies. During the two-year period of 7/1/21 through 7/1/23, 3,901 inspections were performed. Sarah Rogers has accepted the position of Director of Enforcement. There are vacancies in one part-time pharmacist inspector position and one full-time senior inspector position.

PHARMACEUTICAL PROCESSORS

Annette Kelley, MS, CSAC, Deputy Executive Director presented the Pharmaceutical Processors Report. As of November 17, 2023, the Pharmaceutical Processors Program consist of 6,253 Registered Patients, 30 Registered Parents/Guardians, 91 Registered Agents, 3,888 Portal-Issued Written Certifications, 820 Portal-Enrolled Practitioners, and 3,695 Registered Cannabis Products. The Board and agency staff continued to meet bi-monthly with the Virginia Cannabis Control Authority to address the transition of the medical cannabis program to the VCCA on January 1, 2024.

DISCIPLINARY PROGRAM

Ellen B. Shinaberry, PharmD, Deputy Executive Director presented the Disciplinary Program Report. As of November 14, 2023, the Board has a total of 378 current cases consisting of 219 Patient Care Cases and 159 Non-Patient Care Cases.

EXECUTIVE DIRECTOR'S REPORT

Ms. Juran provided a verbal report regarding meetings she has attended or presented at since the last board meeting and upcoming meetings.

CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS

LISA ANNE PUCHALSKI, PHARMACY TECHNICIAN

Sean Murphy, Assistant Attorney General and Jess Weber, DHP APD Specialist presented a presentation for a Possible Summary Suspension for Lisa Anne Puchalski.

DECISION	Upon a motion by Garvin, and duly seconded by Richards-Spruill, the Board unanimously voted to summarily suspend the Pharmacy Technician Registration of Lisa Anne Puchalski, notice Ms. Puchalski for a Formal Hearing, and offer a Consent Order in lieu of a Formal Hearing.
MARY BURNETT, PHARMACIST	David Robinson, Assistant Attorney General and Chris Andreolli, DHP APD Specialist presented a presentation for a Possible Summary Suspension for Mary Burnett.
DECISION	Upon a motion by Nash, and duly seconded by Garvin, the Board unanimously voted to summarily suspend the Pharmacist license of Mary Burnett, notice Ms. Burnett for a Formal Hearing, and offer a Consent Order in lieu of a Formal Hearing.
RENEE TODD, PHARMACY TECHNICIAN TRAINEE	Jess Weber, DHP APD Specialist, presented a consent order for Board consideration regarding Renee M. Todd.
DECISION	Upon a motion by Kocot, and duly seconded by Dowdy, the Board unanimously voted to accept the Consent Order for the Pharmacy Technician Trainee Registration for Renee Todd.
MEETING ADJOURNED:	With all business concluded, the meeting adjourned at approximately 4:00PM

_____ _____

Caroline Juran, Executive Director

DATE

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CHEMICALS INTO SCHEDULE I AND CONFORMING SCHEDULES TO FEDERAL SCHEDULING ACTIONS

Wednesday, December 6, 2023

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

CALL TO ORDER: A full board meeting was called to order at 9:07AM.

PRESIDING: Dale St Clair, PharmD, Chairman

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

MEMBERS ABSENT: Sarah Melton, PharmD

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director
Ryan Logan, RPh, Deputy Executive Director
Ellen B. Shinaberry, PharmD, Deputy Executive Director
Annette Kelley, MS, CSAC, Deputy Executive Director
Mykl Egan, JD, Disciplinary Case Manager
Shannon Harris, Administrative and Office Specialist III
Sorayah Haden, Executive Assistant
Arne Owens, DHP Director
James Jenkins, RN, DHP Deputy Director
Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs
James Rutkowski, JD, Senior Assistant Attorney General

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

The Chairman indicated the public hearing is being held to consider the placement of two chemicals into Schedule I in consultation with the Department of Forensic Science (DFS) and in accordance with subsection D of 54.1-3443. Chemicals are:

- 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-(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.

Additionally, the public hearing is being held to consider the placement of zuranolone into Schedule IV to conform with recent federal scheduling action and in accordance with subsection E of 54.1-3443.

PUBLIC COMMENT:

Robyn Weimer provided public comment on behalf of DFS. She confirmed that DFS has identified the two chemicals with hallucinogenic properties that the Board should consider placing into Schedule I.

MEETING ADJOURNED: 9:11AM

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Caroline Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, January 29, 2024

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on January 29, 2024, at 11:00 AM, to consider the summary suspension in case number 233362.

PRESIDING: Dale St. Clair, Chairman

MEMBERS PRESENT:
Larry Kocot
Kristopher Ratliff
Sarah Melton
Patricia Richards-Spruill
Ling Yuan
Michelle Hoffer

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Caroline Juran, Executive Director
Annette Kelley, Deputy Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean Murphy, Assistant Attorney General
Jess Webber, DHP Adjudication Specialist

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

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

DAWN SHAWNTEL LEWIS
Registration No. 0230-022668

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 233362 regarding the pharmacy technician registration of Dawn Shawntel Lewis.

DECISION:

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

ADJOURN:

With all business concluded, the meeting adjourned at 11:13 AM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, February 5, 2024
2:00 PM

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on February 5, 2024, at 2:00 PM, to consider terms of a settlement proposal for case no. 214342.

PRESIDING: Dale St. Clair, Chair

MEMBERS PRESENT: Cheri Garvin
Sarah Melton
Larry Kocot
Patricia Richards-Spruill
Michelle Hoffer
Shannon Dowdy

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

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

CLOSED MEETING: Upon a motion by Mrs. Garvin, and duly seconded by Mr. Kocot, the Board voted 7-0, to convene a closed meeting pursuant to § 2.2-3711(A)(13) of the Code of Virginia ("Code"), for the purpose of deliberation regarding a possible settlement in the matter of Case No 214342. Additionally, she moved that Caroline Juran, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.

RECONVENE:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened an open meeting and announced the decision (Motion by Garvin/Second by Richards-Spruill).
DECISION:	Upon a motion by Mr. Kocot and duly seconded by Ms. Dowdy, the Board unanimously voted (7-0) to accept the proposed settlement terms as agreed upon by the Board.
ADJOURN:	With all business concluded, the meeting adjourned at 2:30 PM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
POSSIBLE SUMMARY SUSPENSION PRESENTATION & MINUTES OF A PANEL OF THE BOARD

Wednesday, February 7, 2024
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 1:02 PM for the purpose of a possible summary suspension presentations.

PRESIDING: Dale St. Clair, Chairman

MEMBERS PRESENT:
Ms. Michelle Hoffer
Mrs. Patricia Richards-Spruill
Ms. Cheri Garvin
Dr. Ling Yuan
Mr. Larry Kocot
Dr. Sarah Melton
Dr. Shannon Dowdy

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
David Robinson, Assistant Attorney General
Rebecca Ribley, Adjudication Specialist
Sorayah Haden, Executive Assistant

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

PURPOSE:
CASE NO. 233711

David Robinson, Assistant Attorney General, presented a summary of the evidence in this case. Mr. Robinson was assisted by Rebecca Ribley, Adjudication Specialist.

DECISION: Upon a motion by Ms. Garvin and duly seconded by Mr. Kocot, the Board unanimously voted (8-0) that with the evidence presented, Chenaniah Towner poses a substantial danger to the public; and therefore, the Board voted to summarily suspended Mr. Towner's pharmacy technician registration, to notice him for a formal hearing, and offer a consent order in lieu of the formal hearing.

AMANDA WHITMAN License No. Pending	A formal hearing was held in the matter of Amanda Whitman 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 September 15, 2023. With eight (8) members of the Board present, a quorum of the board was established. Christine Andreoli, Adjudication Specialist, presented the case. Amanda Whitman was present at the hearing and was not represented by counsel.
WITNESSES	Renee White, Senior Investigator for DHP testified in person on behalf of the Commonwealth. Amanda Whitman testified on her own behalf.
CLOSED MEETING:	Upon a motion by Ms. Garvin, and duly seconded by Mrs. Richards-Spruill, 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 Amanda Whitman. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, and Sorayah Hayden 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. (Garvin/Kocot)
DECISION:	Upon a motion by Ms. Hoffer, and duly seconded by Mrs. Richards-Spruill, the Board voted 8-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Dr. Dowdy, and duly seconded by Dr. Yuan, the board voted 6-2 to grant Ms. Whitman her pharmacist license and to issue a reprimand.

LISA ANNE PUCHALSKI
Registration No.: 0230-037809

A formal hearing was held in the matter of Lisa A. Puchalski to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician in Virginia as provided in the notice dated December 19, 2023.
Jess Weber, Adjudication Specialist, presented the case on behalf of the Commonwealth.

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

Ms. Puchalski was not present at the hearing.

WITNESSES

Christopher Moore, former DHP Senior Investigator, Neil Pastore, Walgreens Asset Protection Specialist, and Phillip Weaver, Pharmacy Manager Walgreens, testified by telephone for the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the Board voted 8-0, to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Lisa A. Puchalski. Additionally, she moved that Ellen Shinaberry, Caroline Juran, Jim Rutkowski, and Sorayah Hayden 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. (Garvin/Kocot)

DECISION:

Upon a motion by Ms. Hoffer, and duly seconded by Dr. Melton, the Board voted 8-0 to accept the Findings of Fact and Conclusions of Law as presented by the Commonwealth.

Upon a motion by Dr. Yuan, and duly seconded by Ms. Garvin, the board voted 8-0 to revoke the pharmacy technician registration of Lisa A. Puchalski.

ADJOURNED: 4:13 PM

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, February 14, 2024

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on February, 2024, at 1:00 PM, to consider summary suspensions in case numbers 233304, 233586, and 232931.

PRESIDING: Dale St. Clair, Chairman

MEMBERS PRESENT:
Cheri Garvin
Kristopher Ratliff
Sarah Thomason
Shannon Dowdy
Wendy Nash
Michelle Hoffer

STAFF PRESENT:
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Caroline Juran, Executive Director
James Rutkowski, Senior Assistant Attorney General
Sean Murphy, Assistant Attorney General
David Robinson, Assistant Attorney General
Jess Webber, DHP Adjudication Specialist
Rebecca Ribley, DHP Adjudication Specialist
Anne Joseph, DHP Adjudication Specialist

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

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

MARTA SERRANO MILLER
Registration No. 0245-010304

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 233304 regarding the pharmacy technician trainee registration of Marta Serrano Miller. Mr. Murphy was assisted by Anne Joseph, Sr. Adjudication Specialist.

DECISION:

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

LATOYA CHARESE DAVENPORT
Registration No. 0245-009541

David Robinson, Assistant Attorney General, presented a summary of the evidence in case no. 233586 regarding the pharmacy technician trainee registration of LaToya Davenport. Mr. Robinson was assisted by Rebecca Ribley, Adjudication Specialist.

DECISION:

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

SELENA BEALS Registration No. 0245-008313	David Robinson, Assistant Attorney General, presented a summary of the evidence in case no. 233586 regarding the pharmacy technician trainee registration of Selena Beals. Mr. Robinson was assisted by Jess Weber, Adjudication Specialist.
DECISION:	Upon a motion by Mr. Ratliff and duly seconded by Ms. Hoffer, the Board unanimously voted (7-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Selena Beals poses a substantial danger to the public; and therefore, the registration of Ms. Beals shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Beals in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 1:26 PM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of March 15, 2024

In the Governor's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	3/29/2017	2119 days; 6.9 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-20	NOIRA	Increase in fees	9/29/2023	3 days	The Board will consider increase of fees to fund Board activities as required by statute
18VAC110-20	Proposed	Centralized warehouser or wholesale distributor verification of Schedule VI drugs for ADDs in hospitals	6/10/2022	3 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-21	Proposed	2022 pharmacists initiating treatment	6/21/2023	3 days	Implements 2022 legislation regarding pharmacists initiating treatment; replaces emergency regulations

In the Secretary's Office

VAC	Stage	Subject Matter	Submitted from agency	Time in current location	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	708 days	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	3/21/2022	708 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-21	Fast-Track	Repeal of outdated sections	4/18/2023	208 days	Repeals outdated regulations regarding pharmacy technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	4/18/2023	199 days	Implements changes identified during the periodic review process
18VAC110-20	Fast-Track	Amendment to clarify application of 18VAC110-20-735	6/21/2023	195 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable

					formulations of naloxone
18VAC110-20	Proposed	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555	6/21/2023	73 days	Response to a petition for rulemaking to allow certain ADDs exemption from requirements under regulations

In the Office of the Attorney General

VAC	Stage	Subject Matter	Date submitted	Office; time in office	Notes
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	164 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation
18VAC110-20	Proposed	Pharmacy working conditions	12/18/2023	84 days	Implements legislation from 2022 Session regarding pharmacy working conditions

In the Department of Planning and Budget

None.

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date
18VAC110-20	Exempt/ Final	September 2023 scheduling of chemicals in Schedule I	1/1/2024	1/31/2024

18VAC110-21	Emergency/ NOIRA	2023 pharmacists initiating treatment	1/15/2024	12/26/2023
18VAC110-20	Exempt/ Final	December 2023 scheduling of chemicals in Schedule I	1/29/2024	2/28/2024
18VAC110-20	Exempt/ Final	December 2023 scheduling for conformity with federal action	1/29/2024	2/28/2024
18VAC110-60	Exempt/ Final	Repeal of the medical cannabis program regulations	4/8/2024	4/8/2024

Legislative Report
Board of Pharmacy
March 28, 2024

Duplicative bills have been removed from list.

HB 94 Nonresident pharmacies; pharmacy benefits administrators.

Chief patron: Wachsmann

DEAD BILL

Nonresident pharmacies; pharmacy benefits administrators. Removes a provision permitting a registered nonresident pharmacy that provides services as a pharmacy benefits administrator from operating without designating a Virginia licensed pharmacist in charge.

01/18/24 House: Subcommittee recommends striking from docket (8-Y 0-N)
02/13/24 House: Left in Health and Human Services

HB 104 Provider contracts; pharmacies allowed to refuse to fill certain prescriptions.

Chief patron: Wachsmann

DEAD BILL

Provider contracts; pharmacies; refusal to fill certain prescriptions. Requires a provider contract between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent to contain a specific provision allowing the pharmacy to refuse to fill a prescription for a drug that is reimbursed below the actual cost of the medication.

02/13/24 House: Left in Labor and Commerce

HB 257 Sickle cell anemia; prescription of opioids for pain management.

Chief patron: Mundon King

Prescription of opioids; sickle cell anemia. Exempts prescribers from certain requirements of the Prescription Monitoring Program related to prescribing opioids if the opioid is prescribed to a patient for pain management related to sickle cell anemia.

01/23/24 House: Subcommittee recommends reporting (6-Y 2-N)
01/25/24 House: Reported from Health and Human Services (15-Y 7-N)
01/31/24 House: VOTE: Passage (63-Y 35-N)
02/29/24 Senate: Reported from Education and Health (13-Y 2-N)
03/04/24 Senate: Passed Senate (39-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 342 Naloxone or other opioid antagonists; possession by state agencies, guidelines for private employer.

Chief patron: Hope

Naloxone or other opioid antagonists; possession and administration by state agencies. Requires state agencies to possess naloxone or other opioid antagonists used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose and permits employees of any state agency to possess and administer naloxone or other opioid antagonists.

02/01/24 House: Subcommittee recommends reporting with substitute (8-Y 0-N)
02/06/24 House: Reported from Health and Human Services with substitute (22-Y 0-N)
02/12/24 House: VOTE: Block Vote Passage (100-Y 0-N)
02/29/24 Senate: Reported from Education and Health (15-Y 0-N)
03/04/24 Senate: Reported from Finance and Appropriations with substitute (15-Y 0-N)
03/06/24 Senate: Passed Senate with substitute (40-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 516 Prescription drugs; labels provided for blind and disabled users.

Chief patron: Hope

Prescription drugs; labels; blind and disabled users. Requires pharmacies to notify any person receiving a prescription drug that an accessible prescription label is available upon request at no cost and to provide to individuals who are blind, visually impaired, or otherwise print disabled accessible prescription labels that meet specified accessibility requirements. The bill requires the Board of Pharmacy to promulgate regulations implementing the provisions of the bill no later than April 1, 2025.

02/06/24 House: Subcommittee recommends reporting (5-Y 2-N)
02/08/24 House: Reported from Health and Human Services (17-Y 5-N)

02/13/24 House: VOTE: Passage (61-Y 37-N)
02/21/24 Senate: Assigned Education and Health Sub: Health Professions
02/23/24 Senate: Senate subcommittee amendments and substitutes offered
02/29/24 Senate: Reported from Education and Health with substitute (13-Y 0-N 2-A)
03/04/24 Senate: Passed Senate with substitute (39-Y 0-N)
03/05/24 House: Senate substitute agreed to by House 24108563D-S1 (74-Y 26-N)
03/05/24 House: VOTE: Adoption (74-Y 26-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 570 Prescription Drug Affordability Board; established, drug cost affordability review, report.

Chief patron: Delaney

Prescription Drug Affordability Board established; drug cost affordability review. Establishes the Prescription Drug Affordability Board for the purpose of protecting the citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products. The bill requires the Board to meet in open session at least four times annually, with certain exceptions and requirements enumerated in the bill. Members of the Board are required to disclose any conflicts of interest, as described in the bill. The bill also creates a stakeholder council for the purpose of assisting the Board in making decisions related to drug cost affordability. The bill tasks the Board with identifying prescription, generic, and other drugs, as defined in the bill, that are offered for sale in the Commonwealth and, at the Board's discretion, conducting an affordability review of any prescription drug product. The bill lists factors for the Board to consider that indicate an affordability challenge for the health care system in the Commonwealth or high out-of-pocket costs for patients. The bill also provides that any person aggrieved by a decision of the Board may request an appeal of the Board's decision and that the Attorney General has authority to enforce the provisions of the bill. The bill provides that the Board shall establish no more than 12 upper payment limit amounts annually between January 1, 2025, and January 1, 2028.

The bill requires the Board to report its findings and recommendations to the General Assembly twice annually, beginning on July 1, 2025, and December 31, 2025. Provisions of the bill shall apply to state-sponsored and state-regulated health plans and health programs and obligate such policies to limit drug payment amounts and reimbursements to an upper payment limit amount set by the Board, if applicable, following an affordability review. The bill specifies that Medicare Part D plans shall not be bound by such decisions of the Board.

The bill also requires the nonprofit organization contracted by the Department of Health to provide prescription drug price transparency to provide the Board access to certain data reported by manufacturers. The bill has a delayed effective date of January 1, 2025.

02/01/24 House: Reported from Labor and Commerce with substitute (12-Y 10-N)
02/07/24 House: Subcommittee recommends reporting (5-Y 2-N)
02/09/24 House: Reported from Appropriations (11-Y 9-N)
02/13/24 House: VOTE: Passage (52-Y 46-N)
02/26/24 Senate: Reported from Commerce and Labor (10-Y 5-N)
02/29/24 Senate: Reported from Finance and Appropriations (10-Y 4-N)
03/05/24 Senate: Passed Senate (25-Y 15-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1006 Health insurance; freedom of choice, delivery of prescription drugs or devices.

Chief patron: Wachsmann

DEAD BILL

Health insurance; pharmacies; freedom of choice; delivery of prescription drugs or devices. Prohibits an insurer, health maintenance organization, corporation providing preferred provider subscription contracts, or pharmacy benefits manager from imposing upon any person receiving pharmaceutical benefits any policy or practice requiring or incentivizing a prescription drug or device to be sent (i) directly to a health care provider for administration to a patient, (ii) to a specific pharmacy selected by such insurer, organization, corporation, or pharmacy benefits manager, or (iii) to the residence of such person.

02/13/24 House: Left in Labor and Commerce

HB 1035 Places of public accommodation; possession and administration of epinephrine.

Chief patron: Bennett-Parker

Places of public accommodation; possession and administration of epinephrine. Permits every place of public accommodation, defined in relevant law as all places or businesses offering or holding out to the general public goods, services, privileges, facilities, advantages, or

accommodations, to make epinephrine available for administration and permits any employee of such place of public accommodation who is authorized by a prescriber and trained in the administration of epinephrine to possess and administer epinephrine to a person present in such place of public accommodation believed in good faith to be having an anaphylactic reaction. Current law limits such permission to every public place, defined in relevant law as any enclosed, indoor area used by the general public, and any employee of such public place.

01/23/24 House: Reported from Health and Human Services (21-Y 1-N)
01/29/24 House: VOTE: Passage (88-Y 10-N)
02/22/24 Senate: Reported from Education and Health (15-Y 0-N)
02/26/24 Senate: Passed Senate (40-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1041 Health insurance; cost-sharing, pharmacy benefits managers' compensation and duties, civil penalty.

Chief patron: O'Quinn

DEAD BILL

Health insurance; cost-sharing; pharmacy benefits managers' compensation and duties: civil penalty. Amends provisions related to rebates provided by carriers and health benefit plans to health plan enrollees by defining "defined cost-sharing," "price protection rebates," and "pharmacy benefits management services." The bill requires that an enrollee's defined cost-sharing for each prescription drug be calculated at the point of sale based on a price that is reduced by an amount equal to at least 80 percent of all rebates received or expected to be received in connection with the dispensing or administration of the prescription drug.

The bill prohibits a pharmacy benefits manager from deriving income from pharmacy benefits management services provided to a carrier or health benefit plan except for income derived from a pharmacy benefits management fee. The bill requires the amount of any pharmacy benefits management fees to be set forth in the agreement between the pharmacy benefits manager and the carrier or health benefit plan and that such fee not be based on the acquisition cost or any other price metric of a drug; the amount of savings, rebates, or other fees charged, realized, or collected by or generated based on the activity of the pharmacy benefits manager; or the amount of premiums, deductibles, or other cost-sharing or fees charged, realized, or collected by the pharmacy benefits manager from enrollees or other persons on behalf of an

enrollee. The bill requires a pharmacy benefits manager to annually certify to the State Corporation Commission that it has met certain requirements.

The bill establishes a pharmacy benefits manager duty, which includes the duties of care and good faith and fair dealing, owed to any enrollee, provider, or health benefit plan that receives pharmacy benefits management services from the pharmacy benefits manager or that furnishes, covers, receives, or is administered a unit of a prescription drug for which the pharmacy benefits manager has provided pharmacy benefits management services. The bill requires the Commission to define by regulation the scope of such duty and provides for a private cause of action for any person aggrieved by the breach of such duty.

02/06/24 House: Subcommittee recommends continuing to 2025
02/08/24 House: Continued to 2025 in Labor and Commerce

HB 1067 Pharmacy technicians; expansion of allowable duties.

Chief patron: Hodges

AGENCY BILL

Pharmacy technicians; expansion of allowable duties. Allows pharmacy technicians to clarify quantity or refills for a prescription issued for a Schedule VI drug. Current law only allows pharmacy technicians to accept refill authorizations. The bill also allows pharmacy technicians to accept electronic transfer of a refill for a Schedule VI drug upon order of the pharmacist-in-charge or pharmacist on duty if the refill is not an on-hold prescription. The bill defines "on-hold prescription" as a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

01/25/24 House: Subcommittee recommends reporting (8-Y 0-N)
01/30/24 House: Reported from Health and Human Services (22-Y 0-N)
02/05/24 House: VOTE: Block Vote Passage (98-Y 0-N)
02/22/24 Senate: Reported from Education and Health (15-Y 0-N)
02/26/24 Senate: Passed Senate (40-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1068 Pharmacy outsourcing and pharmacy technician remote database access; regulations.

Chief patron: Hodges

Board of Pharmacy; regulations related to pharmacy outsourcing and pharmacy technician remote database access. Directs the Board of Pharmacy (the Board) to promulgate regulations related to pharmacy outsourcing and pharmacy technician remote database access. The bill directs the Board to adopt emergency regulations to implement the provisions of the bill. SB607 (McDougle) conformed to this legislation.

02/06/24 House: Subcommittee recommends reporting with substitute (7-Y 0-N)
02/08/24 House: Reported from Health and Human Services with substitute (22-Y 0-N)
02/13/24 House: VOTE: Block Vote Passage (99-Y 0-N)
02/29/24 Senate: Reported from Education and Health with substitute (15-Y 0-N)
03/04/24 Senate: Passed Senate with substitute (39-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1187 Xylazine; penalty for manufacturing, selling, etc., for human consumption.

Chief patron: Hodges

Xylazine; manufacturing; selling; giving; distributing; possessing; veterinary use exemption; penalties. Provides that any person who knowingly manufactures, sells, gives, distributes, or possesses with the intent to manufacture, sell, give, or distribute the substance xylazine, when intended for human consumption, is guilty of a Class 5 felony. Under the bill, any person who knowingly possesses xylazine, when intended for human consumption, is guilty of a Class 1 misdemeanor. Under the bill, it is not an offense to (i) manufacture xylazine for legitimate veterinary use; (ii) distribute or sell xylazine for authorized veterinary use; (iii) possess, administer, prescribe, or dispense xylazine in good faith for use by animals within the course of legitimate veterinary practice; or (iv) possess or administer xylazine pursuant to a valid prescription from a licensed veterinarian. This bill is identical to SB 614.

02/02/24 House: Subcommittee recommends reporting with substitute (8-Y 0-N)
02/07/24 House: Reported from Courts of Justice with substitute (22-Y 0-N)
02/13/24 House: VOTE: Block Vote Passage (99-Y 0-N)
02/21/24 Senate: Reported from Courts of Justice (9-Y 0-N)

02/28/24 Senate: Reported from Finance and Appropriations (15-Y 0-N)
03/01/24 Senate: Passed Senate (40-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1194 Therapeutically equivalent drug products; provisions for return of outdated drugs.

Chief patron: Hodges

DEAD BILL

Therapeutically equivalent drug products; provisions for return of outdated drugs. Requires drug manufacturers to implement provisions for the return of drugs past their expiration date by pharmacies in order for their products to be eligible for dispensing as a therapeutically equivalent drug.

02/13/24 House: Left in Health and Human Services

HB 1333 Drug Control Act; adds certain chemicals to Schedules I, II, IV, and V of Act.

Chief patron: Wachsmann

Drug Control Act; Schedule I; Schedule II; Schedule IV; Schedule V. Adds certain chemicals to Schedules I, II, IV, and V of the Drug Control Act. The Board of Pharmacy has added these substances in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill incorporates HB 1450 and is identical to SB 111.

01/30/24 House: Reported from Health and Human Services with substitute (22-Y 0-N)
02/05/24 House: VOTE: Block Vote Passage (98-Y 0-N)
02/15/24 Senate: Reported from Education and Health (13-Y 0-N)
02/19/24 Senate: Passed Senate (39-Y 0-N)
03/08/24 Governor: Approved by Governor-Chapter 62 (effective 7/1/24)

HB 1336 Crisis stabilization services; facilities licensed by DBHDS, nursing homes.

Chief patron: Sickles

Crisis stabilization services; facilities licensed by Department of Behavioral Health and Developmental Services; nursing homes; dispensing and administration of drugs; emergency. Permits facilities licensed by the Department of Behavioral Health and Developmental Services that provide crisis stabilization services to maintain a stock of Schedules II through VI controlled substances necessary for immediate treatment of patients admitted to such facility. Under current law, maintenance of a stock of Schedule VI controlled substances is allowed under certain conditions, but a stock of Schedules II through V controlled substances may be maintained only if authorized by federal law and Board of Pharmacy regulations. The bill also allows automated drug dispensing systems and remote dispensing systems to be used by state facilities established pursuant to Title 37.2 (Behavioral Health and Developmental Services), facilities that provide crisis stabilization services, nursing homes, and other facilities authorized by the Board of Pharmacy that meet certain conditions. The bill contains an emergency clause, directs the Board of Pharmacy to adopt emergency regulations to implement the provisions of the bill, incorporates HB 1038, and is identical to SB 568.

EMERGENCY

01/30/24 House: Reported from Health and Human Services with substitute (22-Y 0-N)
02/05/24 House: VOTE: Block Vote Passage (98-Y 0-N)
02/15/24 Senate: Reported from Education and Health (15-Y 0-N)
02/19/24 Senate: Passed Senate (39-Y 0-N)
03/08/24 Governor: Approved by Governor-Chapter 63 (effective 3/8/24)

HB 1402 Health insurance; pharmacy benefits managers, reporting requirements, civil penalty.

Chief patron: Reaser

Health insurance; pharmacy benefits managers; reporting requirements; civil penalty. Provides that a person that violates the existing requirement to obtain a license prior to providing pharmacy benefits management services or otherwise acting as a pharmacy benefits manager may be subject to a civil penalty of $5,000 for each day on which such violation occurs. The bill adds additional requirements to existing reporting requirements for insurance carriers relating to pharmacy benefits managers. Such additional requirements include (i) the

aggregate amount of a pharmacy benefits manager's retained rebates, as defined in the bill; (ii) a pharmacy benefits manager's aggregate retained rebate percentage, as defined in the bill; and (iii) the aggregate amount of administrative fees received by a pharmacy benefits manager. This bill is identical to SB 660.

01/30/24 House: Subcommittee recommends reporting with amendments (6-Y 1-N)
02/01/24 House: Reported from Labor and Commerce with amendment(s) (22-Y 0-N)
02/07/24 House: VOTE: Block Vote Passage (100-Y 0-N)
02/19/24 Senate: Reported from Commerce and Labor (15-Y 0-N)
02/22/24 Senate: Passed Senate (40-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 1432 Attorney General; Pharmacy Benefits Manager and Third-Party Administrator Oversight Work Group.

Chief patron: Hodges

DEAD BILL

Attorney General; Pharmacy Benefits Manager and Third-Party Administrator Oversight Work Group; report. Directs the Attorney General to convene the Pharmacy Benefits Manager and Third-Party Administrator Oversight Work Group to examine the impact of Rutledge v. Pharmaceutical Care Management Association, 141 S. Ct. 474 (2020), and to formulate legislative recommendations for reducing prescription drug costs, minimizing health care expenses, reducing bureaucratic impediments to affordable health care, enhancing transparency, and improving overall health outcomes for residents of the Commonwealth. The bill requires such work group to submit a report of its findings and recommendations to the General Assembly by November 1, 2025.

01/29/24 House: Subcommittee recommends laying on the table (4-Y 2-N)
02/13/24 House: Left in Rules

HB 1497 Pharmacy technician profession; Board of Pharmacy to review framework.

Chief patron: Willett

DEAD BILL

Board of Pharmacy; pharmacy technician profession; work group; report. Requires the Board of Pharmacy to convene a work group of relevant stakeholders to review and make recommendations related to the regulatory framework for the pharmacy technician profession, educational barriers to the pharmacy technician profession, compensation of pharmacy technicians, and the educational requirements of pharmacy technicians. The bill requires the Board to report its findings and recommendations to the Chairmen of the House Committee on Health and Human Services and the Senate Committee on Education and Health by November 1, 2024. The bill also requires the Board to promulgate emergency regulations within 280 days of the work group's completion based on the work group's recommendations.

02/01/24 House: Continued to 2025 in Rules

SB 111 Drug Control Act; adds certain chemicals to Schedules I, II, IV, and V of Act.

Chief patron: Peake

Drug Control Act; Schedule I; Schedule II; Schedule IV; Schedule V. Adds certain chemicals to Schedules I, II, IV, and V of the Drug Control Act. The Board of Pharmacy has added these substances in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to HB 1333.

01/11/24 Senate: Reported from Education and Health (15-Y 0-N)
01/16/24 Senate: Read third time and passed Senate (38-Y 0-N)
02/22/24 House: Reported from Health and Human Services (21-Y 0-N)
02/27/24 House: VOTE: Block Vote Passage (97-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

SB 119 Drug manufacturers; permitting and registration, certain conditions related to 340B-covered drugs.

Chief patron: Lucas

Drug manufacturers; permitting and registration; certain conditions related to 340B-covered drugs. Requires a drug manufacturer, as a condition of obtaining a permit or as a condition of registration or renewal of registration, to certify that it does not limit the number of contract pharmacies or covered entities, as defined in relevant law, to which it ships 340B-covered drugs and that it does not impose requirements, exclusions, reimbursement terms, or other conditions on a contract pharmacy or covered entity that differ from those applied to pharmacies or entities that are not contract pharmacies or covered entities on the basis that the pharmacy or entity is a contract pharmacy or covered entity or that the pharmacy or entity dispenses 340B-covered drugs.

02/01/24 Senate: Reported from Education and Health (15-Y 0-N)
02/07/24 Senate: Reported from Finance and Appropriations (15-Y 0-N)
02/09/24 Senate: Passed Senate (40-Y 0-N)
02/27/24 House: Subcommittee recommends reporting (8-Y 0-N)
02/27/24 House: Reported from Health and Human Services (20-Y 1-N)
03/01/24 House: VOTE: Passage (92-Y 5-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

SB 122 Pharmaceutical Services, Office of; establishes in Department of General Services, report.

Chief patron: VanValkenburg

DEAD BILL

Department of General Services; Office of Pharmaceutical Services; report. Establishes in the Department of General Services an Office of Pharmaceutical Services to develop and execute a plan to consolidate state agency prescription drug purchasing and pharmacy benefit management programs to increase efficiency in prescription drug purchasing and constrain spending on prescription drugs. The bill directs the Department to provide to the Governor and the General Assembly an interim report on the development of the plan by November 1, 2024, and a final report on the plan by November 1, 2025.

02/07/24 Senate: Reported from General Laws and Technology with substitute (15-Y 0-N)
02/12/24 Senate: Passed by indefinitely in Finance and Appropriations (13-Y 1-N)

SB 186 Wholesale prescription drug importation program; Sec. of Health and Human Resources to establish.

Chief patron: Subramanyam

Secretary of Health and Human Resources; work group; wholesale prescription drug importation programs; report. Directs the Secretary of Health and Human Resources to convene a work group to investigate wholesale prescription drug importation programs in other states and evaluate best practices for the establishment and application of such a program in the Commonwealth. The bill requires the Secretary of Health and Human Resources to provide a report to the Governor, the House Committees on Appropriations and Health and Human Services, and the Senate Committees on Finance and Appropriations and Education and Health by November 1, 2024.

02/01/24 Senate: Reported from Education and Health with substitute (15-Y 0-N)
02/08/24 Senate: Reported from Finance and Appropriations with substitute (15-Y 0-N)
02/12/24 Senate: Education and Health Committee substitute rejected 24106622D-S1
02/12/24 Senate: Finance and Appropriations Committee substitute agreed to 24107494D-S2
02/12/24 Senate: Passed Senate (40-Y 0-N)
02/23/24 House: Subcommittee recommends reporting (6-Y 0-N)
02/23/24 House: Reported from Rules (16-Y 0-N)
02/28/24 House: Reported from Appropriations (22-Y 0-N)
03/04/24 House: VOTE: Block Vote Passage (97-Y 0-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

SB 274 Prescription Drug Affordability Board; established, drug cost affordability review, report.

Chief patron: Deeds

Prescription Drug Affordability Board established; drug cost affordability review. Establishes the Prescription Drug Affordability Board for the purpose of protecting the citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products. The bill requires the Board to meet in open session at least four times annually, with certain exceptions and requirements enumerated in the bill.

Members of the Board are required to disclose any conflicts of interest, as described in the bill. The bill also creates a stakeholder council for the purpose of assisting the Board in making decisions related to drug cost affordability. The bill tasks the Board with identifying prescription, generic, and other drugs, as defined in the bill, that are offered for sale in the Commonwealth and, at the Board's discretion, conducting an affordability review of any prescription drug product. The bill lists factors for the Board to consider that indicate an affordability challenge for the health care system in the Commonwealth or high out-of-pocket costs for patients. The bill also provides that any person aggrieved by a decision of the Board may request an appeal of the Board's decision and that the Attorney General has authority to enforce the provisions of the bill. The bill provides that the Board shall establish no more than 12 upper payment limit amounts annually between January 1, 2025, and January 1, 2028.

The bill requires the Board to report its findings and recommendations to the General Assembly twice annually, beginning on July 1, 2025, and December 31, 2025. Provisions of the bill shall apply to state-sponsored and state-regulated health plans and health programs and obligate such policies to limit drug payment amounts and reimbursements to an upper payment limit amount set by the Board, if applicable, following an affordability review. The bill specifies that Medicare Part D plans shall not be bound by such decisions of the Board.

The bill also requires the nonprofit organization contracted by the Department of Health to provide prescription drug price transparency to provide the Board access to certain data reported by manufacturers. The bill has a delayed effective date of January 1, 2025.

01/18/24 Senate: Rereferred from Education and Health (15-Y 0-N)
02/05/24 Senate: Reported from Commerce and Labor with substitute (10-Y 5-N)
02/08/24 Senate: Reported from Finance and Appropriations (9-Y 6-N)
02/13/24 Senate: Read third time and passed Senate (23-Y 16-N)
02/20/24 House: Reported from Labor and Commerce (12-Y 10-N)
02/23/24 House: VOTE: Passage (50-Y 47-N)
Governor: Governor's Action Deadline 11:59 p.m., April 8, 2024

HB 120 DPOR and DHP; certain suspensions not considered disciplinary action.

Chief patron: Sullivan

Department of Professional and Occupational Regulation; Department of Health Professions; certain suspensions not considered disciplinary action. Prohibits any board

of the Department of Professional and Occupational Regulation or the Department of Health Professions issuing a suspension upon any regulant of such board pursuant to such regulant's having submitted a check, money draft, or similar instrument for payment of a fee required by statute or regulation that is not honored by the bank or financial institution named from considering or describing such suspension as a disciplinary action.

01/18/24 House: Subcommittee recommends reporting (8-Y 0-N)
01/23/24 House: Reported from General Laws (21-Y 0-N)
01/30/24 House: Reported from Health and Human Services (22-Y 0-N)
02/05/24 House: VOTE: Block Vote Passage (98-Y 0-N)
02/14/24 Senate: Reported from General Laws and Technology (15-Y 0-N)
02/19/24 Senate: Passed Senate (39-Y 0-N)
03/08/24 Governor: Approved by Governor-Chapter 18 (effective 7/1/24)

HB 722 Regulatory Budget Program; established, report.

Chief patron: Webert

DEAD BILL

Department of Planning and Budget; Regulatory Budget Program established; report. Directs the Department of Planning and Budget to establish a Regulatory Budget Program under which each executive branch agency subject to the Administrative Process Act shall reduce overall regulatory requirements by 30 percent by January 1, 2027. The bill requires the Department to report to the Speaker of the House of Delegates and the Chairman of the Senate Committee on Rules on the status of the Program no later than October 1 of each year, beginning October 1, 2025. Finally, the bill provides that the Department, in consultation with the Office of the Governor, shall issue guidance for agencies regarding the Program and how an agency can comply with the requirements of the Program. The bill has an expiration date of January 1, 2027.

01/25/24 House: Subcommittee recommends striking from docket (8-Y 0-N)
01/30/24 House: Stricken from docket by General Laws (22-Y 0-N)

HB 1428 Regulatory boards; application review timelines.

Chief patron: Shin

DEAD BILL

Department of Professional and Occupational Regulation; application review timelines. Requires each regulatory board within the Department of Professional and Occupational Regulation to adopt a timeline of each stage that a completed application for licensure, certification, or registration will undergo as it is reviewed by such board. The bill also requires that such regulatory board approve any completed application within 30 days of its receipt unless such board has reasonable certainty that such application includes grounds for denial.

02/08/24 House: Subcommittee recommends striking from docket (7-Y 0-N)
02/08/24 House: Stricken from docket by General Laws (20-Y 0-N)

SB 682 Health professions; universal licensure, requirements.

Chief patron: Suetterlein

DEAD BILL

Health professions; universal licensure; requirements. Requires health regulatory boards within the Department of Health Professions to recognize licenses or certifications issued by other United States jurisdictions, as defined in the bill, as fulfillment for licensure or certification in the Commonwealth if certain conditions are met. The bill also requires such health regulatory boards to recognize work experience as fulfillment for licensure or certification in the Commonwealth if certain conditions are met. The bill does not apply to licensure for physicians or dentists.

02/08/24 Senate: Reported from Education and Health with substitute (15-Y 0-N)
02/09/24 Senate: Continued to 2025 in Rules (8-Y 6-N 1-A)

Agenda Topic: Consideration to amend EMS-related regulations

Staff Note: Federal law passed in 2017 directs DEA to issue a registration for a new category for EMS agencies. DEA published proposed rules in 2020. Additionally, FDA enforcement of DSCSA requirements in November 2024 will present challenges for hospital pharmacies to continue the current model of exchanging emergency drug kits with EMS.

Included in Packet:

- Excerpts of 21 USC §823
- DEA Notice of Proposed Rulemaking
- Draft amendments of relevant board regulations

Action Needed: Referral to Regulation Committee meeting scheduled for May 2, 2024 with recommendations to full board on June 25, 2024 for adoption as emergency regulatory action.

(3) any prior conviction record of the applicant under Federal or State laws relating to controlled substances or to chemicals controlled under Federal or State law;

(4) any past experience of the applicant in the manufacture and distribution of chemicals; and

(5) such other factors as are relevant to and consistent with the public health and safety.

(j) Registration to manufacture certain controlled substances for use only in a clinical trial

(1) For purposes of registration to manufacture a controlled substance under subsection (e) for use only in a clinical trial, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, not later than 180 days after the date on which the application is accepted for filing.

(2) For purposes of registration to manufacture a controlled substance under subsection (a) for use only in a clinical trial, the Attorney General shall, in accordance with the regulations issued by the Attorney General, issue a notice of application not later than 90 days after the application is accepted for filing. Not later than 90 days after the date on which the period for comment pursuant to such notice ends, the Attorney General shall register the applicant, or serve an order to show cause upon the applicant in accordance with section 824(c) of this title, unless the Attorney General has granted a hearing on the application under section 958(i) of this title.

(k) Emergency medical services that administer controlled substances

(1) Registration

For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

(A) shall register an emergency medical services agency if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices; and

(B) may deny an application for such registration if the Attorney General determines that the issuance of such registration would be inconsistent with the requirements of this subsection or the public interest based on the factors listed in subsection (g).

(2) Option for single registration

In registering an emergency medical services agency pursuant to paragraph (1), the Attorney General shall allow such agency the option of a single registration in each State where the agency administers controlled substances in lieu of requiring a separate registration for each location of the emergency medical services agency.

(3) Hospital-based agency

If a hospital-based emergency medical services agency is registered under subsection (g), the agency may use the registration of the hospital to administer controlled substances in accordance with this subsection without being registered under this subsection.

(4) Administration outside physical presence of medical director or authorizing medical professional

Emergency medical services professionals of a registered emergency medical services agency may administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is—

(A) authorized by the law of the State in which it occurs; and

(B) pursuant to—

(i) a standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State authority; or

(ii) a verbal order that is—

(I) issued in accordance with a policy of the agency; and

(II) provided by a medical director or authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient—

(aa) in the case of a mass casualty incident; or

(bb) to ensure the proper care and treatment of a specific patient.

(5) Delivery

A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency—

(A) designates the unregistered location for such delivery; and

(B) notifies the Attorney General at least 30 days prior to first delivering controlled substances to the unregistered location.

(6) Storage

A registered emergency medical services agency may store controlled substances—

(A) at a registered location of the agency;

(B) at any designated location of the agency or in an emergency services vehicle situated at a registered or designated location of the agency; or

(C) in an emergency medical services vehicle used by the agency that is—

(i) traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency; or

(ii) otherwise actively in use by the agency under circumstances that provide for security of the controlled substances consistent with the requirements established by regulations of the Attorney General.

(7) No treatment as distribution

The delivery of controlled substances by a registered emergency medical services agency

pursuant to this subsection shall not be treated as distribution for purposes of section 828 of this title.

(8) Restocking of emergency medical services vehicles at a hospital

Notwithstanding paragraph (13)(J), a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of section 828 of this title, provided all of the following conditions are satisfied:

(A) The registered or designated location of the agency where the vehicle is primarily situated maintains a record of such receipt in accordance with paragraph (9).

(B) The hospital maintains a record of such delivery to the agency in accordance with section 827 of this title.

(C) If the vehicle is primarily situated at a designated location, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

(9) Maintenance of records

(A) In general

A registered emergency medical services agency shall maintain records in accordance with subsections (a) and (b) of section 827 of this title of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration, without regard to subsection 827(c)(1)(B) of this title.

(B) Requirements

Such records—

(i) shall include records of deliveries of controlled substances between all locations of the agency; and

(ii) shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

(10) Other requirements

A registered emergency medical services agency, under the supervision of a medical director, shall be responsible for ensuring that—

(A) all emergency medical services professionals who administer controlled substances using the agency's registration act in accordance with the requirements of this subsection;

(B) the recordkeeping requirements of paragraph (9) are met with respect to a registered location and each designated location of the agency;

(C) the applicable physical security requirements established by regulation of the Attorney General are complied with wherever controlled substances are stored by the agency in accordance with paragraph (6); and

(D) the agency maintains, at a registered location of the agency, a record of the standing orders issued or adopted in accordance with paragraph (9).

(11) Regulations

The Attorney General may issue regulations—

(A) specifying, with regard to delivery of controlled substances under paragraph (5)—

(i) the types of locations that may be designated under such paragraph; and

(ii) the manner in which a notification under paragraph (5)(B) must be made;

(B) specifying, with regard to the storage of controlled substances under paragraph (6), the manner in which such substances must be stored at registered and designated locations, including in emergency medical service vehicles; and

(C) addressing the ability of hospitals, emergency medical services agencies, registered locations, and designated locations to deliver controlled substances to each other in the event of—

(i) shortages of such substances;

(ii) a public health emergency; or

(iii) a mass casualty event.

(12) Rule of construction

Nothing in this subsection shall be construed—

(A) to limit the authority vested in the Attorney General by other provisions of this subchapter to take measures to prevent diversion of controlled substances; or

(B) to override the authority of any State to regulate the provision of emergency medical services consistent with this subsection.

(13) Definitions

In this section:

(A) The term "authorizing medical professional" means an emergency or other physician, or another medical professional (including an advanced practice registered nurse or physician assistant)—

(i) who is registered under this chapter;

(ii) who is acting within the scope of the registration; and

(iii) whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(B) The term "designated location" means a location designated by an emergency medical services agency under paragraph (5).

(C) The term "emergency medical services" means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(D) The term "emergency medical services agency" means an organization providing emergency medical services, including such an organization that—

(i) is governmental (including fire-based and hospital-based agencies), nongovernmental (including hospital-based agencies), private, or volunteer-based;

(ii) provides emergency medical services by ground, air, or otherwise; and

(iii) is authorized by the State in which the organization is providing such services to provide emergency medical care, includ-

ing the administering of controlled substances, to members of the general public on an emergency basis.

(E) The term "emergency medical services professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(F) The term "emergency medical services vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(G) The term "hospital-based" means, with respect to an agency, owned or operated by a hospital.

(H) The term "medical director" means a physician who is registered under subsection (g) and provides medical oversight for an emergency medical services agency.

(I) The term "medical oversight" means supervision of the provision of medical care by an emergency medical services agency.

(J) The term "registered emergency medical services agency" means—

(i) an emergency medical services agency that is registered pursuant to this subsection; or

(ii) a hospital-based emergency medical services agency that is covered by the registration of the hospital under subsection (g).

(K) The term "registered location" means a location that appears on the certificate of registration issued to an emergency medical services agency under this subsection or subsection (g), which shall be where the agency receives controlled substances from distributors.

(L) The term "specific State authority" means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(M) The term "standing order" means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(N) The term "verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

(*l*)[2] "Factors as may be relevant to and consistent with the public health and safety" defined

In this section, the phrase "factors as may be relevant to and consistent with the public health and safety" means factors that are relevant to and consistent with the findings contained in section 801 of this title.

(*l*)[2] Required training for prescribers

(1) Training required

As a condition on registration under this section to dispense controlled substances in schedule II, III, IV, or V, the Attorney General shall require any qualified practitioner, beginning with the first applicable registration for the practitioner, to meet the following:

(A) If the practitioner is a physician (as defined under section 1395x(r) of title 42) and the practitioner meets one or more of the following conditions:

(i) The physician holds a board certification in addiction psychiatry or addiction medicine from the American Board of Medical Specialties.

(ii) The physician holds a board certification from the American Board of Addiction Medicine.

(iii) The physician holds a board certification in addiction medicine from the American Osteopathic Association.

(iv) The physician has, with respect to the treatment and management of patients with opioid or other substance use disorders, or the safe pharmacological management of dental pain and screening, brief intervention, and referral for appropriate treatment of patients with or at risk of developing opioid or other substance use disorders, completed not less than 8 hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by—

(I) the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Dental Association, the American Association of Oral and Maxillofacial Surgeons, the American Psychiatric Association, or any other organization accredited by the Accreditation Council for Continuing Medical Education (ACCME) or the Commission for Continuing Education Provider Recognition (CCEPR);

(II) any organization accredited by a State medical society accreditor that is recognized by the ACCME or the CCEPR;

(III) any organization accredited by the American Osteopathic Association to provide continuing medical education; or

(IV) any organization approved by the Assistant Secretary for Mental Health

[2] So in original. Two subsecs. (*l*) have been enacted.

TABLE 1—INFORMATION ON PARTICIPATING IN THE PUBLIC MEETINGS AND ON SUBMITTING COMMENTS TO THE PROPOSED RULE ON REQUIREMENTS FOR ADDITIONAL TRACEABILITY RECORDS FOR CERTAIN FOODS DOCKET

Activity	Date	Electronic address	Other information
First public meeting	November 6, 2020; 8:30 a.m.–3:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by October 28, 2020 ..	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 9, 2020	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	
Notice confirming opportunity to make oral presentation.	by October 16, 2020 ..	.....	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https://www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.
Second public meeting	November 18, 2020; 9:30 a.m.–4:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 6, 2020	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 16, 2020 ..	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	
Notice confirming opportunity to make oral presentation.	by October 23, 2020 ..	.....	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https://www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.
Third public meeting	December 2, 2020; 11:30 a.m.–6:30 p.m. EST.	Webcast information will be sent upon completion of registration.	Webcast will have closed captioning.
Advance registration	by November 18, 2020	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	There is no registration fee for the public meetings. Early registration is recommended.
Request to make oral presentation.	by October 26, 2020 ..	*https://www.fda.gov/food/news-events-cfsan/workshops-meetings-webinars-food-and-dietary-supplements*.	
Notice confirming opportunity to make oral presentation.	by November 9, 2020	.....	An Agency representative will confirm the opportunity to make an oral presentation and will provide the approximate time on the public meeting agenda to do so.
Submitting either electronic or written comments.	Submit comments by January 21, 2021.	*https://www.regulations.gov*	See **ADDRESSES** for additional information on submitting comments.

IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at: *https://www.regulations.gov.* You may also view the transcript at the Dockets Management Staff (see **ADDRESSES**).

Dated: September 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–21935 Filed 10–2–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1306, and 1307

[Docket No. DEA–377]

RIN 1117–AB37

Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The ''Protecting Patient Access to Emergency Medications Act of 2017,'' (hereafter the ''Act'') which became law on November 17, 2017, amended the Controlled Substances Act to allow for a new registration category for emergency medical services agencies that handle controlled substances. It also established standards for registering emergency medical services agencies, and set forth new requirements for delivery, storage, and recordkeeping related to their handling of controlled substances. In addition, the Act allows emergency medical services professionals to administer controlled substances outside the physical

presence of a medical director or authorizing medical professional pursuant to a valid standing or verbal order. The Drug Enforcement Administration proposes to amend its regulations to make them consistent with the Act and to otherwise implement its requirements.

DATES: Electronic comments must be submitted, and written comments must be postmarked, on or before December 4, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Management and Budget (OMB) on or before December 4, 2020.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–377'' on all correspondence, including any attachments.

• *Electronic Comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon completion of your submission, you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *Regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. Commenters should be aware that the electronic Federal Docket Management System will not accept any comments after 11:59 p.m. Eastern Time on the last day of the comment period.

• *Paper Comments:* Paper comments that duplicate electronic submissions are not necessary. Should you wish to mail a paper comment *in lieu of* an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152–2639.

• *Paperwork Reduction Act Comments:* All comments concerning collections of information under the Paperwork Reduction Act must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comment refers to RIN 1117–AB37/Docket No. DEA–377.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Regulatory Drafting and Policy Support Section (DPW), Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA or ''the Administration'') for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information or personal identifying information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Outline

I. Background and Purpose

A. Legal Authority

On November 17, 2017, the ''Protecting Patient Access to Emergency Medications Act of 2017,'' Public Law 115–83 (131 Stat. 1267) (''the Act''), became law.

The Act amended a section of the CSA, 21 U.S.C. 823, by adding a new subsection, 21 U.S.C. 823(j). This new subsection alters a number of CSA requirements ''[f]or the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services.'' 21 U.S.C. 823(j)(1). The Act also specifically authorizes the Attorney General (and thus the Administrator of DEA by delegation) to issue certain regulations to implement the Act. *Id.* 823(j)(11).

B. Purpose

The purposes of this proposed rule are twofold. First, this proposed rule is to codify in DEA regulations the statutory amendments made by the Act. Such proposed changes are merely conforming DEA's implementing regulations to statutory amendments of the CSA that have already taken effect. Second, this proposed rule amends DEA

regulations in some ways that do not directly codify the Act's amendments. These limited changes are authorized by the CSA, as amended by the Act, and seek to implement the Act and effectuate its purposes.

C. Background

When an individual experiences a medical emergency, his or her entry into the healthcare system may not start with the care of a physician within a traditional clinical setting, but instead with the intervention of emergency medical services (EMS) personnel affiliated with a local EMS agency at the incident site. EMS personnel, who provide emergency medical services by ground, air, or otherwise, respond to 37 million calls annually.[1] EMS involves the evaluation and management of patients with acute traumatic and medical conditions in a prehospital environment,[2] and is an important component of medical care, as early medical intervention saves lives and often reduces the severity of injury.[3] The nature of medical intervention at the incident site and during transport to the hospital can vary widely depending on the severity and type of injury or impairment, and may include the administering of controlled substances.[4]

The delivery of emergency medical care is primarily a local function; and, accordingly, a wide variety of organizational structures are utilized across the nation. EMS programs may be a part of the local municipal government, hospital, or independent government agency, or may be contracted by local government with a private entity. Each state has a State EMS licensing office that is responsible for the overall planning, coordination, and regulation of the State EMS system, as well as licensing or certifying EMS providers and ambulances.[5] These agencies are often located within the State health department, but may also be found as part of the public safety department or as independent agencies.[6]

D. Summary of the Act and Changes to the CSA

The Act established uniform EMS agency requirements for the administration of controlled substances while ensuring adequate safeguards against theft and diversion. The Act added a new subsection to the CSA, 21 U.S.C. 823(j), and in the process redesignated the previous subsection (j) as subsection (k). The new 21 U.S.C. 823(j) makes a number of notable changes to the CSA. The Act makes five key changes.

First, the Act creates a new registration category under the CSA for EMS agencies, directing the Attorney General (and thus the Administrator of DEA by delegation) to register such an agency under the CSA if the agency submits an application demonstrating that it is authorized to conduct emergency medical services under the laws of each State in which the agency practices. 21 U.S.C. 823(j)(1)(A). Pursuant to 21 U.S.C. 823(j)(1)(B), the Act authorizes the Attorney General to deny the application of an EMS agency if registering it would be inconsistent with other requirements of 21 U.S.C. 823(j) or with the public interest based on the factors of 21 U.S.C. 823(f).

Second, the Act directs the Attorney General (and thus the Administrator) to allow a registered EMS agency to obtain a single registration for each State in which the agency administers controlled substances, rather than requiring the agency to obtain a separate registration for each location at which it operates within that State. 21 U.S.C. 823(j)(2). The Act also provides that a hospital-based emergency medical services agency registered under 21 U.S.C. 823(f) may use the registration of the hospital to administer controlled substances under 21 U.S.C. 823(j), without requiring the agency to acquire a separate registration. 21 U.S.C. 823(j)(3).

Third, subject to certain restrictions, the Act authorizes EMS professionals of a registered EMS agency to administer controlled substances in schedule II, III, IV, or V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. 21 U.S.C. 823(j)(4). EMS professionals are only allowed to make such administrations if authorized by State law and pursuant to standing or verbal orders that satisfy a number of statutory conditions. *Id.*

Fourth, the Act provides a variety of requirements for how registered EMS agencies must deliver controlled substances from registered to unregistered locations, store controlled substances, restock EMS vehicles at a hospital, maintain records, and otherwise conduct their operations. 21 U.S.C. 823(j)(5)–(10).

Fifth, the Act specifically authorizes the Attorney General (and thus the Administrator) to issue regulations regarding the delivery and storage of controlled substances by EMS agencies. *Id.* 823(j)(11).

II. Summary of Proposed Changes

The Act amended the CSA to add regulatory provisions pertaining to the handling of controlled substances by EMS professionals, and the majority of this proposed rule merely reiterates those statutory requirements. The portion of this proposed rule that goes beyond those statutory requirements includes proposed changes to the registration, security, recordkeeping, inventory, and administering requirements for EMS agencies, which are discussed below.

Consistent with the Act, DEA is proposing regulations to explicitly include EMS agencies handling controlled substances as registrants under the CSA,[7] and to delineate the security, and recordkeeping requirements for EMS registrants who store, transport, and administer controlled substances. DEA is also proposing regulations that would codify, in DEA regulations, the Act's provisions that allow EMS personnel to administer controlled substances in schedules II–V outside of the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if authorized in the State in which the medical service occurs and pursuant to a standing order or verbal order.[8] In addition, DEA is proposing

[1] National EMS Assessment, 2011. The National EMS Assessment, led by researchers at the University of North Carolina at Chapel Hill, incorporated data from the National Association of State EMS Officials 2011 EMS Industry Snapshot: Emergency Medical Services for Children Program 2010–2011 report, the 2007 Indian Health Services Tribal EMS Pediatric Assessment, and the National EMS Database.

[2] FICEMS 2011 National EMS Assessment.

[3] Kuehl, Alexander. ''25.'' Prehospital Systems and Medical Oversight. Dubuque, IA: Kendall/Hunt Pub., 2002. (''For most prehospital medical conditions, patient outcome is assumed to be beneficially influenced by early medical intervention, and contemporary prehospital care systems are a well-defined practice of medicine in the United States.'').

[4] A non-exhaustive list of common controlled substance pharmaceuticals utilized by EMS include the benzodiazepine class of drugs for seizures and sedation as well as morphine (schedule II), fentanyl (schedule II), and meperidine (schedule II) for pain management.

[5] *http://www.ems.gov.*

[6] *Id.*

[7] Consistent with 21 U.S.C. 823(j)(3), DEA is proposing regulations that would continue to allow an EMS agency based in a hospital that is registered under § 1301.13 to use the hospital's registration to administer controlled substances, without being separately registered as an EMS agency.

[8] 21 U.S.C. 823(j)(13)(M) defines *standing order* as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823(j)(13)(N) defines *verbal order* as an oral directive that is given through any method of communication including

regulations that codify the Act's amendments allowing EMS agencies to receive controlled substances from hospitals for the purpose of restocking EMS vehicles, and allowing EMS agencies and hospitals to deliver controlled substances to each other in the event of shortages of such substances, public health emergencies, or mass casualty events.

In this manner, DEA will bring its regulations into conformity with the Act's amendments to the CSA. In particular, DEA's proposed 21 CFR 1300.06 would add 21 U.S.C. 823(j)(13)'s new definitions of relevant terms to DEA regulations. Section 1301.12 would be amended to reflect the statutory amendments of 823(j)(2) and 823(j)(5), and § 1301.13 would be amended to bring it into conformity with 823(j)(1). Proposed § 1301.20(a) is adapted directly from the statutory amendment, specifically from 823(j)(1)–(3). The proposed provisions of § 1301.80(a) would add provisions from 823(j)(6). Proposed § 1304.03(j) is taken from 823(j)(9)(A). Proposed § 1306.07(e) would add the provisions of 823(j)(4) and 823(j)(10)(D) to DEA regulations, while proposed § 1307.14 would add those of 823(j)(8).

Not all of the proposed amendments to DEA regulations, however, directly codify the Act's statutory amendments in DEA regulations. Some of the proposed changes—specifically, §§ 1301.20(b), 1301.80(b), 1304.03(i), 1304.04, 1304.27, 1306.07(f), and 1307.15—implement the purposes of the Act more broadly, consistent with the Administrator's authority to promulgate regulations under 21 U.S.C. 821, 21 U.S.C. 823(j)(11), and 21 U.S.C. 871(b).

A. Definitions

The Act contains a provision, 21 U.S.C. 823(j)(13), defining the terms used throughout its other provisions. In order to conform to the Act, DEA is proposing to add these new definitions to its regulations as part of a new section, 21 CFR 1300.06. This includes defining the terms ''authorizing medical professional,'' ''designated location,'' ''emergency medical services,'' ''emergency medical services agency,'' ''emergency medical services professional,'' ''emergency medical services vehicle,'' ''hospital-based,'' ''medical director,'' ''medical oversight,'' ''registered emergency medical services agency,'' ''registered location,'' ''specific state authority,'' ''standing order,'' and ''verbal order.''

Additionally, the Act contains provisions that allows DEA to issue regulations specifying, with regard to the delivery of controlled substances under 21 U.S.C. 823(j)(5), the types of locations that may be designated. 21 U.S.C. 823(j)(11)(A)(i). In order to conform with the Act, DEA has identified this type of location as a ''stationhouse'' and is proposing to add the definition of a ''stationhouse'' to its regulations as part of 21 CFR 1300.06.

B. Registration for Emergency Medical Services Agencies

1. Current Regulations for EMS Registration

Pursuant to 21 CFR 1301.12(a), controlled substances may only be delivered to, and distributed or dispensed from, a DEA registered location. In addition, under the CSA and DEA regulations, a separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person. 21 U.S.C. 822(e); 21 CFR1301.12(a).

Until the passage of the Act, the CSA and its implementing regulations did not directly mention EMS. Historically, DEA has not specifically registered EMS agencies to procure or dispense controlled substances. Instead, generally, EMS vehicles have obtained controlled substances for dispensing pursuant to a physician's instructions by operating under the registration of a hospital through one of two options.

Under the first option, an EMS vehicle owned and operated by a hospital handles controlled substances under the hospital's registration.[9] The EMS vehicle obtains controlled substances from the hospital's pharmacy or emergency room, as an extension of the hospital pharmacy. Under the second option, an EMS agency is registered under a hospital registration by agreement—that is, a private EMS agency enters into a formal agreement with a specified hospital to act as the hospital's agent. The hospital supplies each EMS vehicle with a prepared kit containing controlled substances needed by the EMS agency and replenishes the kit as necessary. Many EMS agencies are currently using hospital registrations to stock and operate their EMS vehicles at those hospitals in this manner.

2. Proposed Regulations for EMS Registration

The Act authorized the Attorney General (and thus, by delegation, the Administrator) to register EMS agencies, which allowed for a new registration category for EMS professionals to administer controlled substances in schedule II–V to patients receiving emergency medical services. 21 U.S.C. 823(j)(1). The Act thereby effectively amends the CSA to add a new category of registrant—an EMS agency—and to require DEA to grant registrations to those agencies if certain conditions are met. Thus, in conformity with the Act, DEA proposes to amend 21 CFR 1301.13 and to add 21 CFR 1301.20 to provide for the registration of EMS agencies.

As part of this regulatory change, DEA is proposing to add § 1301.20(a) to its regulations, which will describe the registration requirements for EMS agencies registered under § 1301.13. The proposed registration requirements of § 1301.20(a) are taken directly from the Act, 21 U.S.C. 823(j)(1)–(3).

DEA recommends three options to allow EMS agencies to transition their registrations, in accordance with the Act. The three options for EMS agencies to transition are: (1) Transition immediately on the effective date established by DEA; (2) transition at the expiration of their current registration; or (3) transition three to six months prior to their renewal date. DEA recommends that registrants contact their local DEA field office to complete this transition.

C. Designated Location of an Emergency Medical Services Agency

Many EMS agencies currently utilize what is sometimes termed the ''hub-and-spoke'' model where the agency has a main or central location and several stationhouses managed by the main location. The stationhouses are strategically placed throughout a geographical area to provide timely responses to emergency medical needs of the residents of the area. Under DEA's current registration regulations, if only the main location is registered with DEA, the employees of each of the individual (unregistered) stationhouses are not allowed to acquire or store controlled substances at the unregistered stationhouse.

To lessen the burden for EMS agencies with several stationhouses in a single state, the Act allows EMS agencies to choose the option of a single registration in each state where the EMS

by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

[9] EMS agencies' use of this option is now explicitly authorized by the Act, 21 U.S.C. 823(j)(3), and DEA is proposing to add this option to its regulations as 21 CFR 1301.20(a)(2).

agency operates, 21 U.S.C. 823(j)(2), and DEA proposes to amend its regulations accordingly through proposed § 1301.20(a)(1). The Act and the proposed regulation still require EMS agencies that operate EMS facilities in multiple states to have a separate registration in each state where the agency operates, however. In addition, under the Act and § 1301.20(a)(2) of these proposed regulations, hospital-based EMS agencies are allowed to operate under the registration of a hospital to administer controlled substances without being separately registered pursuant to 21 U.S.C. 823(j)(3).

Additionally, the Act amended the CSA to specifically authorize EMS agencies to designate specific unregistered locations where controlled substances would be delivered and stored, but requires registered EMS agencies to provide notice of these locations to the Attorney General at least 30 days before delivery. 21 U.S.C. 823(j)(5). DEA proposes to bring its regulations into conformity with the Act by adding 21 CFR 1301.20(b). Consistent with the Attorney General's authority under 21 U.S.C. 823(j)(11)(A)(ii) to prescribe how EMS agencies provide notice of designated locations, that regulation proposes to require notification of the name and physical address of the designated location through DEA's website, *www.DEAdiversion.usdoj.gov.* Pursuant to proposed § 1301.20(b), an EMS agency still must obtain a DEA registration for the registered location at which it receives controlled substances from distributers. After an EMS agency has been approved for a DEA registration, the EMS agency may identify designated locations through DEA's website, *www.DEAdiversion.usdoj.gov.* An EMS agency that has thus identified designated locations may deliver controlled substances to that designated location 30 days after notification to DEA.

The Act also authorizes the Attorney General to issue regulations specifying the types of locations that may be designated by an EMS agency. 21 U.S.C. 823(j)(11)(A)(i). Pursuant to this authority, DEA is proposing to include a provision in § 1301.20(b) that would allow an EMS agency to label stationhouses as the types of location that would be considered a ''designated location'' of the EMS agency. Additionally, only agency locations that satisfy the proposed regulation's definition of stationhouse (*i.e.,* enclosed structures housing EMS agency vehicles within the state of the emergency medical services agency's registration, and which are actively and primarily being used for emergency response) may be selected as ''designated locations'' by EMS agencies that are registered with DEA. Thus, for example, a location that serves primarily as a residence (such as a house or apartment building) does not meet the proposed definition of a stationhouse and may not be selected as a ''designated location'' by an EMS agency that is registered with DEA. In contrast, a building that is actively serving primarily to house the equipment of a county fire and rescue department, for example, is a stationhouse under the proposed rule (and thus may be selected as a ''designated location'' by an EMS agency that is registered with DEA) regardless of whether such building is also used for overnight accommodation by EMS personnel.

As discussed above, the provisions of proposed § 1301.20(b) outline the process by which a stationhouse is ''designated'' under an existing EMS agency registration. This notification must occur at least 30 days prior to the first delivery of controlled substances to the unregistered designated location of the agency. Unless an objection is raised by DEA, an unregistered location automatically becomes a designated location of the agency 30 days after notification of the designated location is made to DEA.

Additionally, parts of proposed § 1301.80 would codify in DEA regulations the Act's list of the locations where a registered EMS agency may store controlled substances. *See* 21 U.S.C. 823(j)(6). The permissible locations include both the registered and designated location(s) of the agency, and inside an EMS vehicle situated at a registered location or designated location of the agency. Furthermore, the controlled substances may be stored inside any EMS vehicle used by the agency that is traveling from or returning to a registered or designated location of the agency. *Id.* These provisions directly incorporate the Act and make it clear to registrants that under the specified conditions, DEA is allowing the transportation of controlled substances between both registered and designated locations of the agency.

D. Emergency Medical Services Vehicles

Both the Act and the proposed definition of emergency services vehicles in § 1300.06 define EMS vehicles as ambulances, fire apparatus, supervisor trucks, or other vehicles used by an EMS agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations. *See* 21 U.S.C. 823(j)(13)(F). Under the control of the consultant practitioner registration or hospital registration, controlled substances can be supplied to and stored in an EMS vehicle. Proposed § 1301.80 allows a registered EMS agency to store controlled substances in an EMS vehicle located at a registered location, a designated location, or in an EMS vehicle used by the agency that is traveling from, or returning to, a registered or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

E. Proposed Changes to Recordkeeping Requirements

1. Records and Inventories

The transportation of controlled substances for administration to EMS patients presents unique recordkeeping concerns. With regard to non-practitioners that transport controlled substances (*e.g.,* manufacturers, distributors, exporters, importers), DEA can track the movement of the controlled substances through recordkeeping and reporting requirements within the two-registrant integrity system. Generally, the registrant that transports controlled substances maintains a record of, and would report delivery of the controlled substances, while the registrant that receives the controlled substances must account for the received controlled substances. Every registrant is required to maintain complete and accurate records of each substance manufactured, imported, received, sold, delivered, exported, or disposed of. 21 CFR 1304.21(a). This two-registrant integrity system provides an effective means of protection against diversion in that the transfer of the controlled substances shall be verified by two separate registrants, thus helping to ensure that controlled substances are not diverted for illicit use.

EMS agencies are typically the last registrants to possess controlled substances prior to administering to a patient at the scene of an emergency. As such, the two-registrant integrity system does not exist beyond the transfer to an EMS agency, in the traditional sense of registrant recordkeeping. Therefore, DEA is proposing recordkeeping regulations for EMS agencies to incorporate the Act's CSA amendments regarding recordkeeping, and to ensure an accurate accounting of the controlled substances outside the two-registrant integrity system.

DEA proposes § 1304.03(i) to require EMS agencies to maintain records of the EMS personnel whose State license or certification gives them the ability to administer controlled substances, in compliance with their State laws. Because states have differing requirements for the ability to handle controlled substances, maintaining records of employees authorized to handle controlled substances will help DEA identify the source of any diversion occurring at EMS agencies.

Proposed § 1304.03(i) is not based directly on the text of the Act, but instead on DEA's general authority under the CSA to prevent diversion of controlled substances by requiring registrants to maintain records. *See* 21 U.S.C. 823(j)(12)(B) (nothing in the Act is to be construed to limit the authority of the Attorney General to take measures to prevent diversion).

a. Restocking

Following an emergency response where controlled substances were administered, EMS personnel may not have enough time to return to their stationhouse to restock their EMS vehicle with controlled substances. Depending on the circumstances, the stationhouse may be a considerable distance from the hospital where the EMS personnel brought a patient, or the volume of emergencies may be so great that the ambulance does not have time to return to the stationhouse. Rural EMS systems in the United States may face transport distances of 20 to 100 miles to the nearest hospital.[10] Thus, the Act allows non hospital-based EMS agencies to receive controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. 21 U.S.C. 823(j)(8). DEA's proposed § 1307.14(a) codifies this allowance in DEA regulations.

b. Maintenance of Records

Under § 1304.04(a), controlled substance records for all DEA registrants are required to be maintained for at least two years from the date of such inventory or records. Under this proposed rule, DEA would require maintenance of records of deliveries of controlled substances between all locations of the agency. Following the Act, 21 U.S.C. 823(j)(9)(B)(ii), DEA also proposes in § 1304.04(a)(5) to require that records be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

Because EMS agencies have a unique registration that differs from other types of registrants, DEA is also proposing to add a new section to its regulations that describes the additional recordkeeping requirements applicable to EMS agencies. Consistent with the Act's amendments to the CSA, 21 U.S.C. 823(j)(9), proposed § 1304.27(a) would require an EMS agency to maintain records for each controlled substance administered or disposed of in the course of providing emergency medical services. Under proposed § 1304.27(a), any EMS personnel who disposes of or administers controlled substances to a patient in the course of providing emergency medical care must record the name of the controlled substance(s) and detailed information about the circumstances surrounding the administration of the controlled substance(s) (*e.g.,* name of the substance, date dispensed, identification of the patient). EMS personnel do not have independent authority to administer controlled substances; therefore, more stringent recordkeeping requirements are necessary when allowing administration of controlled substances without direct oversight.

DEA proposes in § 1304.27(b)(3) that an EMS agency must maintain records of controlled substances delivered between registered and designated locations of the agency (except agencies restocking at the hospital under which the EMS agency is operating, because the hospital is required to keep records of such restocking). These records, for example, should include the name of the controlled substance(s), finished form, number of units in the commercial container, date delivered, and the address of the EMS agency location where the controlled substances were delivered. In the event of theft or loss of controlled substances, registrants must report such occurrence in accordance with the theft and loss reporting requirements of 21 CFR part 1304.

Finally, under 21 U.S.C. 823(j)(8)(c) of the Act, designated locations of an EMS agency must notify the registered location of their EMS agency within 72 hours of receiving controlled substances from a hospital for the purpose of restocking an EMS vehicle following an emergency response. DEA's proposed § 1304.27(c) would codify this requirement in DEA regulations. However, EMS agencies that operate under a hospital-based registration and receive restock of controlled substances from the hospital under which the agency is operating would be exempt from these requirements. In this specific instance, under proposed § 1307.14(a)(2), hospitals would already have a record of the controlled substances that the hospital delivered to the EMS agency operating under that hospital's registration. As such, it would be duplicative to require that EMS agency to obtain a receipt of those controlled substances because the EMS agency would be reporting receipt of the controlled substances back to the hospital that issued the controlled substances in the first place.

F. Proposed Changes for Security Requirements

1. Security Controls

Every DEA registrant must follow certain security requirements to prevent the theft or loss of controlled substances, and the Act authorizes the Attorney General to issue regulations specifying the manner in which controlled substances must be stored by EMS agencies. 21 U.S.C. 823(j)(11)(B). Pursuant to this authorization, DEA proposes to implement physical security requirements for EMS agencies similar to those already established for practitioners in § 1301.75. Although § 1301.75 addresses general physical security controls for practitioners, EMS agencies have some unique security concerns that require additional security controls as discussed below.

a. Storage of Controlled Substances

Pursuant to its authorization under the Act to issue regulations regarding EMS agencies' storage of controlled substances, DEA proposes to add § 1301.80 to address additional security concerns for EMS agencies. First, although designated locations of EMS agencies are not individually registered, they are allowed to store controlled substances in certain secured locations. Proposed § 1301.80(a)(1) through (4) specifies the locations within an EMS agency where controlled substances may be stored, and implements the Act's allowance in 21 U.S.C. 823(j)(6) of storage at EMS registered locations, at designated locations, inside of EMS vehicles stationed at registered or designated locations, and inside of EMS vehicles that are actively in use by the agency.

In addition, DEA proposes to add § 1301.80(b) to allow two options for storage components in which EMS agencies may store controlled substances. This change is not taken directly from the Act's statutory amendments to the CSA, but instead implements the Act's authorization to the Attorney General to ''specify . . .

[10] Williamson, H.A., Jr. (2001). Emergency Care. In J.P. Geyman, T.E. Norris & L.G. Hart (Eds.), *Textbook of Rural Medicine* (pp. 93–102). New York: The McGraw-Hill Companies, Inc.

the manner in which [controlled] substances must be stored at registered and designated locations, including in EMS vehicles.'' 21 U.S.C. 823(j)(11)(B).

The first option in proposed § 1301.80(b)(1) would allow for an EMS agency to store controlled substances in a securely locked, substantially constructed cabinet or safe that cannot be readily removed. This storage component must be located at a secured location, as stated in proposed § 1301.80(i).

The second option in proposed § 1301.80(b)(2) would allow an EMS agency to store controlled substances in an automated dispensing system (ADS) machine, under specific conditions. An ADS is ''a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains all transactions in information.'' 21 CFR 1300.01. Currently, DEA regulations permit retail pharmacies to install and operate ADS machines at long-term care facilities as a way of preventing the accumulation of surplus controlled substances at those facilities. *See id.* § 1301.27. At an EMS agency registered or designated location, an ADS machine effectively would serve as a controlled substance storage locker with advanced capabilities and would provide a mechanism for storing stocks of controlled substances before they are secured in emergency vehicles as well as for monitoring the dissemination of those substances.

The proposed conditions in § 1301.80(b)(2) under which an EMS agency could use an ADS machine to store controlled substances include the following: (1) The ADS machine must be located at an EMS agency registered location or designated location; (2) the EMS agency cannot permit any entity other than the registered EMS agency to install and operate the ADS machine; (3) the ADS machine cannot be used to directly dispense controlled substances to an ultimate user; and (4) EMS agency must operate the ADS machine in compliance with requirements of State law. It is necessary that access to the ADS machine be limited to employees of the EMS agency in order to account for and monitor dissemination of controlled substances.

In sum, proposed § 1301.80(b) would provide alternative options for short-term or long-term storage of controlled substances that are actively being transported or stored in a fixed location.

b. Delivery

As discussed in Section C, the Act allows for controlled substances to be delivered between a registered location and a designated location of an EMS agency. 21 U.S.C. 823(j)(5). Also, pursuant to its authorization to issue regulations regarding the delivery of controlled substances under 21 U.S.C. 823(j)(11), DEA proposes that medical directors determine who accepts deliveries of controlled substances because medical directors provide oversight for EMS agencies. Specifically, proposed § 1301.80(c) would require that the delivery of controlled substances at a registered or designated location be accepted by a medical director of the agency or a person designated in writing by the medical director. For record keeping purposes of the delivery of controlled substances, proposed § 1304.27(b)(3) would require the medical director of the agency or designated person accepting the controlled substances to provide their signature, title, date received, quantity, and any additional information required. The proposed regulations specify the requirements that would be set forth regarding the delivery of controlled substances for emergency medical services.

G. Proposed Administration Requirements

DEA proposes to add § 1306.07(e), which implements 21 U.S.C. 823(j)(4) in DEA regulations, allowing EMS professionals of registered EMS agencies to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services.[11] Medical directors and EMS professionals authorized to administer controlled substances under their State license may administer controlled substances in the course of providing emergency medical services. However, under 21 U.S.C. 823(j)(4) and proposed § 1306.07(e), an EMS professional who is outside the physical presence of a medical director or authorizing medical professional must not only have authority from their EMS agency to administer controlled substances, but such administration must also be pursuant to a proper standing or verbal order issued and adopted by one or more medical directors of the agency, as discussed below.

1. Standing Orders

Many agencies have given their EMS personnel the autonomy to administer controlled substances in the event of an emergency by establishing what is commonly known as a standing order. The Act defines a standing order as a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services. 21 U.S.C. 823(j)(13)(M). DEA's proposed § 1300.06 incorporates this definition into DEA regulations.

The Act and proposed § 1306.07(e) would allow standing orders to be used by EMS professionals. Under both the Act and the proposed regulation, such EMS professionals must be authorized by their individual State to administer controlled substances. *See* 21 U.S.C. 823(j)(4). Standing orders that are developed by a state authority may be issued and adopted by the medical director of an EMS agency. Under the Act and proposed § 1306.07(e), only the medical director of an EMS agency is given the authority to issue and adopt a standing order. *See* 21 U.S.C. 823(j)(4). Also, under both the Act and proposed § 1306.07(e), the EMS agency is required to maintain a record of the standing orders issued and adopted by a medical director at the registered location of the agency. 21 U.S.C. 823(j)(10)(D).

2. Verbal Orders

In the absence of standing orders, EMS personnel may receive a verbal order. Under the Act and proposed § 1300.06, a verbal order is an oral directive through any method of communication including by radio or telephone, directly to an EMS professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional. *See* 21 U.S.C. 823(j)(13)(N). The Act and proposed § 1300.06 define ''authorizing medical professional'' as an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant) who is registered under 21 U.S.C. 823, who is acting within the scope of the registration, and whose scope of practice under a State license

[11] Currently, the regulations in 21 CFR part 1306 relate primarily to prescriptions, and thus 21 CFR 1306.01 states part 1306's scope as generally consisting of ''[r]ules governing the issuance, filling and filing of prescriptions pursuant to . . . 21 U.S.C. 829.'' Because DEA is proposing to add provisions related to the administration of controlled substances by EMS agencies to part 1306, DEA is also proposing to amend § 1306.01 to broaden part 1306's stated scope to ''the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users.''

or certification includes the ability to provide verbal orders. *See* 21 U.S.C. 823(j)(13)(A).

Under the Act and proposed § 1306.07(e), an EMS professional may administer directly a controlled substance in schedules II–V outside of the presence of a practitioner in the course of providing emergency medical services if the administration is authorized by State law and is pursuant to a verbal order that is issued in accordance with the policy of the agency. Such authorization must be provided by a medical director or authorizing medical professional in response to a request by the EMS professional with respect to a specific patient, either in the case of a mass casualty incident, or to ensure the proper care and treatment of a specific patient. Under proposed § 1307.15 and consistent with the Act under 21 U.S.C. 823(j)(4)(B), EMS agencies must contact the Special Agent in Charge (SAC) for the area or DEA Headquarters Diversion Control Division for approval of shortages, public health emergencies, or mass casualty events.

III. Regulatory Analyses

As explained above, DEA is issuing this proposed rule to amend its regulations in order to make them consistent with the changes made to the CSA by the ''Protecting Patient Access to Emergency Medications Act of 2017,'' and to otherwise implement the Act's requirements. DEA conducted an analysis of the statutory and regulatory changes of this proposed rule, the results of which are discussed below.

Executive Orders 12866 (Regulatory Planning and Review), 13563 (Improving Regulation and Regulatory Review), and 13771 (Reducing Regulation and Controlling Regulatory Costs)

This proposed rule was developed in accordance with the principles of Executive Orders (E.O.) 12866, 13563, and 13771. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 is supplemental to and reaffirms the principles, structures, and definitions governing regulatory review as established in E.O. 12866. E.O. 12866 classifies a ''significant regulatory action,'' requiring review by the Office of Management and Budget (OMB), as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy; a sector of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

DEA expects that the annual economic impact of this proposed rule, in the form of changes in transfers, to range from a decrease of $302,885 to an increase of $550,612 at a 7 percent discount rate; or from a decrease of $379,584 to an increase of $690,043 at a 3 percent discount rate. Fees paid to DEA are considered transfer payments and not costs.[12] Annual changes in labor burden costs as a result of this proposed rule are expected to range from a decrease of $12,696 to an increase of $42,782 at a 7 percent discount rate; or from decrease of $16,253 to an increase of $49,879 at a 3 percent discount rate. Therefore, this proposed rule is not an economically significant regulatory action. The analysis of transfers, cost savings, and benefits is below. The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and while the proposed rule is not economically significant, it has been determined that it is a significant regulatory action under E.O. 12866. Accordingly, this rule has been submitted to OMB for review.

E.O. 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017, and published in the **Federal Register** on February 3, 2017. 82 FR 9339. Section 2(a) of E.O. 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment or otherwise promulgates a new regulation. In furtherance of this requirement, section 2(c) of E.O. 13771 requires that the new incremental costs associated with new regulations, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. Guidance from OMB, issued on April 5, 2017, explains that the above requirements only apply to each new ''significant regulatory action that . . . imposes costs.'' Additionally, this guidance states that ''Generally, 'one-time' regulatory actions (*i.e.,* those actions that are not periodic in nature) that expand consumption and/or production options would qualify as E.O. 13771 deregulatory actions.'' While DEA has determined that this proposed rulemaking is a ''significant regulatory action,'' DEA anticipates that it will be classified as an enabling rule by OMB because it allows EMS agencies to consolidate many registrations in the same State under a single registration, and EMS personnel to administer controlled substances in schedules II–V pursuant to a standing or verbal order, which was previously not authorized. Therefore, this proposed rule is not expected to be an E.O. 13771 regulatory action.

Analysis of the Proposed Rule's Economic Impact

DEA analyzed the impact of the following provisions of the proposed rule: Allowing EMS agencies to register under the CSA with a single registration for each State in which an agency operates, along with the proposed security and recordkeeping requirements for such a registrant; allowing EMS personnel to administer controlled substances in schedules II–V outside the presence of a medical director or authorizing medical professional when authorized in the State and pursuant to a standing or verbal order; and allowing EMS agencies and hospitals to transfer controlled substances between each other in order to restock EMS vehicles or to deliver controlled substances in the event of shortages, public health emergencies, or mass casualty events. Additionally, this proposed rule is incorporating into regulation several new terms defined in the Act.

Benefits of the proposed rule are expected to be generated by reducing regulatory uncertainty among EMS agencies and personnel regarding the administration, transfer, and disposal of controlled substances, and these benefits will be discussed qualitatively. By allowing EMS registrants to consolidate multiple registrations into a single registration for each State in which they currently operate, there will be a resulting reduction in transfer payments for current registrants. The proposed rule may also result in an increase in transfer payments for EMS agencies that are currently not separately registered. The expected net change in transfer payments is quantified below. There are also labor

[12] OMB Circular A–4.

burden costs associated with obtaining a DEA registration for any EMS agencies that must become separately registered after this rule is promulgated. These costs or cost savings are discussed and quantified below. DEA expects the recordkeeping and security requirements of this proposed rule to have no impact, as they are codifications of existing practice among EMS agencies. Finally, the newly defined terms being incorporated into regulation by this proposed rule will have no impact on regulated entities.

Registrations for Emergency Medical Services Agencies

While this proposed rule is allowing for a new registration category for EMS agencies that handle controlled substances, many EMS agencies have already obtained separate DEA registrations as ''Mid-level Practitioner—Ambulance Service'' (MLP–AS).[13] As of November 2019, there were 3,521 MLP–AS registrants, 1,413 of which are private sector entities that pay a registration fee of $731 every three years. The remaining 2,108 are governmental entities that are fee-exempt. DEA reviewed its registration database and determined that 395 of the 1,413 fee-paying registrations are held by EMS agencies with other existing registrations in the same State. Because the proposed rule allows EMS agencies to obtain a single registration for each State in which they operate, these 395 registrations can be consolidated under other existing registrations, reducing the total amount of registration fees collected by DEA. The resulting annual reduction in transfer payments from registrants to DEA amounts to $96,248.[14]

Similarly, of the 2,108 fee-exempt registrations, 411 can be consolidated into an agency's existing registration in the same State, reducing the labor-related paperwork burden for these agencies, as they no longer need to complete multiple registration renewal applications for the same State every three years. Combining the 411 fee-exempt registrations with the 395 fee-paying registrations results in a total of 806 registration renewal applications that are eliminated. The resulting annual cost savings generated from this reduction in labor burden is $3,026.[15]

DEA assumes that all other EMS agencies not registered as MLP–AS currently operate under the registration of another DEA registrant in one of two ways: A DEA registered practitioner, typically a licensed physician, serves as the medical director of the EMS agency; or for EMS agencies operated by hospitals, the agency will utilize that hospital's registration. In the latter case, hospital-based EMS agencies can continue to operate under the registration of their hospital after promulgation of this proposed rule. In the former case, practitioners who serve as the medical director of an EMS agency may utilize a single registration for their personal place of business and EMS agency locations,[16] or they may hold practitioner registrations separate from their personal place of business registration for each EMS agency location that they oversee. Because this proposed rule allows a medical director holding multiple registrations to transfer those existing registrations directly to one EMS agency, EMS agencies operating under this arrangement will not need a new registration. However, for EMS agencies currently operating under their medical director's registered personal place of business, a new EMS agency registration for each state in which they operate will be required. Additionally, affected non-governmental EMS agencies must pay the $731 registration fee.

Accurately measuring how many EMS agencies fall into the two aforementioned categories is not possible using DEA registration data, because DEA has not historically collected data on how many practitioners hold multiple registrations for the purposes of serving as the medical director of an EMS agency. Therefore, DEA chose to estimate how many new registrations will be required by considering the entire range of possible scenarios, and calculated the outcome if either 0 percent, 50 percent, or 100 percent of EMS agencies will receive a transferred practitioner registration from their medical director. While DEA cannot accurately assess the likelihood of each of these scenarios given the lack of available data, DEA considers the 50 percent scenario to be the most plausible of the three estimates because it is the mid-point of the upper and lower bounds.

In order to calculate the range of impacted entities, DEA must first estimate the total population of EMS agencies active in the United States. Because DEA registration data are insufficient for these purposes, DEA used the latest data available from the National Highway Traffic Safety Administration's (NHTSA) Office of EMS. According to an NHTSA research note published in 2014,[17] there are an estimated 21,283 governmental and non-governmental EMS agency locations throughout the United States. The 21,283 figure is NHTSA's estimation of the total population using data gathered from 49 of 50 States.[18]

DEA then analyzed its registration database to match current MLP–AS registrants with the corresponding EMS organizational types defined in the NHTSA research note.[19] Because the survey data used by NHTSA to develop these organizational types did not include California (CA), Illinois (IL), Washington (WA), or Virginia (VA), the total number of EMS agency locations categorized by type amounts to 15,516 instead of the total 21,283 estimated EMS agency locations throughout the United States. DEA assumes that the distribution of EMS agencies by

[13] These existing registrations will be transitioned to the new ''Emergency Medical Services Agency'' registration category created by this proposed rule.

[14] 395 × $731 = $288,745. Dividing this figure by three to account for the three-year registration cycle, and rounding to the nearest whole dollar gives $96,248.

[15] *See* approved burden estimates for DEA form 224A within the 1117–0014 Supporting Statement *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005*. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (806). The product ($9,078.14) is then divided by three in order to account for the three-year registration renewal period, and rounded to the nearest whole dollar. The loaded hourly wage of $140.79 is based on the median hourly wages for Occupation Code 29–1069 Physicians and Surgeons, All Other ($96.58). May 2018 National Occupational Employment and Wage Estimates, United States, Bureau of Labor Statistics, *https://www.bls.gov/oes/current/oes_nat.htm#29-1069* (last visited November, 2019). Average benefits for employees are 31.4 percent of total compensation. Employer Costs for Employee Compensation—June, 2019, Bureau of Labor Statistics, *https://www.bls.gov/news.release/pdf/ecec.pdf* (last visited November, 2019). The 31.4 percent of total compensation equates to a 45.77 percent (31.4/68.6) load on wages and salaries. $96.58 × (1 + 0.4577) = $140.79.

[16] Under this scenario, the EMS agency must pick up controlled substances from the practitioner's personal place of business.

[17] *https://www.ems.gov/pdf/812041-Natl_EMS_Assessment_2011.pdf*. The comprehensive national assessment that this research note is based on, the first of its kind, has not been updated since 2011. Prior to this national assessment, data on the number and type of EMS agencies operating throughout the United States was fragmented and considered to be inaccurate. Therefore, DEA considers this is the most accurate data regarding EMS agency demographics available.

[18] CA data were not available.

[19] The NHTSA research note breaks down the demographics of EMS agencies into the following organizational types: ''Fire-Department-Based,'' ''Governmental Non-Fire-Based,'' ''Hospital-Based,'' ''Private Non-Hospital,'' ''Tribal,'' ''Other EMS Agency,'' and ''Emergency Medical Dispatch.'' The ''Other EMS Agency'' organizational type is not defined in the research note or national assessment survey on which the research note is based; however, for the purposes of this analysis, DEA considers this category to be made up of private sector entities. The ''Emergency Medical Dispatch'' category is excluded from this analysis because dispatch agencies will not be required to obtain a DEA registration.

organizational type in CA, IL, WA, and VA broadly matches the national distribution. Therefore, DEA adjusted for this missing data by calculating the percent of the total for each organizational type for the 46 reporting States and applied those percentages to the estimated 21,283 EMS agencies in the entire United States.[20] DEA was then able to categorize current MLP–AS registrants as Fire-Department-Based, Governmental Non-Fire-Based, Private Non-Hospital, or Tribal, according to their registration name.[21]

It is reasonable to assume that a portion of these estimated EMS agencies not separately registered operate multiple locations in the same State. The NHTSA research note states that EMS agencies are ''licensed in each State to provide service to a specific location or service area. EMS service areas can be very large, as in a geopolitical boundary, such as a county, city or municipality, or as small as the local service area of a single EMS agency station.'' This definition suggests that the 21,283 total EMS agencies estimated by NHTSA includes EMS agencies operating multiple stations in the same State. Because only one registration is required for multiple ''agencies,'' as defined by NHTSA, DEA must adjust its calculation of the number of EMS agencies not separately registered to account for this.

In order to estimate how many EMS agencies not separately registered operate more than one location in a State, DEA used the existing MLP–AS registrant category as a model. It is reasonable to assume that the characteristics of the population of EMS agencies registered as MLP–AS are broadly representative of the characteristics of the population of EMS agencies that are not separately registered. As discussed previously, the fee-paying MLP–AS registrant category contains 1,413 registrations that can be consolidated into 1,018 registrations. Similarly, the fee-exempt category contains 2,108 registrations that can be consolidated into 1,697 registrations.

DEA used these figures to calculate a State-level ''agency-to-location'' ratio of 0.72 for fee-paying registrants,[22] and 0.81 for fee-exempt registrants.[23] These ratios are then applied to the estimated 6,705 private-sector and 13,342 governmental EMS agency locations not separately registered with DEA, respectively, to determine the expected total number of EMS agencies that require separate registrations as a result of this proposed rule.[24] This calculation yields an estimated total of 15,634 EMS agencies that will be separately registered, 4,827 of which are fee-paying, and 10,807 of which are fee-exempt. Removing the 1,018 fee-paying and 1,697 fee-exempt MLP–AS registrants from these respective totals yields an estimated 3,809 fee-paying and 9,110 fee-exempt EMS agencies that must obtain a separate registration after this rule is promulgated. These calculations are summarized in table 1 below.

TABLE 1

EMS agency org type	Reported pop	% of reported pop	Est. pop	Est. number of reg*	Current MLP–AS	MLP–AS reg eliminated	Post-rule MLP–AS	Non-MLP–AS reg eliminated	Total reg eliminated	Fee status
Fire-Dep't-Based	6,388	41.17	8,762	7,097	1,145	251	894	1,414	1,665	Exempt.
Gov't Non-Fire	3,255	20.98	4,465	3,617	960	160	800	688	848	Exempt.
Hospital-Based	901	5.81	1,236	N/A	N/A	N/A	N/A	N/A	N/A	N/A.
Private Non-Hospital	3,910	25.20	5,363	3,861	1,413	395	1,018	1,107	1,502	Paying.
Tribal	84	0.54	115	93	3	0	3	22	22	Exempt.
Other EMS**	978	6.30	1,342	966	0	N/A	0	376	376	Paying.
Total	15,516	100	21,283	15,634	3,521	806	2,715	3,607	4,413	

* Figures in this column are calculated by multiplying the corresponding row of the Est. Pop column by either the fee-paying ''Agency-to-Location'' ratio of 0.72 or the fee-exempt ''Agency-to-Location'' ratio of 0.81, depending on each registrant's fee status reported in the Fee Status column.
** Category not defined in the 2011 National Assessment; assumed to be private-sector entities.

As discussed previously, DEA's methodology for estimating the number of new EMS agency registrations must account for situations in which a practitioner is currently using a single DEA registration to serve as the medical director of multiple EMS agency locations. Because DEA does not have the ability to identify how many EMS agencies are currently operating in this manner, DEA chose to calculate a range of between 0 percent and 100 percent of EMS agencies that may have a DEA registration transferred from a practitioner. If 100 percent of the estimated 3,809 fee-paying EMS agencies not separately registered are currently operating under a practitioner registration that will be transferred from their medical director, there will be no increase in fees (transfer payments) from these future registrants to DEA. If 0 percent of these 3,809 fee-paying EMS agencies operate under a practitioner registration that can be transferred from their medical director, there will be an increase in fees (transfer payments) of $928,126 to DEA on an annual basis.[25] Likewise, calculations for the 50 percent scenario yield an estimated increase in fees (transfer payments) of $464,185.[26]

Similarly, if 100 percent of the estimated 1,483[27] fee-paying registrations able to be consolidated currently operate under a practitioner that is using a single DEA registration to serve as the medical director of an EMS, there will be an annual reduction in transfer payments of $361,358.[28] This transfer payment reduction is combined with the previously calculated reduction in transfers of $96,248 from the 806 MLP–AS registrations that will be consolidated, resulting in a total

[20] For example, of the 15,516 EMS agency locations reported to NHTSA by organizational type, 6,388 were Fire-Department-Based. 6,388 is 41.17 percent % of 15,516. 41.17 percent of 21,283 is 8,762. This calculation is repeated for each organizational type and the results are reported in the ''Est. Pop'' column of Table 1.

[21] In order to classify EMS agencies currently registered as MLP–AS as either ''Fire-Department-Based'' or ''Governmental Non-Fire-Based,'' DEA filtered all fee-exempt MLP–AS registrants into two groups based on whether their registration name contained the word ''fire.''

[22] 1,018/1,413 = 0.72.

[23] 1,697/2,108 = 0.81.

[24] An ''agency-to-location'' ratio is not applied to the estimated 1,236 hospital-based EMS agencies, beacuse this proposed rule does not impact their registration status.

[25] 3,809 × $731 = 2,784,379. This figure is divided by three in order to account for the three-year registration cycle, resulting in $928,126 (figure is rounded).

[26] 3,809 × .5 = 1,905 (rounded). (1,905 × $731)/3 = $464,185.

[27] Sum of the ''Private Non-Hospital'' and ''Other EMS'' rows of the Non-MLP–AS Registrations Eliminated column of Table 1. 1,107 + 376 = 1,483.

[28] 1,483 × $731 = $1,084,037. This figure is divided by three in order to account for the three-year registration cycle, resulting in $361,358.

reduction in transfers of $457,606. However, if 0 percent of agencies are operating in this manner, only the 806 MLP–AS consolidated registrations are relevant, resulting in a net increase in transfer payments of $831,878.[29] Calculations for the 50 percent scenario yield an estimated reduction in fees (transfer payments) of $277,049.[30] This results in a net increase of $187,136 for the midpoint scenario.[31] Therefore, DEA estimates the annual net change in transfer payments as a result of this proposed rule will range between a decrease of $457,606 and an increase of $831,878, with the midpoint of these estimates resulting in an increase of $187,136.

For the respective 0 percent, 50 percent, and 100 percent scenarios, DEA converted the estimated annual change in transfer payments calculated above into annualized present values at a 7 percent discount rate and a 3 percent discount rate over 12 years, or three registration cycles.[32] The results of this analysis are summarized below in Table 2.

TABLE 2

	100% of registrations Are transferred	50% of registrations are transferred	0% of registrations are transferred
Annual Change in Transfer Payments—MLP–AS (Consolidated)	$(96,248)	$(96,248)	$(96,248)
Annual Change in Transfer Payments—EMS not Separately Registered	0	464,185	928,126
Annual Change in Transfer Payments—EMS Not Separately Registered (Consolidated)	(361,358)	(180,801)	0
Net Annual Change in Transfer Payments	(457,606)	187,163	831,878
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 7%)	(302,885)	123,864	550,612
Annualized Net Change in Transfer Payments Over 12 Years (Discounted 3%)	(379,584)	155,229	690,043

All figures are rounded.

Labor Burden of Applications for DEA Registrations and Renewals

As detailed previously, of the estimated 4,827 fee-paying EMS agency locations and 10,807 fee-exempt EMS agency locations not separately registered, only 3,809 and 9,110 (a total of 12,919) will require separate registrations after the promulgation of this proposed rule, respectively. If 100 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a decrease in labor burden of $16,568,[33] due to the estimated 4,413 [34] unnecessary registration renewal applications that can be consolidated under one registration in a state. The previously calculated annual cost savings of $3,026 (*see* note 15) from the consolidation of existing MLP–AS registrants is added to this total, resulting in an annual total labor burden reduction of $19,594. DEA converted the $19,594 decrease in labor burden into an annualized present value of $12,969 at a 7 percent discount rate and $16,253 at a 3 percent discount rate over three registration cycles, or 12 years.[35]

However, if 0 percent of these 12,919 EMS agencies will have an existing practitioner registration transferred from their medical director, there will be a one-time increase in labor burden of $272,830 [36] due to the initial registration application paperwork for 12,919 registrants, and a triennial labor burden increase of $136,431,[37] due to 12,919 registration renewals every three years. DEA converted the one-time burden of $272,830 and the triennial burden of $136,431 into an annualized present value of $42,782 at a 7 percent discount rate and $49,879 at a 3 percent discount rate over three registrations cycles, or 12 years.[38]

Finally, under the 50 percent scenario, there will be a one-time increase in labor burden of $136,426 [39] due to the initial registration application paperwork for 6,460 registrants, and a triennial labor burden increase of $38,824,[40] due to 4,253 registration renewals every three years. DEA converted the one-time burden of

[29] $928,126 (calculated in note 25) − $96,248 = $831,878.

[30] 1,483 × .5 = 742 (rounded). ((742 x $731)/3) + $96,248 = $277,049.

[31] $464,185 (calculated in note 26) − $277,049 = $187,136.

[32] The present value of $(457,606) over 12 years equals $(3,634,620.91) at 7 percent and $(4,555,011.95) at 3 percent. The present value of $831,878 over 12 years equals $6,607,305.99 at 7 percent and $8,280,516.93 at 3 percent. The present value of $187,136 over 12 years equals $1,486,362.54 at 7 percent and $1,862,752.49 at 3 percent. Dividing these respective results by 12 to account for three registration cycles yields the annualized net change in transfer payments found in Table 2.

[33] *See* approved burden estimates for DEA form 224A within the 1117–0014 Supporting Statement *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005*. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (4,413). The product ($49,704.50) is then divided by three in order to account for the three-year registration renewal period.

[34] As calculated previously, there are 395 fee-paying and 411 fee-exempt MLP–AS registrations that will be consolidated under a single registration in a State. Of the EMS agencies that are not separately registered, an estimated 3,607 can be consolidated under a single registration in a State. Combining 806 with 3,607 results in 4,413.

[35] The present value of $19,594 over 12 years equals $195,038.75 at 3 percent and $155,629 at 7 percent. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

[36] *See* approved burden estimates for DEA form 224 within the 1117–0014 Supporting Statement *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005*. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224 (0.15), by the estimated number of forms (12,919). The result is rounded.

[37] *See* approved burden estimates for DEA form 224A within the 1117–0014 Supporting Statement *https://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201903-1117-005*. This labor burden estimate is derived by multiplying the loaded hourly wage for physicians ($140.79) by the hour burden per electronic DEA form 224A (0.08), by the estimated number of forms (12,919), resulting in $145,509.28. This figure is reduced by $9,078 to account for the triennial cost savings from the consolidation of existing MLP–AS registrants calculated in note 15, resulting in $136,431.

[38] The present value of $272,830 in year 1 and $136,431 in years 4, 7, and 10 equal $598,549.04 at 3 percent and $513,380.84 at 7 percent discount rates. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

[39] 12,919 × 0.5 = 6,460 registrants. $140.79 × 0.15 × 6,460 = $136,426. The result is rounded.

[40] (12,919 × 0.5) − (4,413 × 0.5) = 4,253. $140.79 × 0.08 × 4,253 = $47,902 (rounded). This figure is reduced by $9,078 to account for the triennial cost savings from the consolidation of existing MLP–AS registrants calculated in note 15, resulting in $38,824.

$136,426 and the triennial burden of $38,824 into an annualized present value of $16,753 at a 7 percent discount rate and $18,950 at a 3 percent discount rate over three registration cycles, or 12 years.[41]

Table 3 summarizes the estimated net change in labor burden cost for both scenarios as a result of this proposed rule.

TABLE 3

	100% of registrations are transferred	50% of registrations are transferred	0% of registrations are transferred
Annualized Net Change in Labor Burden Over 12 Years (Discounted 7%)	$(12,969)	$16,753	$42,782
Annualized Net Change in Labor Burden Over 12 Years (Discounted 3%)	(16,253)	18,950	49,879

Security and Recordkeeping Requirements

Because some EMS agencies are currently registered under the practitioner business activity as MLP–AS, this proposed rule adopts similar physical security controls for EMS agencies as practitioners. EMS agencies will be authorized to store controlled substances at EMS registered locations and designated locations inside of a securely locked, substantially constructed cabinet or safe that cannot be readily removed or an automated dispensing system; inside EMS vehicles stationed at registered or designated locations; and inside EMS vehicles that are actively in use by the agency. DEA expects currently unregistered EMS agencies to be operating in a similar manner as registered MLP–AS, and such EMS agencies are already in compliance with the minimum physical security requirements outlined above. Therefore, DEA expects the physical security requirements of this proposed rule to be a codification of existing practice that will impose no costs.

The recordkeeping provisions of this proposed rule require EMS agencies to record the details of any administration, disposal, acquisition, distribution, or delivery of controlled substances and make these records readily retrievable. DEA believes that EMS agencies are already collecting and storing these records as a normal course of their business operations, and therefore these recordkeeping requirements will have no economic impact on EMS registrants. Designated EMS locations with vehicles that restock controlled substances at a hospital after an emergency event or receive controlled substances from another designated location must also notify the registered location of the EMS agency within 72 hours. Because designated EMS locations have 72 hours to notify registered locations, and because designated and registered locations are likely to communicate on a more frequent basis during their normal course of business, DEA does not expect these events to require any additional communication between designated and registered locations. Therefore, this provision will also have no economic impact on EMS registrants. DEA requests comment on the impact of this proposed rule's recordkeeping requirements.

Reducing Regulatory Uncertainty

Prior to the CSA amendments of the ''Protecting Patient Access to Emergency Medications Act of 2017,'' the CSA did not explicitly explain exactly how its rules governing the administration, disposal, delivery, acquisition, and distribution of controlled substances applied to EMS agencies. Most adhered to rules governing mid-level practitioners in the absence of regulation that addressed the unique circumstances of EMS operations, and advocacy groups frequently highlighted their concerns regarding the need for regulations to specifically address EMS operations.

With the Act, and this proposed rule codifying the resulting CSA amendments into DEA regulation, EMS registrants have clear rules that direct their behavior regarding controlled substances. DEA expects there to be benefits resulting from this reduction in regulatory uncertainty, especially the explicit authorization of standing and verbal orders, by allowing EMS vehicles to restock their supply of controlled substances at hospitals following an emergency, and by allowing EMS vehicles and hospitals to transfer controlled substances between each other in the event of a shortage, public health emergency, or mass casualty event. DEA does not have a method to quantify the impact of these reductions in regulatory uncertainty; however, DEA believes the regulatory clarity provided by this proposed rule will result in a benefit to EMS agencies, EMS professionals, and the public. Furthermore, due to the Act and proposed rule's authorization of standing and verbal orders afforded to EMS personnel which was previously not authorized, DEA considers this rule to be an enabling rule for the purposes of E.O. 13771.

Executive Order 12988, Civil Justice Reform

The proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have direct effects on one or more Indian tribes via Indian Health Services.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) (RFA), has reviewed this rule and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. This proposed rule will have no bearing in reference to costs associated with registration fees.

[41] The present value of $136,426 in year 1 and $38,824 in years 4, 7, and 10 equal $227,403.22 at 3 percent and $201,033.37 at 7 percent discount rates. Dividing these results by 12 to account for three registration cycles yields the annualized present values.

All fees will be substantially the same irrespective of status, as there is no distinction in fee, when an applicant requests registration or modification for an EMS agency.

The RFA requires agencies to analyze options for regulatory relief of small entities unless it can certify that the rule will not have a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. DEA evaluated the impact of this rule on small entities, and discussions of its findings are below.

As discussed in the above economic analysis of the proposed rule, because DEA is not able to identify how many EMS agencies currently operate under the practitioner registration of their medical director, DEA chose to assess the impact of this proposed rule by considering the full range of possible scenarios. Thus, DEA considered the impact of the proposed rule if 0 percent, 50 percent, or 100 percent of EMS agencies receive an existing DEA registration from a practitioner. For the purposes of this analysis, DEA conservatively assumes that 0 percent of EMS agencies will have a DEA registration transferred from a practitioner because this is the scenario with the largest possible economic impact on affected entities, including small entities.

There are three types of EMS agencies that are affected by this proposed rule: hospital-based, private, and governmental. Of these types, some agencies currently hold their own DEA registrations while others operate under the registration of another DEA registrant. As detailed previously, DEA estimated that 3,809 private EMS agencies and 9,110 governmental EMS agencies are currently not separately registered with DEA, while 1,018 private EMS agencies and 1,697 governmental EMS agencies are currently registered with DEA. Additionally there are an estimated total of 1,236 hospital entities [42] that are affected by this proposed rule. DEA assumes all EMS agencies are affected in some way by this proposed rule, therefore, this proposed rule is expected to affect a substantial number of small entities.

These three types of entities are affected by at least one of the following four quantifiable impacts of the proposed rule: registration fees, recordkeeping and security requirements, the labor burden of obtaining a DEA registration, and the labor burden of renewing a DEA registration. Only the 4,827 private EMS agencies are affected by registration fees. Governmental EMS agencies are fee-exempt and hospital-based agencies can continue to operate under their hospital's registration. All three types of entities, whether separately registered or not, are affected by the security and recordkeeping requirements of the proposed rule. However, there is no impact because these entities are expected to already be in compliance with these requirements. Both the estimated 3,809 private agencies and 9,110 governmental agencies not separately registered must incur the labor burden of registering and renewing their registration with DEA every three years. Hospital-based agencies already incur this labor burden, and this proposed rule will have no further impact on these entities. The following table summarizes the estimated impact of the provisions of the proposed rule for each type of EMS agency.

TABLE 4—PROVISIONS OF PROPOSED RULE

	Registration fees		Records & Security		DEA form 224		DEA form 224A	
	Affected entities	Impact per entity [43]	Affected entities	Impact per entity	Affected entities	Impact per entity [44]	Affected entities	Impact per entity [45]
Hospital-based EMS	N/A	N/A	1,236	$0	N/A	N/A	N/A	N/A
Private EMS	3,809	218	4,827	0	3,809	21	3,809	4
Government EMS	N/A	N/A	10,807	0	9,110	21	9,110	4

DEA compared the combined annual economic impact per entity of the proposed rule with the annual revenue of the smallest of small entities in each affected industry sector. For each of the affected industry sectors, the annual increase was not more than 0.6 percent of average annual revenue for the smallest entities. The table below summarizes the results.

TABLE 5

NAICS code	NAICS code description	Number of affected entities	Number of smallest affected entities	Average revenue per smallest entity	Annual impact per entity ($)	Impact % of revenue
622110	General Medical and Surgical Hospitals	1,236	20	$190,600	$0	0.00%
621910	Ambulance Services	16,239	373	44,150	243	0.55%

[42] DEA does not have the ability to identify how many hospital registrants operate an EMS agency under the hospital's registration. However, DEA used NHTSA's national EMS assessment data to estimate the total number of hospital-based EMS agencies to be 1,236 (see Table 1). Therefore, DEA considers 1,236 hospital entities to be affected by this proposed rule.

[43] The impact per entity of registration fees is calculated by dividing the net annual change in transfer payments for the 0 percent range in Table 2 ($831,878) by the number of affected private entities (3,809). The final figure is rounded to the nearest whole dollar.

[44] The impact per entity of the labor burden for DEA form 224 is found by dividing the total labor burden for DEA form 224 calculated in note 36 ($272,830) by the number of affected entities (12,919). The final figure is rounded to the nearest whole dollar.

[45] The impact per entity of the labor burden for DEA form 224A is found by first dividing the triennial labor burden for DEA form 224A calculated in note 37 ($145,509) by three to account for the three year registration cycle. This annualized labor burden ($48,503) is then divided by the number of affected entities (12,919). The final figure is rounded to the nearest whole dollar.

While this rule affects a substantial number of small entities, because the economic impact for the smallest entities is not significant, the proposed rule will not have a significant impact on small entities as a whole. In summary, DEA's evaluation of economic impact by size category indicates that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

In accordance with the Unfunded Mandates Reform Act (UMRA) of 1995, 2 U.S.C. 1501 *et seq.,* DEA has determined that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year.'' Therefore, neither a Small Government Agency Plan nor any other action is required under URMA of 1995.

Paperwork Reduction Act of 1995

Pursuant to section 3507(d) of the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), DEA has identified the following collections of information related to this proposed rule and has submitted this collection request to the OMB for review and approval. This proposed rule would update DEA's regulations to provide for registration of EMS agencies and to require EMS agencies to maintain certain records and provide notice to DEA in certain circumstances. A person is not required to respond to a collection of information unless it displays a valid OMB control number. Copies of existing information collections approved by OMB may be obtained at *http://www.reginfo.gov/public/do/PRAMain.*

A. Collections of Information Associated With the Proposed Rule

1. Title: Emergency Medical Services Recordkeeping and Notice Requirements.

OMB Control Number: 1117–New.

Form Number: N/A.

DEA is proposing to create a new collection of information by establishing new recordkeeping and notice requirements for EMS agencies.

For each EMS professional employed by a registered EMS agency, the agency would be required to maintain those documents, as required by the State in which the professional practices, which describe the conditions and extent of the professional's authorization to dispense or administer controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration.

EMS agencies would also be required to maintain records of all controlled substances received, administered, or otherwise disposed of. Such records would be maintained, whether electronically or otherwise, at each registered and designated location of the agency where such controlled substances are received, administered, or otherwise disposed of.

For each dose of controlled substances administered or disposed of in the course of providing emergency medical services, these records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the date the substance was administered or disposed of; (4) identification of the patient, if applicable; (5) amount administered; (6) the initials of the person who administered the substance; (7) the initials of the medical director or authorizing medical professional issuing the standing or verbal order; (8) the amount disposed of, if applicable; (9) the manner disposed of; and (10) the initials of the person who disposed of the substance and of one witness to the disposal.

For controlled substances acquired from or distributed to another registrant, the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) name, address, and registration number of the person to or from whom the substance was transferred; and (7) the name and title of the person in receipt of the transferred substance.

For deliveries of controlled substances between a designated location and a registered location—except hospital-based agencies restocking at the hospital under which the agency is operating—the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers transferred; (5) the date of the transfer; (6) the name and address of the designated location to which the substance is delivered; and (7) the name and title of the person in receipt of the transferred substance.

For destruction of a controlled substance (*e.g.,* expired inventory), the records must include: (1) The name of the substance; (2) the finished form of the substance; (3) the number of units or volume of finished form in each commercial container; (4) the number of units or volume of finished form and commercial containers destroyed; (5) the date of the destruction; (6) the name, address, and registration number of the person to whom the substance was distributed, if applicable; and (7) the name and title of the person destroying the substance.

Additionally, designated locations of EMS agencies would be required to notify their registered locations within 72 hours of any receipt of controlled substances in the following circumstances: (1) An EMS vehicle primarily situated at the designated location acquires controlled substances from a hospital while restocking following an emergency response; or (2) a designated location receives controlled substances from another designated location of the same EMS agency.

DEA does not have a good basis to estimate the number of respondents and burden related to this collection of information, because there is no available data regarding the administration, receipt, delivery, acquisition or distribution, and disposal of controlled substances specific to the operation of EMS agencies. Therefore, DEA submits the following estimated number of respondents and burden associated with this collection of information and will update this estimate with data when the collection is renewed:

Number of respondents: 21,283.

Frequency of response: average of 52 per year.

Number of responses: average of 1,106,716 per year.

Burden per response: .0833 hour.

Total annual hour burden: 92,226 hours.

Figures are rounded.

2. *Title:* Application for Registration-DEA 224, Application for Registration Renewal-DEA 224A.

OMB Control Number: 1117–0014.

Form Numbers: DEA–224, DEA–224A.

DEA is proposing to modify an existing collection of information by establishing new registration rules for EMS agencies.

Under proposed § 1301.13, EMS agencies, if authorized by state law, may register as a new type of business activity. A new ''EMS Agency'' business activity will be added to the application for registration and application for registration renewal forms to allow EMS agencies to obtain a DEA registration that will permit EMS agencies to deliver controlled substances to their

designated locations without obtaining a separate registration as a Distributor. This registration will allow EMS personnel to administer controlled substances outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services. Upon issuance of an EMS agency registration, the EMS agency should use the online system to identify all of the locations it intends to designate under the EMS agencies' DEA registration.

To lessen the burden for EMS agencies with several stationhouses in a single state, DEA proposes to allow EMS agencies to choose the option of a single registration in each state where the EMS agency operates. If the agency operates EMS facilities in multiple states, the agency must have a separate registration in each state where the agency operates.

DEA estimates the following number of respondents and burden associated with this collection of information:

Number of respondents: 621,472.

Frequency of response: 1 per year.

Number of responses: 621,472 per year.

Burden per response: 0.10 hour.

Total annual hour burden: 65,943 hours.

Figures are rounded.

B. Request for Comments Regarding the Proposed Collections of Information

Written comments and suggestions from the public and affected agencies concerning the proposed collections of information are encouraged. Consistent with 44 U.S.C. 3506(c)(2), DEA solicits comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of DEA.
- The accuracy of DEA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Please send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for DOJ, Washington, DC 20503. Please state that your comments refer to RIN 1117–AB37/Docket No. DEA–377.

All comments must be submitted to OMB on or before November 4, 2020. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Exports, Imports, Security measures.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements.

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1307

Drug traffic control.

For the reasons stated in the preamble, the Drug Enforcement Administration proposes to amend 21 CFR parts 1300, 1301, 1304, 1306, and 1307 as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 822, 829, 871(b), 951, 958(f).

■ 2. Add § 1300.06 to read as follows:

§ 1300.06 Definitions relating to emergency medical services agencies.

(a) Any term not defined in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802).

(b) As used in parts 1301, 1304, 1306, and 1307 of this chapter, the following terms shall have the meanings specified:

(1) *Authorizing medical professional* means an emergency or other physician, or other medical professional (including an advanced practice registered nurse or physician assistant)—

(i) Who is registered under 21 U.S.C. 823;

(ii) Who is acting within the scope of the registration; and

(iii) Whose scope of practice under a State license or certification includes the ability to provide verbal orders.

(2) *Designated location* means a location designated by an emergency medical services agency under 21 U.S.C. 823(j)(5).

(3) *Emergency medical services* means emergency medical response and emergency mobile medical services provided outside of a fixed medical facility.

(4) *Emergency medical services agency* means an organization providing emergency medical services, including such an organization that—

(i) Is governmental (including fire-based and hospital-based agencies), non-governmental (including hospital-based agencies), private, or volunteer-based;

(ii) Provides emergency medical services by ground, air, or otherwise; and

(iii) Is authorized by the State in which the organization is providing such services to provide emergency medical care, including the administering of controlled substances, to members of the general public on an emergency basis.

(5) *Emergency medical services professional* means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the State in which the professional practices and credentialed by a medical director of the respective emergency medical services agency to provide emergency medical services within the scope of the professional's State license or certification.

(6) *Emergency medical services vehicle* means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

(7) *Hospital-based* means, with respect to an emergency medical services agency, owned or operated by a hospital.

(8) *Medical director* means a physician who is registered under 21 U.S.C. 823(f) and provides medical oversight to an emergency medical services agency.

(9) *Medical oversight* means supervision of the provision of medical care by an emergency medical services agency.

(10) *Registered emergency services agency* means—

(i) An emergency medical services agency that is registered under 21 U.S.C. 823(j); or

(ii) A hospital-based emergency medical services agency that is covered by the registration of the hospital.

(11) *Registered location* means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an emergency medical services agency, which shall be where the agency receives controlled substances from distributors.

(12) *Specific State authority* means a governmental agency or other such authority, including a regional oversight and coordinating body, that, pursuant to State law or regulation, develops

clinical protocols regarding the delivery of emergency medical services in the geographic jurisdiction of such agency or authority within the State that may be adopted by medical directors.

(13) *Standing order* means a written medical protocol in which a medical director determines in advance the medical criteria that must be met before administering controlled substances to individuals in need of emergency medical services.

(14) *Stationhouse* means an enclosed structure that houses one or more emergency medical services agency vehicles within a State in which that emergency medical services agency is registered, and that is actively and primarily being used for emergency response by that emergency medical services agency.

(15) *Verbal order* means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a controlled substance to individuals in need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

■ 3. The authority citation for part 1301 is revised to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 956, 957, 958, 965.

■ 4. In § 1301.12, add paragraph (b)(5) to read as follows:

§ 1301.12 Separate registrations for separate locations.

* * * * *

(b) * * *

(5) A designated location that is identified to the Administration by a registered emergency medical services agency at least 30 days prior to first delivering controlled substances to that unregistered location.

■ 5. In § 1301.13:

■ a. Revise paragraph (d);

■ b. Redesignate rows (e)(1)(v) through (x) as rows (e)(1)(vi) through (xi); and

■ c. Add new row (e)(1)(v).

The revision and addition read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(d) At the time a retail pharmacy, hospital/clinic, practitioner, emergency medical services agency or teaching institution is first registered, that business activity shall be assigned to one of twelve groups, which correspond to the months of the year. The expiration date of the registrations of all registrants within any group will be the last day of the month designated for that group. In assigning any of the above business activities to a group, the Administration may select a group the expiration date of which is not less than 28 months nor more than 39 months from the date such business activity was registered. After the initial registration period, the registration expires 36 months from the initial expiration date.

(e) * * *

(1) * * *

Business activity	Controlled substances	DEA Application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
*	*	*	*	*	*
(v) Emergency Medical Services Agency.	Schedules II–V	New—224 Renewal—224a	731	3	
*	*	*	*	*	*

* * * * *

■ 6. Add § 1301.20 under undesignated heading ''Registration'' to read as follows:

§ 1301.20 Registration for emergency medical services agencies.

(a) An emergency medical services agency shall be issued a registration under § 1301.13 if the agency submits an application demonstrating it is authorized to conduct such activity under the laws of each State in which the agency practices, unless the Administration determines that the issuance of such a registration would be inconsistent with the requirements of 21 U.S.C. 823(j) or the public interest based on the factors listed in 21 U.S.C. 823(f).

(1) An agency has the option of requesting a single registration in each State where the agency administers controlled substances in lieu of a separate registration for each location of the agency within a State.

(2) If a hospital where an emergency medical services agency is based is registered under § 1301.13, the agency may use the registration of the hospital to administer controlled substances in accordance with § 1306.07(e) of this chapter, without being separately registered as an emergency medical services agency.

(b) A registered emergency medical services agency may deliver controlled substances from a registered location of the agency to an unregistered location of the agency only if the agency designates the type of unregistered location as a stationhouse for such delivery; and notifies the Administration at least 30 days prior to the first delivery of controlled substances to the unregistered location. The delivery of controlled substances by a registered emergency medical services agency pursuant to this section shall not be treated as distribution. To notify the Administration, the emergency medical services agency must submit the name and physical address of the designated location online at *www.DEAdiversion.usdoj.gov.*

§§ 1301.78 and 1301.79 [Added and Reserved]

■ 7. Add and reserve §§ 1301.78 and 1301.79 under undesignated heading ''Security Requirements'';

■ 8. Add § 1301.80 under undesignated heading ''Security Requirements'' to read as follows:

§ 1301.80 Security controls for emergency medical services agencies.

(a) A registered emergency medical services agency may store controlled substances at any of the following secured locations:

(1) A registered location of the agency;

(2) A designated location of the agency 30 days following notification to DEA in accordance with § 1301.20;

(3) In an emergency medical services vehicle situated at a registered location or designated location of the agency; or

(4) In an emergency medical services vehicle used by the agency that is traveling from, or returning to, a registered location or designated location of the agency in the course of responding to an emergency, or otherwise actively in use by the agency.

(b) A registered emergency medical services agency may store controlled substances in a storage component that is identified as:

(1) A securely locked, substantially constructed cabinet or safe that cannot be readily removed; which is located at a secured location specified in § 1301.80(a)(1) through (4); or

(2) An automated dispensing machine as defined in § 1300.01; which is

(i) Located at a secured location specified in 1301.80(a)(1) and (2);

(ii) Installed and operated by the emergency medical services agency;

(iii) Not used to directly dispense controlled substances to an ultimate user; and is

(iv) In compliance with the requirements of State law.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 9. The authority citation for part 1304 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 827, 831, 871(b), 958(e)-(g), and 965, unless otherwise noted.

■ 10. In § 1304.03, add paragraphs (i) and (j) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(i) For each emergency medical services professional employed by a registered emergency services agency, the registered agency must maintain in a readily retrievable manner those documents (as required by the State in which an emergency medical services professional practices), which describe the conditions and extent of the professional's authorization to dispense controlled substances, and must make such documents available for inspection and copying by authorized employees of the Administration. Examples of such documentation include protocols, practice guidelines, or practice agreements.

(j) A registered emergency medical services agency shall maintain records, as described in § 1304.27, of all controlled substances that are received, administered, or otherwise disposed of pursuant to the agency's registration.

■ 11. In § 1304.04, revise paragraph (a) introductory text and add paragraphs (a)(4) and (5) to read as follows:

§ 1304.04 Maintenance of records and inventories.

(a) Except as provided in paragraphs (a)(1) and (2) of this section, every inventory and other record required to be kept under this part must be kept by the registrant, and be available for inspection and copying by authorized employees of the Administration, for at least 2 years from the date of such inventory or record.

* * * * *

(4) Records shall include records of deliveries of controlled substances between all locations of the agency.

(5) Records shall be maintained, whether electronically or otherwise, at each registered and designated location of the agency where the controlled substances involved are received, administered, or otherwise disposed of.

* * * * *

■ 12. Add § 1304.27 to read as follows:

§ 1304.27 Additional recordkeeping requirements applicable to emergency medical services agencies.

(a) Each emergency medical services agency registered pursuant to § 1301.20 of this chapter (including a hospital-based emergency medical services agency using a hospital registration under § 1301.20(a)(2) of this chapter) must maintain records for each dose of controlled substances administered or disposed of in the course of providing emergency medical services. The following information shall be included in each record:

(1) Name of the substance;

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

(3) Date administered or disposed of;

(4) Identification of the patient (consumer), if applicable;

(5) Amount administered;

(6) Initials of the person who administered the controlled substance;

(7) Initials of the medical director or authorizing medical professional issuing the standing or verbal order;

(8) Whether a standing or verbal order was issued and adopted;

(9) Amount disposed of, if applicable;

(10) Manner disposed of; and

(11) Initials of person who disposed and witness to disposal.

(b) For each acquisition of a controlled substance from another registrant, or each distribution of a controlled substance to another registrant, each emergency medical services agency registered pursuant to § 1301.20 of this chapter must maintain records with all of the following information:

(1) For each acquisition of a controlled substance from another registrant:

(i) Name of the substance;

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

(iii) Number of units or volume of finished form in each commercial container;

(iv) Number of commercial containers acquired (*e.g.,* 100-tablet bottle or 3-milliliter vial);

(v) Date of the acquisition;

(vi) Name, address, and registration number of the person from whom the substance was acquired; and

(vii) Name and title of the person acquiring the controlled substance.

(2) For each distribution of a controlled substance to another registrant:

(i) Name of the substance;

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

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

(iv) Number of commercial containers distributed;

(v) Date of the distribution;

(vi) Name, address, and registration number of the person to whom the substance was distributed; and

(vii) Name and title of the person in receipt of the distributed controlled substances.

(3) For each delivery of controlled substances between a designated location and a registered location:

(i) Name of the substance;

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

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

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

(v) Date of the delivery;

(vi) Name and address of the designated location to which the substance is delivered; and

(vii) Name and title of the person in receipt of the controlled substances.

(4) For destruction of a controlled substance:

(i) Name of the substance;

(ii) Finished form of the substance (*e.g.,* 10-milligram tablet or 10-milligram

concentration per fluid ounce or milliliter);

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

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

(v) Date of the destruction;

(vi) Manner of disposal of the substance, if applicable;

(vii) Name, address, and registration number of the person to whom the substance was distributed, if applicable; and

(viii) Name and title of the person destroying the controlled substance.

(c) A designated location of an emergency medical services agency that receives controlled substances must notify the agency's registered location within 72 hours of receipt of the controlled substances, in the following circumstances:

(1) An emergency medical services vehicle primarily situated at a designated location of the emergency medical services agency acquires controlled substances from a hospital while restocking following an emergency response;

(2) The designated location of the emergency medical services agency receives controlled substances from another designated location of the same agency.

PART 1306—PRESCRIPTIONS

■ 13. The authority citation for part 1306 is revised to read as follows:

Authority: 21 U.S.C. 821, 823(j), 829, 831, 871(b), unless otherwise noted.

■ 14. Revise § 1306.01 to read as follows:

§ 1306.01 Scope of part 1306.

This part sets forth the process and procedures for dispensing, by way of prescribing and administering controlled substances to ultimate users. The purpose of such procedures is to provide safe and efficient methods for dispensing controlled substances while providing effective controls against diversion.

■ 15. Amend § 1306.07 by adding paragraphs (e) and (f) to read as follows:

§ 1306.07 Administering or dispensing of narcotic drugs.

* * * * *

(e) An emergency medical services professional of a registered emergency medical services agency may administer directly (but not prescribe) controlled substances in schedules II–V outside the physical presence of a medical director or authorizing medical professional in the course of providing emergency medical services if the administration is authorized by law of the State in which it occurs; and is pursuant to:

(1) A standing order that is issued and adopted by one or more medical directors of the agency, including any such order that may be developed by a specific State's authority; or

(2) A verbal order that is:

(i) Issued in accordance with a policy of the agency; and

(ii) Provided by a medical director or an authorizing medical professional in response to a request by the emergency medical services professional with respect to a specific patient —

(A) In the case of a mass casualty incident; or

(B) To ensure the proper care and treatment of a specific patient.

(f) An emergency medical services agency shall maintain, at a registered location of the agency, a record of the standing or verbal orders issued or adopted in accordance with § 1304.13 of this chapter.

PART 1307—MISCELLANEOUS

■ 16. The authority citation for part 1307 is revised to read as follows:

Authority: 21 U.S.C. 821, 822(d), 823(j), 871(b), unless otherwise noted.

■ 17. Add § 1307.14 under undesignated heading ''Special Exceptions for Manufacture and Distribution of Controlled Substances'' to read as follows:

§ 1307.14 Delivery of controlled substances to designated locations of emergency medical services agencies.

(a) Notwithstanding the definition of registered location in § 1300.06 of this chapter, a registered emergency medical services agency may receive controlled substances from a hospital for purposes of restocking an emergency medical services vehicle following an emergency response, and without being subject to the requirements of § 1305.03 of this chapter, provided all of the following criteria are met:

(1) The registered or designated location of the agency operating the vehicle maintains the record of such receipt in accordance with § 1304.27(b) of this chapter;

(2) The hospital maintains a record of such delivery to the agency in accordance with § 1304.22(c) of this chapter; and

(3) If the vehicle is primarily situated at a designated location of an emergency medical services agency, such location notifies the registered location of the agency within 72 hours of the vehicle receiving the controlled substances.

■ 18. Add § 1307.15 under undesignated heading ''Special Exceptions for Manufacture and Distribution of Controlled Substances'' to read as follows:

§ 1307.15 Delivery of controlled substances in emergency situations.

(a) Hospitals and emergency medical services agencies' registered locations, and designated locations may deliver controlled substances to each other, with written approval from the Special Agent in Charge of DEA for the area or DEA Headquarters, in the event of:

(1) Shortages of such substances;

(2) A public health emergency; or

(3) A mass casualty event.

Timothy J. Shea,

Acting Administrator.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 127

[Docket No. USCG–2019–0444]

RIN 1625–AC52

Operational Risk Assessments for Waterfront Facilities Handling Liquefied Natural Gas as Fuel, and Updates to Industry Standards

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to amend its regulations concerning waterfront facilities handling liquefied natural gas (LNG) and liquefied hazardous gas (LHG). The proposed rule would make the following three changes. First, the proposed rule would revise the Coast Guard's existing regulations to allow waterfront facilities handling LNG as fuel to conduct an operational risk assessment instead of a waterway suitability assessment (WSA) without first obtaining Captain of the Port approval. Second, the proposed rule would revise existing regulations to update incorporated technical standards to reflect the most recent published editions. Third, for waterfront facilities handling LNG that must comply with the WSA requirements, the proposed rule would require these facilities to provide information to the Coast Guard regarding the nation of registry for vessels transporting natural gas that are

Draft Amendments for EMS-related Regulations

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 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 stationhouse or other location approved by the DEA and designated by an emergency medical services agency.

"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.

"EMS" means emergency medical services.

"EMS professional" means a health care professional (including a nurse, paramedic, or emergency medical technician) licensed or certified by the state in which the professional practices and credentialed by a medical director of an EMS agency to provide emergency medical services within the scope of the professional's state license or certification.

"EMS vehicle" means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an EMS agency for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances to and from the registered and designated locations.

"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-based" means, with respect to an EMS agency, owned or operated 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.
"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.
"Registered EMS agency" means an EMS agency that maintains a controlled substances registration issued by the board or a hospital-based EMS agency that is covered by the registration of the hospital.
"Registered location" means, for purposes of emergency medical services, a location that appears on a DEA certificate of registration issued to an EMS agency, which shall be where the agency receives controlled substances from distributors.
"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.

"Stationhouse" means an enclosed structure that houses one or more EMS agency vehicles in the state that 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 own use or for the use of a member of his household or for an animal owned by him or a member of his 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 program.
A licensed EMS agency may obtain emergency drugs for administration pursuant to the following allowances:
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.

C. An EMS agency issued a controlled substances registration pursuant to 18VAC110-20-690 (G) and registration from DEA in accordance with federal law may receive controlled substances and deliver the controlled substances to any designated locations. Delivery of the drugs shall not constitute wholesale distribution.

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

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

1. The registered or designated location of the agency operating the EMS vehicle maintains the record of receipt of drugs in accordance with state and federal law;
2. The hospital maintains a record of the delivery to the EMS agency in accordance with state and federal law; and
3. If the 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 receiving the controlled substances.

F. Hospitals, EMS agency registered locations, and EMS agency designated locations may deliver controlled substances to each other with written approval from the DEA in the event of:

1. Shortages of such substances;
2. A public health emergency; or
3. A mass casualty event.

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 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 to receive controlled substances in Schedules II-VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy. The EMS agency shall identify any designated location to which the EMS agency may deliver controlled substances to the board. The EMS agency shall also obtain a registration from DEA in accordance with federal law to prior to such delivery. The EMS agency shall identify on the controlled substances registration application the name and physical address of the designated locations. Any changes to the designated locations shall be submitted to the board in advance of delivering 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 sealed 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.

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

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

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

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

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

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

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

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

A. Drugs shall be stored under conditions that meet USP-NF specifications or manufacturers' suggested storage for each drug.
B. Any drug that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.
C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedules II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.
D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.
E. A registered EMS agency may store controlled substances in an automated dispensing device which is located at a secured site at the registered location or designated location of the EMS agency which is: (i) installed and operated by the EMS agency, (ii) not used to directly dispense controlled substances to an ultimate user, and (iii) is in compliance with the requirements of state law.

~~E~~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 stocking only ~~intravenous fluids with no added~~ Schedule VI drugs or temporarily securing a sealed drug kit when the 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.
~~F~~G. A registered EMS agency may store controlled substances at any of the following secured locations:

(1) A registered location of the EMS agency;
(2) A designated location of the EMS agency of which the board has been notified;
(3) In an EMS vehicle situated at a registered location or designated location of the EMS agency; or
~~(1)~~(4) In an EMS vehicle used by the EMS agency that is traveling from, or returning to, a registered location or designated location of the EMS agency in the course of responding to an emergency, or otherwise actively in use by the EMS

agency.

~~G~~H. Drugs secured in an EMS agency or EMS vehicle shall be stored at an appropriate temperature at all times. If the EMS vehicle cannot maintain appropriate temperature or is out of service, the drug kit may be temporarily maintained withing the building of the EMS agency. The drug kit shall be stored in compliance with subsection C.

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 II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia 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 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 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 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 which describe the conditions and extent of the professional's authorization to dispense controlled substances for each EMS professional 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, but is not limited to, 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 pursuant to the agency's controlled substances registration, and record of the standing or verbal orders issued or adopted.

8. Records required to be maintained by an EMS agency shall be maintained, whether electronically or otherwise, at each registered location and designated location of the EMS agency where the controlled substances involved are received, administered, or otherwise disposed of.

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

A. Each EMS agency holding a controlled substances registration, including a hospital-based EMS agency operating under a hospital registration, must maintain records for each dose of controlled substances administered or disposed of in the course of providing emergency medical services. The following information shall be included in each record:

(1)Name of the substance;
(2)Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per milliliter);
(3)Date administered or disposed of;
(4)Identification of the patient, if applicable;
(5)Amount administered;
(6)Initials of the person who administered the controlled substance;
(7)Initials of the medical director or authorizing medical professional issuing the standing or verbal order;
(8)Whether a standing or verbal order was issued and adopted;
(9)Amount disposed of, if applicable;
(10) Manner disposed of; and
(11) Initials of person who disposed of the substance and witness to disposal.

B. For each acquisition of a controlled substance from another registrant of the board, or each distribution of a controlled substance to another registrant of the board, each EMS agency registered pursuant to this chapter must maintain records with all of the following information:

(1)For each acquisition of a controlled substance from another registrant:
a. Name of the substance;
b. Finished form of the substance (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;
d. Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial);
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 controlled substance.

(2)For each distribution of a controlled substance to another registrant:
a. Name of the substance;
b. Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
c. Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3- milliliter vial);
d. Number of commercial containers distributed;
e. Date of the distribution;
f. Name, address, and registration number of the person to whom the substance was distributed; and
g. Name and title of the person in receipt of the distributed controlled substances.

(3)For each delivery of controlled substances between a designated location and a registered location:
a. Name of the substance;
b. Finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);
c. Number of units or volume of finished form in each commercial container

(e.g., 100-tablet bottle or 3- milliliter vial);

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

e. Date of the delivery;

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

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

(4)For destruction of a controlled substance:

a. Name of the substance;

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

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

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

e. Date of the destruction;

f. Manner of disposal of the substance, if applicable;

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

h. Name and title of the person destroying the controlled substance.

C. A designated location of an EMS agency that receives controlled substances must notify the EMS agency's registered location within 72 hours of receipt of the controlled substances~~,~~ in the following circumstances:

1. An EMS vehicle primarily situated at a designated location of the EMS agency acquires controlled substances from a hospital while restocking following an emergency response;

~~1.~~2. The designated location of the EMS agency receives controlled substances from another designated location of the same agency.

Agenda Item: Adoption of exempt regulations – addition of chemicals from Schedule I

Included in your agenda package are:

- Recommendation from the Department of Forensic Science to place certain chemicals in Schedule I.

- Amendments to 18VAC110-20-322.

Action needed:

- Motion to adopt exempt changes to 18VAC110-20-322 to add chemicals to Schedule I.

Project 7793 - Final

Board of Pharmacy

March 2024 scheduling of chemicals in Schedule I

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

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

1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

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

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

4. Cannabimimetic agents.

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

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

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

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 12, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids:

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

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

c. N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl Norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Synthetic compounds.

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

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

3. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Compounds expected to have depressive properties:

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

b. 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

The placement of drugs listed in this subsection shall remain in effect until March 27, 2025, unless enacted into law in the Drug Control Act.

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

1. 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 [December 5, 2025], unless enacted into law in the Drug Control Act.

Part VI. Labeling and Packaging Standards for Prescriptions

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

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

1. Synthetic opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

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

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

4. Cannabimimetic agents.

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

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

The placement of drugs listed in this subsection shall remain in effect until July 31, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters,

ethers, and salts is possible within the specific chemical designation.

2. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 1-[1-(3-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until October 12, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids.

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

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

c. N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl Norfentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

2. Synthetic compounds.

a. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-

fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

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

3. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Compounds expected to have depressive properties:

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

b. 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

The placement of drugs listed in this subsection shall remain in effect until March 27, 2025, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioid.

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

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

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

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

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

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

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

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

Statutory Authority

§§54.1-2400 and 54.1-3443 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 10, eff. February 11, 2015; amended, Virginia Register Volume 31, Issue 23, eff. August 12, 2015; Volume 32, Issue 5, eff. December 2, 2015; Volume 32, Issue 19, eff. June 15, 2016; Volume 32, Issue 25, eff. September 7, 2016; Volume 33, Issue 4, eff. November 16, 2016; Volume 33, Issue 11, eff. February 22, 2017; Volume 33, Issue 19, eff. June 14, 2017; Volume 34, Issue 1, eff. October 4, 2017; Volume 34, Issue 6, eff. December 13, 2017; Volume 34, Issue 11, eff. February 21, 2018; Volume 34, Issue 19, eff. June 13, 2018; Volume 34, Issue 25, eff. September 5, 2018; Volume 35, Issue 5, eff. November 28, 2018; Errata, 35:7, VA.R. 1060 November 26, 2018; Errata, 35:11, VA.R. 1394-1395 January 21, 2019; amended, Virginia Register Volume 35, Issue 14, eff. April 3, 2019; Volume 35, Issue 20, eff. June 26, 2019; Volume 36, Issue 6, eff. December 11, 2019; Volume 36, Issue 23, eff. August 5, 2020; Volume 37, Issue 5, eff. November 25, 2020; Volume 37, Issue 16, eff. April 28, 2021; Volume 37, Issue 20, eff. June 23, 2021; Volume 37, Issue 26, eff. September 15, 2021; Volume 38, Issue 11, eff. February 16, 2022; Volume 39, Issue 5, eff. November 23, 2022; Volume 39, Issue 10, eff. February 1, 2023; Volume 39, Issue 15, eff. April 12, 2023; Volume 40, Issue 1, eff. September 27, 2023; Volume 40, Issue 4, eff. November 8, 2023; Volume 40, Issue 10, eff January 31, 2024; Volume 40, Issue 12, eff. February 28, 2024.

COMMONWEALTH of VIRGINIA
DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
A Nationally Accredited Laboratory

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To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: January 22, 2023
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 four (4) compounds for recommended inclusion into the Code of Virginia.

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

1. **1-(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.

2. **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.

3. **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.

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

4. **Methyl 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.

Robyn Weimer
Chemistry Program Manager

Agenda Item: Adoption of proposed regulations to replace emergency regulations pursuant to 2023 pharmacists initiating treatment legislation

Included in your agenda package is:

- Proposed regulatory changes to 18VAC110-21-46;
- Town Hall action summary sheet showing no comments on emergency regulations.

Staff Note: Emergency regulations are currently in effect and have an expiration date of June 25, 2025.

Action needed:

- Motion to adopt proposed regulations as presented.

Project 7530 - Proposed

Board of Pharmacy

2023 pharmacists initiating treatment

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

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

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

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

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

counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. 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;

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; and

10. 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, 42 USC § 263a:

a. Group A Streptococcus bacteria infection;

b. Influenza virus infection;

c. COVID-19 virus infection; and

d. Urinary tract infection.

B. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A of this section shall:

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

2. Notify the patient's primary health care provider that treatment has been initiated with such drug, device, controlled paraphernalia, or other supplies or equipment or that such drug, device, controlled paraphernalia, or other supplies or equipment have been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears. If the pharmacist is administering a vaccine pursuant to this section, the pharmacist shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01 of the Code of Virginia.

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

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

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

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

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

Action: 2023 pharmacists initiating treatment

Emergency/NOIRA Stage

Action 6200 / Stage 9951

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	1/3/2024 3:19 pm	Sync Text with RIS
Agency Background Document	4/13/2023	Upload / Replace
Attorney General Certification	7/12/2023	
Governor's Review Memo	12/20/2023	
Registrar Transmittal	12/21/2023	

Status	
Public Hearing	Will be held at the **proposed** stage
Emergency Authority	None specified
Attorney General Review	Submitted to OAG: 4/18/2023 Review Completed: 7/12/2023 Result: Certified
DPB Review	Submitted on 7/12/2023 Policy Analyst: Cari Corr Review Completed: 7/25/2023
Secretary Review	Secretary of Health and Human Resources Review Completed: 12/13/2023
Governor's Review	ORM Review: ORM Approved 12/20/2023 Governor Review Completed: 12/20/2023 Result: Approved
Virginia Registrar	Submitted on 12/21/2023 The Virginia Register of Regulations Publication Date: 1/15/2024 Volume: 40 Issue: 11
Comment Period	Ended 2/14/2024 0 comments
Effective Date	12/26/2023

Expiration Date	6/25/2025

Contact Information	
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This person is the primary contact for this board.

This stage was created by Erin Barrett on 03/27/2023 at 11:29am
This stage was last edited by Erin Barrett on 03/27/2023 at 11:29am

Agenda Item: Amendment of Guidance Document 110-9

Included in your agenda package:

- Guidance Document 110-9 with redline changes (see pages 105 and 107).

Action needed:

- Motion to amend Guidance Document 110-9.

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

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

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

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

Deficiency	Law / Reg Cite	Conditions	$ Monetary Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods.	18VAC110-20-200		First documented occurrence and no drug loss of Schedule II = no penalty Drug loss or repeat = $ penalty 250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Deficiency 113 if only expired drugs not included in inventory.	Over 30 days late and first documented occurrence = no penalty Over 30 days late and repeat = $ penalty 500
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	54.1-3434 and 18VAC110-20-240	Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory.	500

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

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

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

Deficiency	Law / Reg Cite	Conditions	$ Monetary Penalty
24. Sterile compounding of hazardous drugs performed in ~~an area not physically separated from other preparation areas~~ a non-compliant clean room	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for Category 2 CSPs and/or Category 3 CSPs when required by USP	54.1-3410.2		5000
25a. No documentation of initial and at least every 3 months media-fill testing or gloved fingertip testing for persons performing compounding of Category 3 CSPs.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the third month from the date the previous media-fill test and gloved fingertip testing was initiated.	5000
25b. Category 3 compounded sterile preparations intended for use are improperly stored	54.1-3410.2		5000
25c. Category 1 or 2 CSPs intended for use are improperly stored	54.1-3410.2		500

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

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

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

Other Deficiencies

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

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

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

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

Deficiency	Law/Regulation Cite	Conditions
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a Compounded products not properly labeled	54.1-3410.2	

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

Deficiency	Law/Regulation Cite	Conditions
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold
140. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
141. Maintaining floor stock in a long-term care facility when not authorized	18VAC110-20-520 and 18VAC110-20-560	
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization	18VAC110-20-418	
143. Repealed 6/21/2018		
144. Repealed 6/21/2018		
145. Repealed 6/21/2018		
146. Repealed 6/21/2018		
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	54.1-3410.2	
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy	54.1-3404 and 18VAC110-20-240	

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

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

Examples:
Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.
Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/20 – No deficiency.
Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.

Agenda Item: Amendment of Guidance Document 110-33

Included in your agenda package:

- Guidance Document 110-33 with proposed redline changes; and
- Guidance Document 110-33 with proposed changes, clean version.

Action needed:

- Motion to amend Guidance Document 110-33.

Virginia Board of Pharmacy

Pharmacy Interns as Pharmacy Technicians
Pharmacy Technician Ratio
Documentation of Previous Practice

For the purpose of gaining practical experience to meet requirements for becoming a pharmacist, a registered pharmacy intern is by law allowed to perform tasks restricted to pharmacists provided they are directly monitored by a pharmacist. When a pharmacy intern is engaged in obtaining required practical experience hours, to be used either by the college of pharmacy or submitted to the Board on an affidavit, the pharmacy intern is not counted in the pharmacist to pharmacy technician ratio. For example, one pharmacist could be supervising a pharmacy intern for experience and up to four pharmacy technicians at the same time.

The Board has determined that properly registered pharmacy interns may also act as pharmacy technicians without being registered as such during times when they are not gaining practical experience. Pharmacy interns when acting as pharmacy technicians, shall be considered part of the 1:4 pharmacist to technician ratio.

Pharmacy technician trainees performing technician tasks in a pharmacy, are considered to be acting as pharmacy technicians and as such, are included in the 1:4 pharmacist to technician ratio.

Pursuant to 18VAC110-21-141, a pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA. Acceptable documentation of previous practice performing the duties of a pharmacy technician include:

- verification of issuance of a pharmacy technician license or registration in another U.S. jurisdiction;
- official office letterhead from employer verifying practice;
- W-2 with position title and employer's name; or
- written statement from a pharmacist licensed in Virginia or another state, that includes verifiable information such as the pharmacist's license number, confirming previous practice in another state.

Virginia Board of Pharmacy

Pharmacy Interns as Pharmacy Technicians
Pharmacy Technician Ratio
Documentation of Previous Practice

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- verification of issuance of a pharmacy technician license or registration in another U.S. jurisdiction;
- official office letterhead from employer verifying practice;
- W-2 with position title and employer's name; or
- written statement from a pharmacist licensed in Virginia or another state, that includes verifiable information such as the pharmacist's license number, confirming previous practice in another state.

Agenda Item: Amendment of Guidance Document 110-35 to include opioid prescribing information

Included in your agenda package:

- Redline version of Guidance Document 110-35 with proposed amendments;
- Clean version of Guidance Document 110-35 with proposed amendments.

Action needed:

- Motion to amend Guidance Document 110-35 as presented and discussed.

VIRGINIA BOARD OF PHARMACY

GUIDANCE ON
VIRGINIA PRESCRIPTION REQUIREMENTS

Opioid Prescriptions:

- Except as authorized in § 54.1-3408.02, prescriptions for opioids must be electronically transmitted.
- Pursuant to § 54.1-3410, a dispenser who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law.

Written Prescriptions:

- Written prescriptions shall include the patient's first and last name except for expedited partner therapy pursuant to Virginia Code § 54.1-3303. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.

- For prescriptions which provide expedited partner therapy pursuant to Virginia Code § 54.1-3303, "Expedited Partner Therapy" or "EPT" may be entered for the patient's name and address if otherwise unknown. *See* Va. Code § 54.1-3408.01(A).

- The prescription shall contain the prescriber's name, address, and telephone number, and DEA number if for a Schedule II-V prescriptions. Prescriber information shall be either preprinted on the blank, electronically printed, typed, stamped, or printed by hand in a legible manner. Interns and residents in a residency program may use the hospital DEA number and an assigned suffix.

- Prescriptions issued by physician assistants for drugs in Schedule II-V shall also include the name of their collaborating physician or podiatrist. Note: the physician is not required to *co-sign* a physician assistant's prescription for a Schedule II-VI drug.

- As of March 4, 2020, advanced practice registered nurses are no longer issued a separate license for prescriptive authority. Advanced practice registered nurses who have been granted prescriptive authority will have an additional designation of "RX Authority" clearly displayed on their license to practice nursing which begins with the numbers 0024. Advanced practice registered nurses who are authorized for autonomous practice or who are authorized by a practice agreement with a collaborating physician to prescribe Schedule II-VI drugs are not required to include the prescriptive authority number issued to them by the Boards of Nursing and Medicine, if their DEA registration number is included on the prescription. Advanced practice registered nurses who are authorized by a practice agreement to only prescribe

Schedule VI drugs and who do not have a DEA number must include the prescriptive authority number issued to them by the Boards of Nursing and Medicine.

- Written prescriptions shall be legibly written with ink or individually typed or printed.

- Written prescriptions may be prepared by an agent for the prescriber's signature, but shall be manually signed by the prescriber.

- Computer-generated prescriptions that are printed out shall be manually signed by the prescriber.

- Written prescriptions shall be dated with the date the prescription is written.

- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

- Prescriptions for Schedule VI drugs may be preprinted with the drug name, directions for use, quantity, but must still meet all other requirements of individually written prescriptions for patient name, signatures, issue date, and any other required information. Preprinted prescriptions may contain a list of drugs with a checkbox beside the drug name to be selected by the prescriber, but only one drug may be selected for each prescription.

- Schedule II prescriptions shall be written and may not be refilled.

- There is no longer a specific format required for written prescriptions. A pharmacist may substitute an Orange-Book rated "therapeutically equivalent drug product" for a brand name drug unless the prescriber prohibits substitution by indicating "brand medically necessary."

- A prescription blank may only contain one prescription. There are a few limited exceptions to this law such as multiple blanks for the Department of Corrections and chart orders for hospital, nursing home, home infusion, and hospice patients.

- A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

    - The chart order was written for a patient while in a hospital or long term care facility.
    - The pharmacist has all information necessary to constitute a valid outpatient prescription.
    - The pharmacist in an outpatient setting must have direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.

- The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

Requirements of the Virginia Department of Medical Assistance Services for written prescriptions for Medicaid and FAMIS fee-for-service patients:

- Tamper-resistant prescriptions are required for all prescriptions used for Medicaid and FAMIS fee-for-service recipients. Tamper resistant pads are defined as having at least one feature in all three of the following categories:

  1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form,
  2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, or
  3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

Oral Prescriptions:

- Oral prescriptions shall contain all the same information as written prescriptions except for the prescriber's signature, and shall be reduced to writing by the pharmacist receiving the prescription.

- The prescriber or his authorized agent may transmit the prescription. If transmitted by an authorized agent, the pharmacist shall record the full name of the agent. According to Virginia law, an authorized agent may only be an employee of the prescriber under his immediate and personal supervision, or if not an employee may only be someone who holds a license to administer drugs, such as a nurse, physician assistant, or another pharmacist. For Schedule II-V oral prescriptions, DEA may interpret the authority of an agent differently, as well as who can be an authorized agent.

Faxed Prescriptions:

- A faxed prescription that starts out as a written prescription and is placed onto a fax machine in the physician's office and sent via phone to a pharmacy's fax machine where a facsimile image is printed for the pharmacy records must meet all requirements for a written prescription, to include the manual signature of the prescriber.

- Computer-generated prescriptions that are faxed must be manually signed by the prescriber.

- Schedule III-VI prescriptions may be faxed to a pharmacy.

- Schedule II prescriptions (or chart orders) may **only** be faxed to a pharmacy for long term care facility patients, home infusion patients, and hospice patients.

- Pharmacies may not begin the dispensing process when a prescription is faxed directly from the patient, even if the patient brings in the hard copy when they come to pick up the medication. Prescriptions may only be faxed from the prescriber's practice location

Electronically transmitted prescriptions:

- An electronically transmitted prescription is one that is generated from the prescriber's office electronically, sent out as an electronic transmission, is normally routed through a switch to the appropriate pharmacy, and is received by the pharmacy in the form of an electronic transmission or is converted by the switch to a fax, and is printed out on the pharmacy's fax machine. "Electronic prescription" means a written prescription that is generated on an electronic application and transmitted to a pharmacy as an electronic data file. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber that identifies him as the source of the message and indicates his approval of the information contained in the message. If the prescription is generated electronically, but then is printed out in the office and given to the patient, it is no longer an electronic prescription and must follow the guidelines of a written prescription to include bearing the prescriber's manual signature.

- Schedule II - VI prescriptions may be transmitted electronically. Schedule II – V prescriptions must meet all federal requirements including required security and authenticity features, as well as required recordkeeping for the prescriber and pharmacy.

- The application provider used by a prescriber or a pharmacy for electronic prescriptions of Schedules II-V drugs must be reviewed and certified by an approved certification body for compliance with DEA's standards. The application provider must provide a copy of this report to the pharmacy or prescriber using its services. A pharmacy or prescriber shall not dispense or issue an electronic prescription for Schedules II-V drugs until a report is received from the application provider indicating full compliance with DEA's standards. A pharmacy or prescriber may continue dispensing or issuing electronic prescriptions for Schedule VI drugs in compliance with Board regulations prior to receiving a report from the application provider regarding its status of compliance with federal law.

- Individual prescribers authorized to prescribe Schedules II-V drugs who choose to issue electronic prescriptions for Schedules II-V drugs shall first apply to certain federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates.

- An electronic prescription for a Schedule VI drug may either directly populate the pharmacy's automated dispensing system or may be converted by the switch to a fax, and printed out on the pharmacy's fax machine. Federal law does not permit an electronic prescription for a Schedule

II-V drug to be converted to the pharmacy's fax machine. It must directly populate the pharmacy's automated dispensing system in conformity with federal law.

- Please refer to the federal regulations for additional guidance.

Transfer of electronic prescriptions for Schedules II-V Controlled Substances between pharmacies for initial filling:

- Effective August 28, 2023, § 1306.08 of the Code of Federal Regulations was amended to allow the transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing if allowable under existing State or other applicable law.

- The Board interprets Virginia Code § 54.1-3408.02 and 18VAC110-20-360 to condone the transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing when performed in compliance with federal requirements.

- To further understand federal requirements, refer to DEA's *Discussion of Public Comments* in the Federal Register at https://www.federalregister.gov/documents/2023/07/27/2023-15847/transfer-of-electronic-prescriptions-for-schedules-ii-v-controlled-substances-between-pharmacies-for. Of note, DEA addresses comments on the requirement for patient consent, restriction for initial dispensing only, requirement to transfer as electronic data file, the National Council for Prescription Drug Programs' (NCPDP) new SCRIPT Standard Version 2017071, restriction of transfer for one-time basis only, and transfer between two licensed pharmacists.

- The Board is aware that current challenges with technology may not support operationalizing this allowance. Pharmacists are encouraged to consult with their software vendors as appropriate.

Statutes:

Va. Code § 54.1-3408.02

Regulations:

18VAC110-20-360

VIRGINIA BOARD OF PHARMACY

GUIDANCE ON
VIRGINIA PRESCRIPTION REQUIREMENTS

Opioid Prescriptions:

- Except as authorized in § 54.1-3408.02, prescriptions for opioids must be electronically transmitted.
- Pursuant to § 54.1-3410, a dispenser who receives a non-electronic prescription for a controlled substance containing an opioid is not required to verify that one of the exceptions set forth in § 54.1-3408.02 applies and may dispense such controlled substance pursuant to such prescription and applicable law.

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- The Board is aware that current challenges with technology may not support operationalizing this allowance. Pharmacists are encouraged to consult with their software vendors as appropriate.

Statutes:

Va. Code § 54.1-3408.02

Regulations:

18VAC110-20-360

Agenda Item: Repeal of Guidance Document 110-39

Included in your agenda package:

- Guidance Document 110-39;
- Currently effective emergency regulations regarding pharmacy working conditions.

Staff note: With the promulgation of the emergency regulations, the guidance document is no longer needed.

Action needed:

- Motion to repeal Guidance Document 110-39.

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break. A pharmacist on duty may use professional judgment about whether to close the pharmacy provided notice has been posted at least 14 days in advance of the closure;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

Effective dates: 9/29/2023 – 3/28/2025

Board of Pharmacy

Pharmacy working conditions

18VAC110-20-110. Pharmacy permits generally.

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

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

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

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

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

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

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

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

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

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

18VAC110-20-113. Pharmacy working conditions.

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

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

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

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

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

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

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

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

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

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

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

a. drug utilization review;

b. immunization;

c. counseling;

d. verification of prescriptions;

e. patient testing; and

f. all other duties required by §§ 54.1-3300 *et seq.* and 54.1-3400 *et seq.* of the Code of Virginia and 18VAC110-20-10 *et seq;* and

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

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

D. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board.

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

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

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

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

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

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

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

Agenda Topic: Amend TB One-Step and Two-Step statewide protocols

Staff Note: Staff received an inquiry from a pharmacist who contacted VDH to inquire if the local health department would complete the form in Appendix C as the trainer who would observe the placement of a TST. After researching with VDH, Board staff concluded that Appendix C was provided by VDH for inclusion in the statewide protocol as a resource listing detailed procedures for placing the TST, but that the form did not need to be completed by a trainer as it is not part of the pharmacist's education and training listed in the protocol. Staff recommends that this expectation be clarified in the protocols.

Action Needed: Motion to amend the TB One-Step and TB Two-Step statewide protocols as presented or amended.

VIRGINIA BOARD OF PHARMACY

TUBERCULIN SKIN TESTING ONE-STEP PROTOCOL

PURPOSE

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

PHARMACIST EDUCATION AND TRAINING

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

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

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

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

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

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

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

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

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

Note: Appendix C is provided as a resource listing detailed procedures for placing the TST, but a trainer is not required to observe or complete this form as part of the pharmacist's education and training.

INCLUSION CRITERIA

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

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

EXCLUSION CRITERIA

Individuals meeting any of the following criteria:

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

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

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

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

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

CONSIDERATIONS

- Individuals from high-burden TB countries may have received the BCG vaccination 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 TST antigen, also known as purified protein derivative (PPD), read, and interpret the TST. The TST is one of two standard methods for determining whether a person is infected with *Mycobacterium tuberculosis.* This protocol authorizes the pharmacist to dispense and administer the following products with an approved indication for TST.

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

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

PROCEDURES FOR INITIATION OF TB SCREENING

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

healthcare provider for further evaluation and further advised regarding isolation precautions.

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

PROCEDURES FOR MONITORING AND FOLLOW UP

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

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

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

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

DOCUMENTATION

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

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

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and 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 andprovide 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? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
6.	Are you experiencing night sweats? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
7.	Do you have fatigue? *(evaluate symptoms 5, 6, and 7 in context)*	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□

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 □

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? - Lung disease silicosis caused by breathing in tiny bits of silica? - Diabetes? - End stage renal disease or on hemodialysis? - Head or neck cancer? - Leukemia? - Lymphoma? - Hematologic or reticuloendothelial disease?	 Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □
24.	Have you ever had any of the following procedures: - Gastrectomy? - Intestinal bypass? - Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	 Yes □ No □ Yes □ No □ Yes □ No □
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone ≥ 15mg/day for ≥ 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 referal for IGRA testing.		
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.		

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 Conclusions

I. 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.

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.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

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.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ 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.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ 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.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ 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.
_____ 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.
_____ 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).
_____ Uses appropriate hand hygiene methods after placing TST.

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 ¼–½-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.

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.

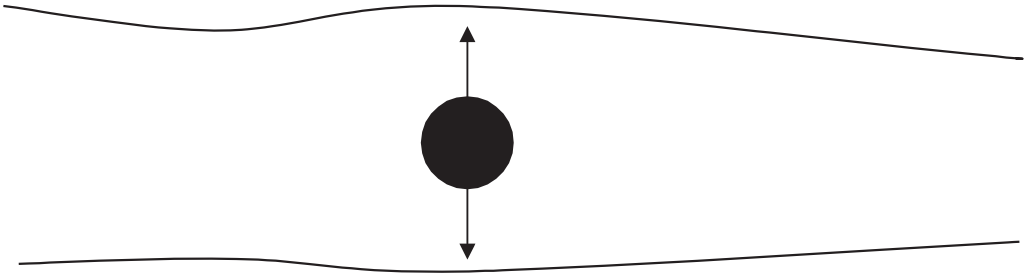
Classification of the Tuberculin Skin Test Reaction[1]

≥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, inducing 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



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf

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

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

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

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

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

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

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

Note: Appendix C is provided as a resource listing detailed procedures for placing the TST, but a trainer is not required to observe or complete this form as part of the pharmacist's education and training.

INCLUSION CRITERIA

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

EXCLUSTION CRITERIA

Individuals meeting any of the following criteria:

- Allergy to any component of the TST or those patients with a previous allergic reaction to a TST
- History of severe reaction (necrosis, blistering, anaphylactic shock, or ulcerations) to a previous TST
- Documented active TB or a clear history of treatment for TB infection or disease
- Extensive burns or eczema at the administration site

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

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

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

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

- Live vaccination administered within the last month[7] (simultaneous/same-day administration of live-vaccines and a TST is acceptable)
- History of a positive TST
- History of documented previous Bacilli Calmette-Guerin (BCG) vaccine

CONSIDERATIONS

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

MEDICATIONS

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

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

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

PROCEDURES FOR INITIATION OF TB SCREENING

Decision to conduct a TST will be based on relevant medical and social history and consideration of contraindications and precautions as outlined in this protocol and in

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

the American Thoracic Society (ATS)/CDC Guideline.[1] In addition, the need for periodic retesting and the presence of individual risk factors for occupational exposures will be used to determine the need for two-step testing. A risk assessment should be conducted by the pharmacist prior to initiation of the TST. The form in Appendix A can be used to complete the risk assessment. This assessment should not be self-administered by the client. The Report of Tuberculosis Screening in Appendix B must be completed at the conclusion of the screening. The Report (Appendix B) may be provided to the patient and may be subsequently provided to an employer, if necessary, and authorized by the patient. If active TB symptoms are present or indicated on the TB risk assessment documentation (see Appendix A), the patient must be immediately referred to a healthcare provider for further evaluation and further advised regarding isolation precautions

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

PROCEDURES FOR MONITORING AND FOLLOW UP

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

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

An initial positive reaction is considered a TB infection and a second TST is not required. The patient will need to receive a chest x-ray and additional evaluation to rule out active TB disease. An initial negative reaction requires a retest 1-3 weeks after the initial TST. Upon retesting, a negative reaction suggests the patient does not have a TB infection, in which case a TST can be repeated annually, if required. However, a positive reaction after retesting is considered a boosted reaction due to a TB infection that occurred a long time ago. In this case, the patient will need to receive a chest x-ray and additional

evaluation to rule out active TB disease. A referral is required for this follow-up and so that treatment considerations can be made if latent TB infection is diagnosed (see Appendix E)[2].

COUNSELING REQUIREMENTS

Individuals receiving TST will receive counseling regarding:

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

DOCUMENTATION

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

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

administration of the TST. The individual may have to be referred back to their primary care provider to obtain necessary certification.

NOTIFICATION AND REFERRAL

Prior to screening the patient for TB, the patient must complete and sign the Patient Authorization section of Appendix A authorizing the pharmacist to notify the primary health care provider or local health department of a positive TST result. If the patient refuses such authorization, the pharmacist shall not screen the patient for TB and shall refer the patient to a primary health care provider for evaluation. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and 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? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
6.	Are you experiencing night sweats? *(evaluate symptoms 5, 6, and 7 in context)*	Yes □ No □
7.	Do you have fatigue? *(evaluate symptoms 5, 6, and 7 in context)*	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□

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 □

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? - Lung disease silicosis caused by breathing in tiny bits of silica? - Diabetes? - End stage renal disease or on hemodialysis? - Head or neck cancer? - Leukemia? - Lymphoma? - Hematologic or reticuloendothelial disease?	 Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No □
24.	Have you ever had any of the following procedures: - Gastrectomy? - Intestinal bypass? - Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)?	 Yes □ No □ Yes □ No □ Yes □ No □
25.	Do you receive treatment with TNF-alpha antagonists (e.g., infliximab, etanercept), steroids (equivalent of prednisone ≥ 15mg/day for ≥ 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 referal for IGRA testing.		
Note: Retesting should only occur in persons who previously tested negative and have new risk factors since last assessment.		

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 Conclusions

I. 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.

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.
_____ Screens patient for contraindications (severe adverse reactions to previous TST).*
_____ Uses well-lit area.

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.¶
_____ Checks label and expiration date on vial.
_____ Marks opening date on multidose vial.
_____ Fills immediately after vial removed from refrigeration.
_____ Cleans vial stopper with antiseptic swab.
_____ Twists needle onto syringe to ensure tight fit.
_____ 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.††
_____ Holds needle bevel-up and tip at 5°–15° angle to skin.
_____ Inserts needle in first layer of skin with tip visible beneath skin.
_____ 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.
_____ Removes needle without pressing area.
_____ Activates safety feature of device per manufacturer's recommendations, if applicable.
_____ Places used needle and syringe immediately in puncture-resistant container without recapping needle.
_____ 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.
_____ 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.
_____ 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).
_____ Uses appropriate hand hygiene methods after placing TST.

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 ¼–½-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.

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.

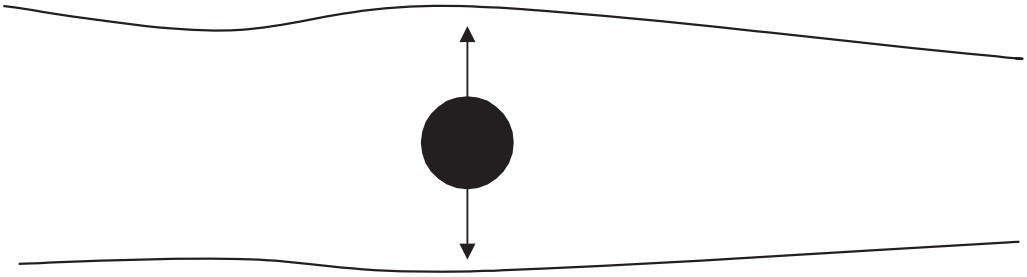
Classification of the Tuberculin Skin Test Reaction[1]

≥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, inducing 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



Measure TSTs Transversely

CDC LTBI: A Guide for Primary Health Care Providers

https://www.cdc.gov/tb/publications/ltbi/pdf/LTBIbooklet508.pdf

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.

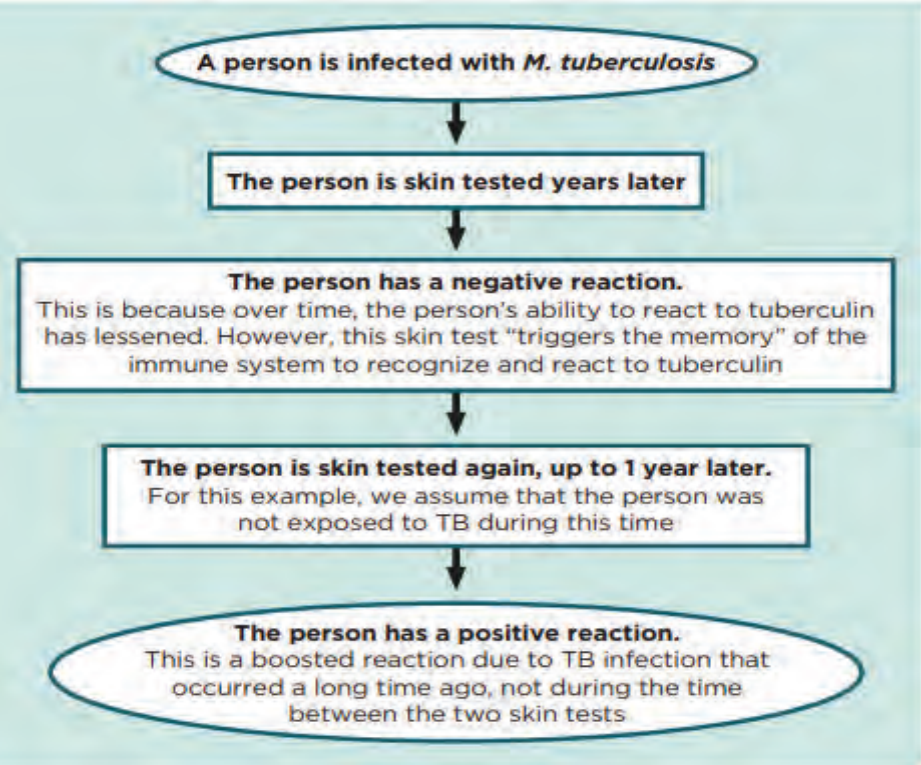
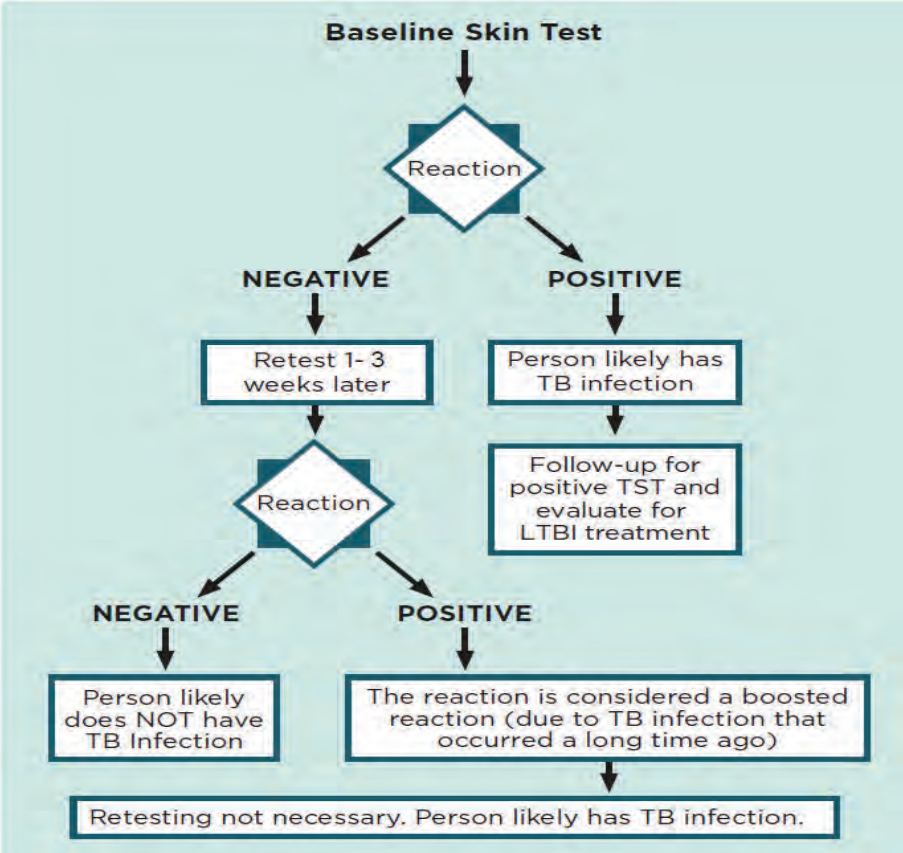


Figure 2: Two-Step TST Testing

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.**


Baseline Skin Test
Reaction
NEGATIVE
POSITIVE
Retest 1- 3 weeks later
Person likely has TB infection
Follow-up for positive TST and evaluate for LTBI treatment
Reaction
NEGATIVE
POSITIVE
Person likely does NOT have TB Infection
The reaction is considered a boosted reaction (due to TB infection that occurred a long time ago)
Retesting not necessary. Person likely has TB infection.

Agenda Topic: Presentation and adoption of 2023 Pharmacist and Pharmacy Technicians Workforce Survey Reports, Barbara Hodgdon, PhD, Deputy Director, DHP Healthcare Workforce Data Center and Data Analytics Division

Action Needed: Motion to accept the 2023 Pharmacist and Pharmacy Technicians Workforce Survey Reports as presented or amended.

DRAFT

Virginia's Pharmacist Workforce: 2023

Healthcare Workforce Data Center

February 2024

Virginia Department of Health Professions
Healthcare Workforce Data Center
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Henrico, VA 23233
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Get a copy of this report from:
http://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/ProfessionReports/

15,384 Pharmacists voluntarily participated in this survey. *Without their effort, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for their ongoing cooperation.*

Thank You!

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Contents

The Pharmacist Workforce: At a Glance:

The Workforce

Licensees:	16,841
Virginia's Workforce:	9,047
FTEs:	7,266

Survey Response Rate

All Licensees:	91%
Renewing Practitioners:	97%

Demographics

Female:	68%
Diversity Index:	55%
Median Age:	44

Background

Rural Childhood:	31%
HS Degree in VA:	47%
Prof. Degree in VA:	49%

Education

Baccalaureate:	27%
Pharm.D./Professional:	73%

Finances

Median Inc.:	$130k-$140k
Health Benefits:	64%
Under 40 w/ Ed debt:	69%

Current Employment

Employed in Prof.:	92%
Hold 1 Full-time Job:	74%
Satisfied?:	87%

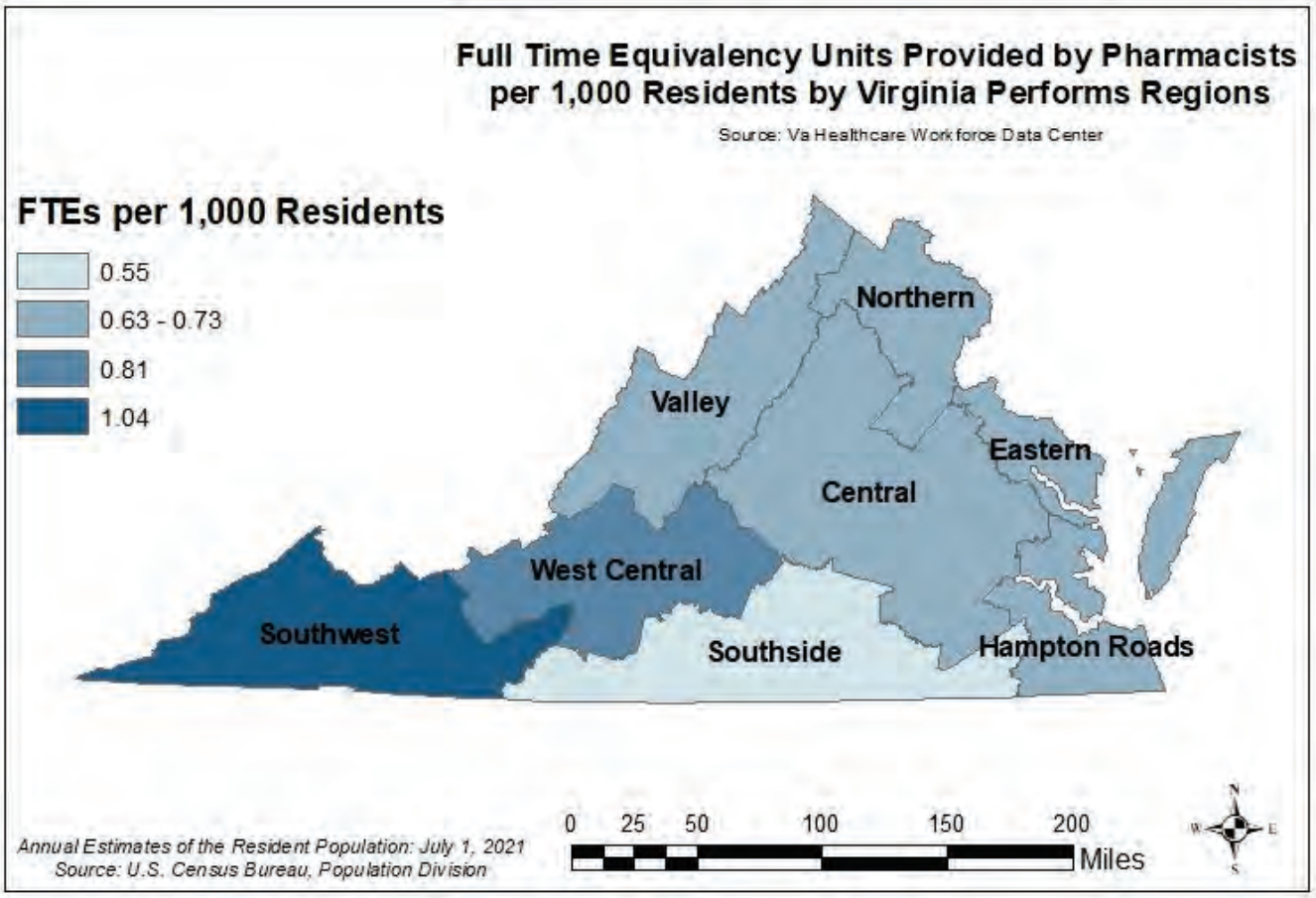
Job Turnover

Switched Jobs in 2022:	6%
Employed over 2 yrs.:	58%

Primary Roles

Patient Care:	73%
Administration:	8%
Education:	1%

Source: Va. Healthcare Workforce Data Center



Results in Brief

A total of 15,384 pharmacists voluntarily took part in the 2023 Pharmacist Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacists. These survey respondents represent 91% of the 16,841 pharmacists who are licensed in the state and 97% of renewing practitioners. The HWDC estimates that the 9,047 pharmacists in the Virginia's workforce during the survey period provided 7,266 full-time equivalency units (FTE).

The majority of Virginia's pharmacists are female, and the median age among those in the workforce is 44. Almost one-third of pharmacists grew up in a rural area, and close to one-quarter of these professionals currently work in non-metro areas of the state. Overall, 10% of Virginia's pharmacists work in a non-metro area. 73% of Virginia's pharmacist workforce have earned a doctorate or other professional degree as their highest educational attainment. Further, 41% of pharmacists currently carry educational debt. Nearly seven out of ten of those under the age of 40 carry education debt. The median debt for those pharmacists with educational debt is between $120,000 and $130,000.

More than nine out of every ten pharmacists are currently employed in the profession, with 74% holding one full-time position. Over the past year, 1% of pharmacists were involuntarily unemployed, while another 2% were underemployed. The typical pharmacist earned between $130,000 and $140,000 in 2023. Around 87% of all pharmacists are satisfied with their current employment situation, including 44% who indicated that they are "very satisfied".

About 91% of all pharmacists work in the private sector, including 62% who work at a for-profit organization. hospital health systems were the most common working establishment type for Virginia's pharmacist workforce, employing 26% of all professionals. Large chain pharmacies (i.e., pharmacies with more than 11 stores) also were common employers. About 47%of pharmacists expect to retire by the age of 65 and 7% of the current workforce expect to retire in the next two years. Half of the current workforce expect to retire by 2048.

Summary of Trends

The total number of licensed pharmacists has grown by almost 32% since 2013. Of these, the number working in the state workforce has also increased, but only by 14%. Additionally, the 6% increase in FTE provided in state by pharmacists between 2013 and 2023 is an even more modest increase.

The diversity index of Virginia's pharmacists increased from 47% in 2013 to 55% in 2023. The percentage of pharmacists who are female also increased, from 62% in 2013 to 68% in 2023. Median age has been relatively stable between 44 and 45 years in the 10 years. The percent under age 40, increased slightly from 37% in 2013 to 38% in 2023.

Educational attainment, specifically those who reported a PharmD, continues to increase in the pharmacist workforce, from 51% in 2013 to 73% in 2023. The percent reporting educational debt has also increased from 35% in 2013 to 41% in 2023. Median educational debt also increased from $90K-$100K in 2013 to $120K-$130K in 2023.

Around 91% of pharmacists reported being employed in the profession, compared to 93% in 2013. Median income increased from $110K-$120K in 2013 to $130K-$140K in 2023. Job satisfaction has decreased from 93% in 2013 to 91% in 2023. Pharmacists intending to retire within 10 years increased from 22% in 2013 to 25% in 2023. Regarding future plans, only 6% intended to increase patient care hours in 2023 compared to 12% in 2013.

A Closer Look:

Licensee Counts		
License Status	**#**	**%**
Renewing Practitioners	15,179	90%
New Licensees	778	5%
Non-Renewals	884	5%
All Licensees	**16,841**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 97% of renewing pharmacists submitted a survey. These represent 91% of pharmacists who held a license at some point in 2023.

Response Rates			
Statistic	**Non Respondents**	**Respondent**	**Response Rate**
By Age			
Under 30	96	621	87%
30 to 34	202	2,086	91%
35 to 39	224	2,750	93%
40 to 44	171	2,336	93%
45 to 49	152	1,888	93%
50 to 54	124	1,772	94%
55 to 59	129	1,462	92%
60 and Over	359	2,469	87%
Total	**1,457**	**15,384**	**91%**
New Licenses			
Issued in 2023	232	546	70%
Metro Status			
Non-Metro	101	1,043	91%
Metro	596	8,277	93%
Not in Virginia	760	6,064	89%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number:	16,841
New:	5%
Not Renewed:	5%

Survey Response Rates

All Licensees:	91%
Renewing Practitioners:	97%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	15,384
Response Rate, all licensees	91%
Response Rate, Renewals	97%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2023.
2. **Target Population:** All pharmacists who held a Virginia license at some point in 2023.
3. **Survey Population:** The survey was available to those who renewed their licenses online. It was not available to those who did not renew, including some pharmacists newly licensed in 2023.

At a Glance:

Workforce

Pharmacist Workforce:	9,047
FTEs:	7,266

Utilization Ratios

Licensees in VA Workforce:	54%
Licensees per FTE:	2.32
Workers per FTE:	1.25

Source: Va. Healthcare Workforce Data Center

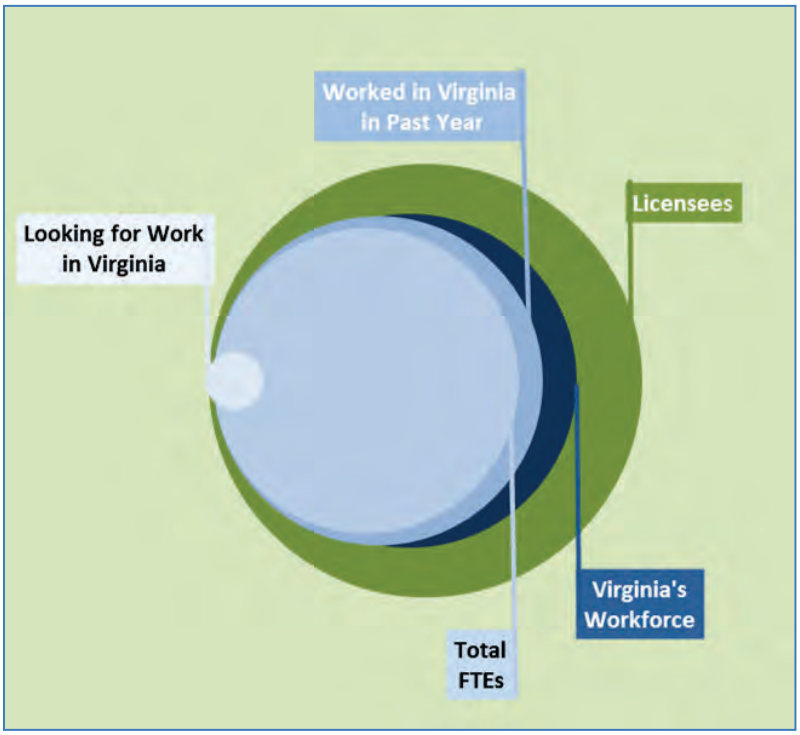
Definitions

1. **Virginia's Workforce:** A licensee with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
2. **Full Time Equivalency Unit (FTE):** The HWDC uses 2,000 hours (40 hours for 50 weeks with 2 weeks off) as its baseline measure for FTEs.
3. **Licensees in VA Workforce:** The proportion of licensees in Virginia's Workforce.
4. **Licensees per FTE:** An indication of the number of licensees needed to create 1 FTE. Higher numbers indicate lower licensee participation.
5. **Workers per FTE:** An indication of the number of workers in Virginia's workforce needed to create 1 FTE. Higher numbers indicate lower utilization of available workers.

Virginia's Pharmacist Workforce		
Status	#	%
Worked in Virginia in Past Year	8,832	98%
Looking for Work in Virginia	216	2%
Virginia's Workforce	**9,047**	**100%**
Total FTEs	**7,266**	
Licensees	**16,841**	

Source: Va. Healthcare Workforce Data Center

This report uses weighting to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia Workforce only. For more information on HWDC's methodology visit: www.dhp.virginia.gov/hwdc



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	108	23%	361	77%	469	7%
30 to 34	295	29%	737	71%	1,031	14%
35 to 39	385	32%	830	68%	1,214	17%
40 to 44	274	28%	695	72%	969	14%
45 to 49	238	29%	572	71%	810	11%
50 to 54	215	27%	569	73%	784	11%
55 to 59	227	32%	483	68%	710	10%
60 +	532	46%	631	54%	1,163	16%
Total	**2,274**	**32%**	**4,877**	**68%**	**7,151**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	68%
% Under 40 Female:	71%

Age

Median Age:	44
% Under 40:	38%
% 55+:	26%

Diversity

Diversity Index:	55%
Under 40 Div. Index:	60%

Source: Va. Healthcare Workforce Data Center

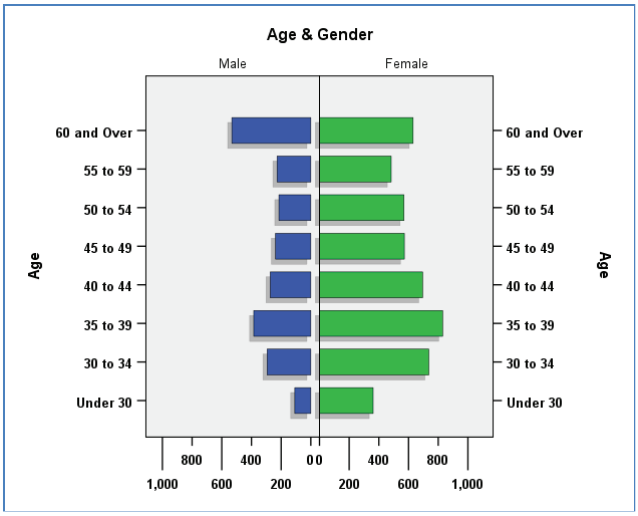
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	59%	4,465	63%	1,561	58%
Black	18%	869	12%	331	12%
Asian	7%	1,432	20%	648	24%
Other Race	1%	103	1%	37	1%
Two or more races	5%	139	2%	71	3%
Hispanic	10%	133	2%	66	2%
Total	**100%**	**7,141**	**100%**	**2,714**	**100%**

** Population data in this chart is from the U.S. Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2022.

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two pharmacists, there is a 55% chance that they would be of a different race/ethnicity (a measure known as the Diversity Index). For Virginia's population as a whole, the comparable number is 60%.

38% of pharmacists are under the age of 40, and 71% of these professionals are female. In addition, pharmacists who are under the age of 40 are just as diverse as Virginia's overall population.



Source: Va. Healthcare Workforce Data Center

At a Glance:

Childhood

Urban Childhood:	17%
Rural Childhood:	31%

Virginia Background

HS in Virginia:	47%
Prof. Education in VA:	49%
HS/Prof. Educ. in VA:	57%

Location Choice

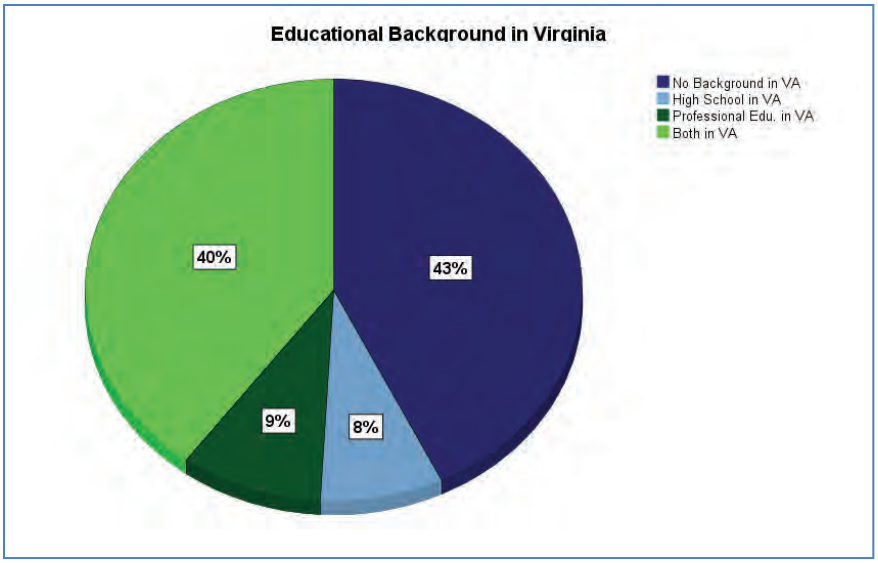
% Rural to Non-Metro:	23%
% Urban/Suburban to Non-Metro:	5%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 million+	21%	59%	21%
2	Metro, 250,000 to 1 million	52%	41%	8%
3	Metro, 250,000 or less	40%	45%	15%
	Non-Metro Counties			
4	Urban pop 20,000+, metro adjacent	57%	32%	11%
6	Urban pop, 2,500-19,999, metro adjacent	64%	26%	10%
7	Urban pop, 2,500-19,999, non adjacent	88%	10%	2%
8	Rural, metro adjacent	53%	37%	9%
9	Rural, non adjacent	67%	22%	11%
	Overall	**31%**	**51%**	**17%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

31% of pharmacists grew up in self-described rural areas, and 23% of these professionals currently work in non-metro counties. Overall, 10% of Virginia's pharmacist workforce currently work in non-metro counties.

Top Ten States for Pharmacy Recruitment

Rank	All Pharmacists			
	High School	#	Professional School	#
1	Virginia	3,292	Virginia	3,341
2	Outside U.S./Canada	910	Pennsylvania	460
3	Pennsylvania	406	Outside U.S./Canada	358
4	New York	304	North Carolina	332
5	Maryland	223	New York	239
6	North Carolina	199	Maryland	231
7	West Virginia	191	West Virginia	192
8	New Jersey	136	Massachusetts	189
9	Florida	119	Washington, D.C.	159
10	Ohio	109	Tennessee	137

Source: Va. Healthcare Workforce Data Center

47% of Virginia's pharmacists received their high school degree in Virginia, and 49% received their initial professional degree in the state.

Among pharmacists who have been licensed in the past five years, 39% received their high school degree in Virginia, and 42% received their initial professional degree in the state.

Rank	Licensed in the Past 5 Years			
	High School	#	Professional School	#
1	Virginia	612	Virginia	678
2	Outside U.S./Canada	215	North Carolina	108
3	Pennsylvania	84	Pennsylvania	101
4	Maryland	68	Outside U.S./Canada	81
5	North Carolina	64	Maryland	78
6	New York	63	Tennessee	76
7	Florida	41	West Virginia	55
8	West Virginia	38	New York	43
9	Texas	29	Massachusetts	39
10	New Jersey	27	Ohio	36

Source: Va. Healthcare Workforce Data Center

46% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2023. 92% of these professionals worked at some point in the past year, including 84% who currently work as pharmacists.

At a Glance:

Not in VA Workforce

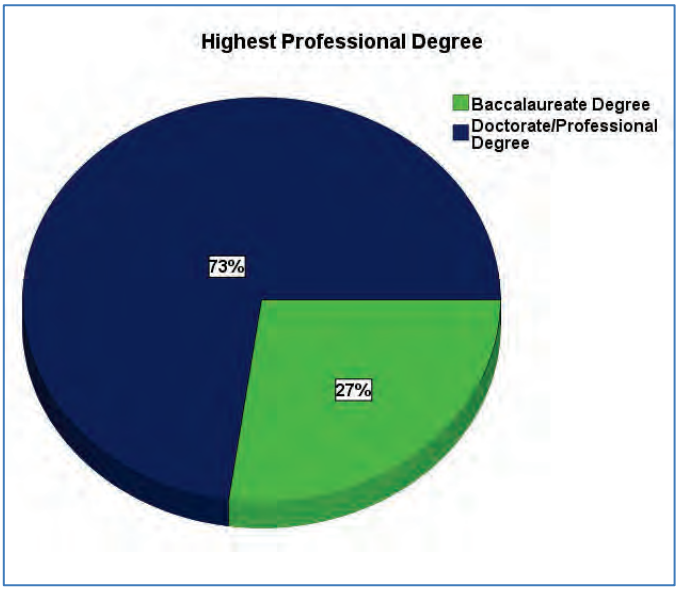
Total:	7,793
% of Licensees:	46%
Federal/Military:	8%
VA Border State/DC:	17%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	1,854	27%
Pharm.D.	4,961	73%
Total	**6,815**	**100%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

41% of pharmacists currently have educational debt, including 69% of those under the age of 40. For those with educational debt, the median debt is between $120,000 and $130,000. Among those under the age of 40 with debt, median is $150,000 to $160,000.

At a Glance:

Education

B.S. Pharmacy: 27%
Pharm.D.: 73%

Educational Debt

Carry debt: 41%
Under age 40 w/ debt: 69%
Median debt: $120k-$130k

Source: Va. Healthcare Workforce Data Center

73% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a Bachelor's degree in Pharmacy.

Educational Debt				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
None	3,209	59%	619	31%
$20,000 or less	152	3%	53	3%
$20,001-$40,000	161	3%	54	3%
$40,001-$60,000	195	4%	90	4%
$60,001-$80,000	149	3%	67	3%
$80,001-100,000	171	3%	96	5%
$100,001-$120,000	144	3%	91	5%
$120,001-$140,000	152	3%	98	5%
$140,001-$160,000	172	3%	134	7%
$160,001-$180,000	148	3%	111	6%
$180,001-$200,000	128	2%	98	5%
Over $200,000	661	12%	503	25%
Total	**5,442**	**100%**	**2,014**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

At a Glance:

Top Specialties

Immunization:	15%
Community Pharmacy:	8%
Ambulatory Care:	4%

Top Board Certifications

BPS - Pharmacotherapy:	6%
BPS - Ambulatory Care:	1%
BCGP - Geriatrics:	1%

Top Residencies (PGY1)

Pharmacy Practice (Post 1993):	12%
Community Pharmacy:	5%
Pharmacy Practice (Pre 1993):	3%

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	1047	12%
Community Pharmacy	432	5%
Pharmacy Practice (Pre 1993)	254	3%
Managed Care Pharmacy	32	<1%
Total	**1,765**	**20%**
PGY2		
Ambulatory Care	105	1%
Critical Care	78	1%
Internal Medicine/Cardiology	54	1%
Oncology	35	<1%
Infectious Disease	32	<1%
Health-system Pharmacy Administration	32	<1%
Pediatrics	29	<1%
Drug Information	24	<1%
Psychiatry	23	<1%
Emergency Medicine	23	<1%
Pharmacotherapy	22	<1%
Solid Organ Transplant	20	<1%
Geriatrics	18	<1%
Other	150	2%
At Least One	**624**	**7%**

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	550	6%
BPS-Ambulatory Care	105	1%
BCGP-Geriatrics	73	1%
BPS-Oncology	43	<1%
BPS- Psychiatric	26	<1%
BPS-Nuclear Pharmacy	10	<1%
BPS- Nutrition	8	<1%
ABAT-Applied Toxicology	2	<1%
Other Board Certification	294	3%
At Least One Certification	**1,011**	**11%**

Source: Va. Healthcare Workforce Data Center

11% of pharmacists hold a board certification, including 6% who hold a certification in Pharmacotherapy. 31% also have a self-designated specialty area, including 15% who have a specialization in immunization.

At a Glance:

Top Services

Immunization:	29%
Medication Management:	25%
Compounding:	19%

Disease Management

Diabetes:	41%
Anticoagulation:	39%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Disease Management in Collaborative Practice		
	#	%
Diabetes	291	41%
Anticoagulation	283	39%
Hypertension	264	37%
Hypercholesterolemia	223	31%
Tobacco Cessation	178	25%
Asthma	152	21%
Travel Medications	96	13%
At least one	**406**	**63%**

Source: Va. Healthcare Workforce Data Center

63% of the 406 pharmacists with a collaborative practice agreement were involved in providing at least one disease management service; diabetes management was the most commonly reported by 41% of those with the agreement. 23% of pharmacists in the state workforce also utilized at least one of the listed statewide protocols.

Services Provided				
Services	Primary		Secondary	
	#	%	#	%
Primary Service, Immunization	2,643	29%	2,643	29%
Primary Service, Medication Therapy Management	2,278	25%	272	3%
Primary Service, Compounding	1,703	19%	184	2%
Primary Service, Central Filling	1,155	13%	158	2%
Primary Service, Remote Order Processing	907	10%	108	1%
Primary Service, Collaborative Practice Agreement	644	7%	74	1%
At Least One	**4,353**	**48%**	**2,889**	**32%**

Source: Va. Healthcare Workforce Data Center

Statewide Protocols		
	#	%
Immunization	1,911	21%
Naloxone	1,667	18%
Lowering Out-of-Pocket Expenses	338	4%
Epinephrine	327	4%
Emergency Contraception	229	3%
Hormonal Contraception	200	2%
Prenatal Vitamins	149	2%
HIV Post-Exposure Prophylaxis	115	1%
HIV Pre-Exposure Prophylaxis	95	1%
Tuberculin Skin Testing	45	1%
At Least One	**2,043**	**23%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment

Employed in Profession: 92%
Involuntarily Unemployed: 1%

Positions Held

1 Full-time: 74%
2 or More Positions: 8%

Weekly Hours:

40 to 49: 54%
60 or more: 4%
Less than 30: 12%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	3	<1%
Employed in a pharmacy-related capacity	6,284	92%
Employed, NOT in a pharmacy-related capacity	265	4%
Not working, reason unknown	0	0%
Involuntarily unemployed	38	1%
Voluntarily unemployed	165	2%
Retired	109	2%
Total	**6,864**	**100%**

Source: Va. Healthcare Workforce Data Center

92% of Virginia's pharmacists are currently employed in the profession, and 1% of all pharmacy professionals are involuntarily unemployed at the survey period. 74% of the state's pharmacist workforce have one full-time job, while 8% of pharmacists have multiple positions. 54% of pharmacists work between 40 and 49 hours per week, while 4% of pharmacy professionals work at least 60 hours per week.

Current Positions		
Positions	#	%
No Positions	312	5%
One Part-Time Position	869	13%
Two Part-Time Positions	109	2%
One Full-Time Position	4,969	74%
One Full-Time Position & One Part-Time Position	408	6%
Two Full-Time Positions	12	0%
More than Two Positions	33	0%
Total	**6,712**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	312	5%
1 to 9 hours	176	3%
10 to 19 hours	228	3%
20 to 29 hours	407	6%
30 to 39 hours	1,247	19%
40 to 49 hours	3,571	54%
50 to 59 hours	448	7%
60 to 69 hours	139	2%
70 to 79 hours	67	1%
80 or more hours	58	1%
Total	**6,653**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	37	1%
$50,000 or less	358	7%
$50,001-$60,000	99	2%
$60,001-$70,000	76	2%
$70,001-$80,000	95	2%
$80,001-$90,000	113	2%
$90,001-$100,000	166	3%
$100,001-$110,000	384	8%
$110,001-$120,000	434	9%
$120,001-$130,000	663	13%
$130,001-$140,000	645	13%
$140,001-$150,000	604	12%
More than $150,000	1,240	25%
Total	**4,914**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $130k-140k

Benefits
Employer Retirement: 65%
Employer Health Insurance: 64%

Satisfaction
Satisfied: 87%
Very Satisfied: 44%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	2,949	44%
Somewhat Satisfied	2,839	43%
Somewhat Dissatisfied	600	9%
Very Dissatisfied	260	4%
Total	**6,648**	**100%**

Source: Va. Healthcare Workforce Data Center

The typical pharmacist earned between $130,000 and $140,000 in 2023. Among pharmacists who received either an hourly wage or a salary as compensation at their primary work location, 68% received health insurance and 70% also had access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Vacation Leave	4,616	73%	78%
Retirement	4,077	65%	70%
Health Insurance	4,021	64%	68%
Dental Insurance	3,934	63%	67%
Paid Sick Leave	3,396	54%	58%
Group Life Insurance	2,779	44%	48%
Signing/Retention Bonus	620	10%	10%
Received At Least One Benefit	**4,896**	**78%**	**83%**

*From any employer at time of survey.
Source: Va. Healthcare Workforce Data Center

A Closer Look:

Underemployment in Past Year		
In the past year did you . . .?	#	%
Experience Involuntary Unemployment?	85	1%
Experience Voluntary Unemployment?	247	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	182	2%
Work two or more positions at the same time?	699	8%
Switch employers or practices?	520	6%
Experienced at least 1	**1,428**	**16%**

Source: Va. Healthcare Workforce Data Center

1% of Virginia's pharmacists experienced involuntary unemployment at some point in 2023. By comparison, Virginia's average monthly unemployment rate was 2.9%.[1]

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	126	2%	51	6%
Less than 6 Months	601	9%	127	15%
6 Months to 1 Year	635	10%	106	13%
1 to 2 Years	1,314	21%	151	18%
3 to 5 Years	1,190	19%	161	19%
6 to 10 Years	958	15%	107	13%
More than 10 Years	1,533	24%	130	16%
Subtotal	**6,357**	**100%**	**833**	**100%**
Did not have location	293		8,180	
Item Missing	2,397		35	
Total	**9,047**		**9,047**	

Source: Va. Healthcare Workforce Data Center

Half of all pharmacists receive a salary or commission at their primary work location, while 44% receive an hourly wage.

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 1%
Underemployed: 2%

Stability

Switched: 6%
New Location: 23%
Over 2 years: 58%
Over 2 yrs, 2nd location: 49%

Employment Type

Salary or Wage: 94%

Source: Va. Healthcare Workforce Data Center

58% of pharmacists have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.

Employment Type		
Primary Work Site	#	%
Salary/ Commission	2,571	50%
Hourly Wage	2,297	44%
By Contract	50	1%
Business/ Practice Income	218	4%
Unpaid	50	1%
Subtotal	**5,187**	**100%**

Source: Va. Healthcare Workforce Data Center

[1] As reported by the U.S. Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fluctuated between a low of 2.5% and a high of 3.3%. The unemployment rate from December 2023 was still preliminary at the time of publication.

At a Glance:

Concentration

Top Region:	27%
Top 3 Regions:	72%
Lowest Region:	1%

Locations

2 or more (2023):	10%
2 or more (Now*):	12%

Source: Va. Healthcare Workforce Data Center

Over half of all pharmacists in the state work in either Northern Virginia or Central Virginia.

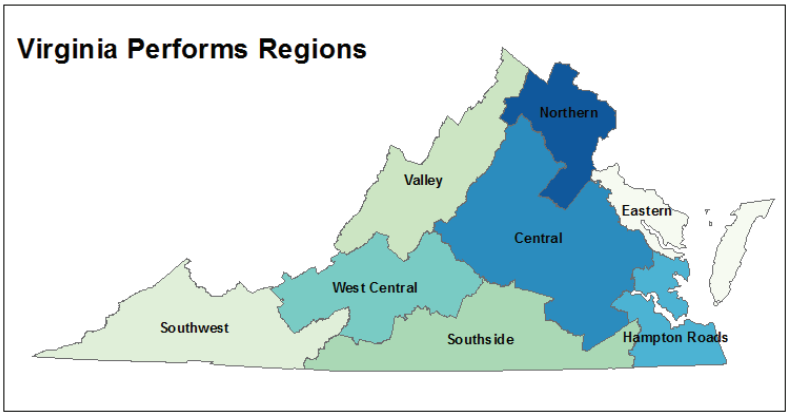
Number of Work Locations				
Locations	Work Locations in 2023		Work Locations Now*	
	#	%	#	%
0	293	3%	305	5%
1	7,887	87%	5,468	83%
2	530	6%	518	8%
3	213	2%	180	3%
4	23	0%	11	0%
5	15	0%	12	0%
6 or More	87	1%	62	1%
Total	**9,047**	**100%**	**6,555**	**100%**

*At the time of survey completion, December 2023. *Source: Va. Healthcare Workforce Data Center*

A Closer Look:

Regional Distribution of Work Locations				
Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	1,690	27%	172	20%
Eastern	77	1%	18	2%
Hampton Roads	1,140	18%	145	17%
Northern	1,723	27%	206	24%
Southside	191	3%	28	3%
Southwest	361	6%	48	6%
Valley	362	6%	50	6%
West Central	687	11%	91	11%
Virginia Border State/DC	33	1%	38	4%
Other US State	49	1%	44	5%
Outside of the US	0	0%	5	1%
Total	**6,313**	**100%**	**845**	**100%**
Item Missing	2,442		22	

Source: Va. Healthcare Workforce Data Center



Over the past year, 10% of Virginia's pharmacists worked at multiple locations.

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	3,641	62%	550	72%
Non-Profit	1,682	29%	174	23%
State/Local Government	198	3%	21	3%
Veterans Administration	153	3%	1	0%
U.S. Military	103	2%	11	1%
Other Federal Gov't	93	2%	10	1%
Total	**5,870**	**100%**	**767**	**100%**
Did not have location	293		8,180	
Item Missing	2,884		101	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

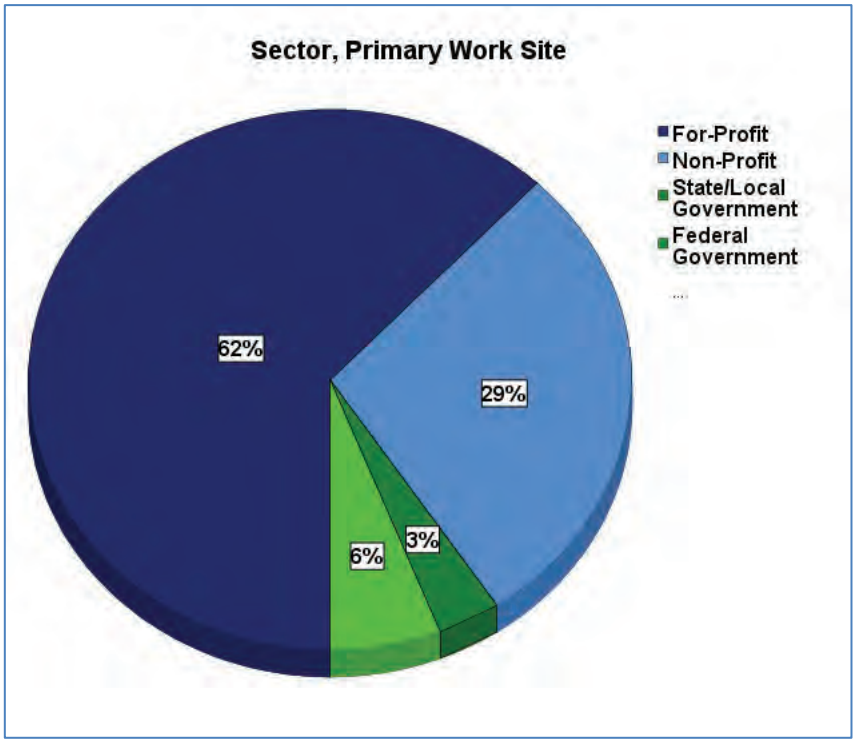
For Profit: 62%
Federal: 6%

Top Establishments

Hospital/Health System: (Inpatient) 26%
Large Chain Pharmacy: (11+ Stores) 25%
Independent Pharmacy: (1-4 Stores) 8%

Source: Va. Healthcare Workforce Data Center

91% of all pharmacists work in the private sector, including 62% who work at a for-profit company. Another 2% of pharmacists work for the federal government, while 3% work for a state or local government.



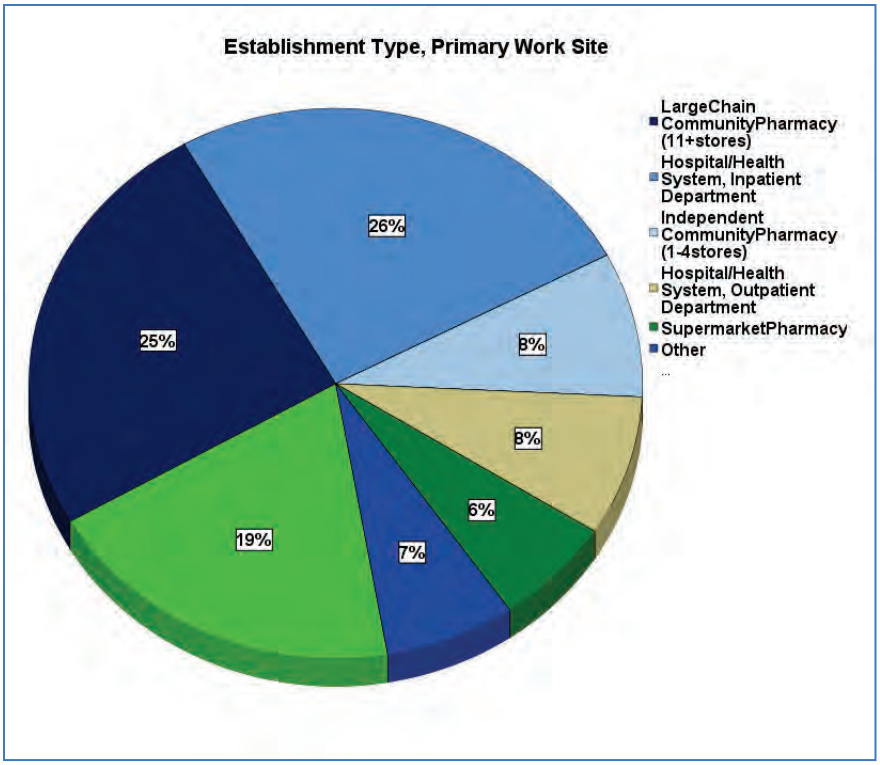
Source: Va. Healthcare Workforce Data Center

Top Location Types				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Hospital/Health System, Inpatient Department	1,476	26%	147	19%
Large Chain Community Pharmacy	1,453	25%	230	30%
Independent Community Pharmacy	491	8%	86	11%
Hospital/Health System, Outpatient Department	476	8%	40	5%
Supermarket Pharmacy	369	6%	46	6%
Clinic-Based Pharmacy	215	4%	50	7%
Benefit Administration	186	3%	10	1%
Mass Merchandiser (i.e., Big Box Store)	181	3%	26	3%
Nursing Home/Long-Term Care	150	3%	22	3%
Academic Institution	114	2%	16	2%
Mail Service Pharmacy	92	2%	8	1%
Home Health/Infusion	84	1%	8	1%
Manufacturer	60	1%	4	1%
Small Chain Community Pharmacy	34	1%	13	2%
Wholesale Distributor	6	<1%	2	<1%
Other	399	7%	54	7%
Total	**5,786**	**100%**	**762**	**100%**
Did Not Have a Location	293		8,180	

Source: Va. Healthcare Workforce Data Center

Hospital, health system, inpatient department is the most common establishment type in Virginia, employing over a quarter of the state's pharmacist workforce.

Large chain community pharmacies of more than 10 stores were the most common establishment type among pharmacists who had a secondary work location.



Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Typical Time Allocation

Patient Care:	80%-89%
Administration:	1%-9%

Roles

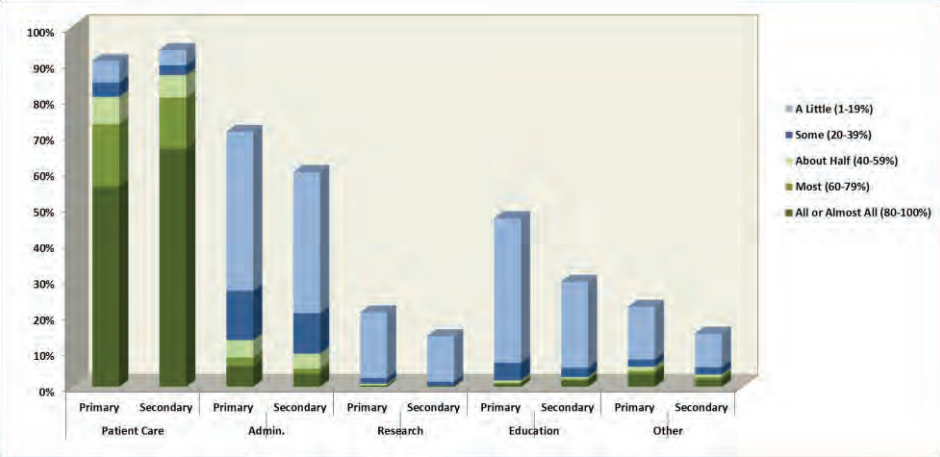
Patient Care:	73%
Administration:	8%
Education:	1%

Patient Care Pharmacists

Median Admin Time:	1%-9%
Ave. Admin Time:	1%-9%

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

A typical pharmacist spends most of her time in patient care activities. In fact, almost three-quarters of pharmacists fill a patient care role, defined as spending at least 60% of their time in that activity.

Time Allocation										
Time Spent	Patient Care		Admin.		Research		Education		Other	
	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site
All or Almost All (80-100%)	56%	66%	6%	4%	0%	0%	1%	2%	4%	2%
Most (60-79%)	17%	14%	2%	1%	0%	0%	0%	0%	1%	1%
About Half (40-59%)	8%	6%	5%	4%	0%	0%	1%	1%	1%	1%
Some (20-39%)	4%	3%	14%	11%	2%	1%	5%	3%	2%	2%
A Little (1-20%)	6%	4%	44%	39%	18%	13%	40%	24%	15%	9%
None (0%)	9%	6%	29%	40%	79%	86%	53%	71%	78%	85%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	193	4%	-	-
50 to 54	259	5%	0	0%
55 to 59	607	12%	145	7%
60 to 64	1,408	27%	508	26%
65 to 69	1,803	35%	810	41%
70 to 74	461	9%	255	13%
75 to 79	137	3%	89	5%
80 or over	54	1%	34	2%
I do not intend to retire	288	6%	113	6%
Total	**5,211**	**100%**	**1,954**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacists

Under 65: 47%

Under 60: 20%

Pharmacists 50 and over

Under 65: 33%

Under 60: 7%

Time until Retirement

Within 2 years: 7%

Within 10 years: 25%

Half the workforce: By 2048

Source: Va. Healthcare Workforce Data Center

47% of Virginia's pharmacists expect to retire before the age of 65, while 19% plan on working until at least age 70. Among pharmacists who are age 50 and over, 33% still plan on retiring by age 65, while 26% expect to work until at least age 70.

Within the next two years, 3% of Virginia's pharmacists plan on leaving the profession and 2% expect to leave the state. Meanwhile, 8% of pharmacists expect to pursue additional educational opportunities, and 6% plan on increasing the number of hours that they devote to patients.

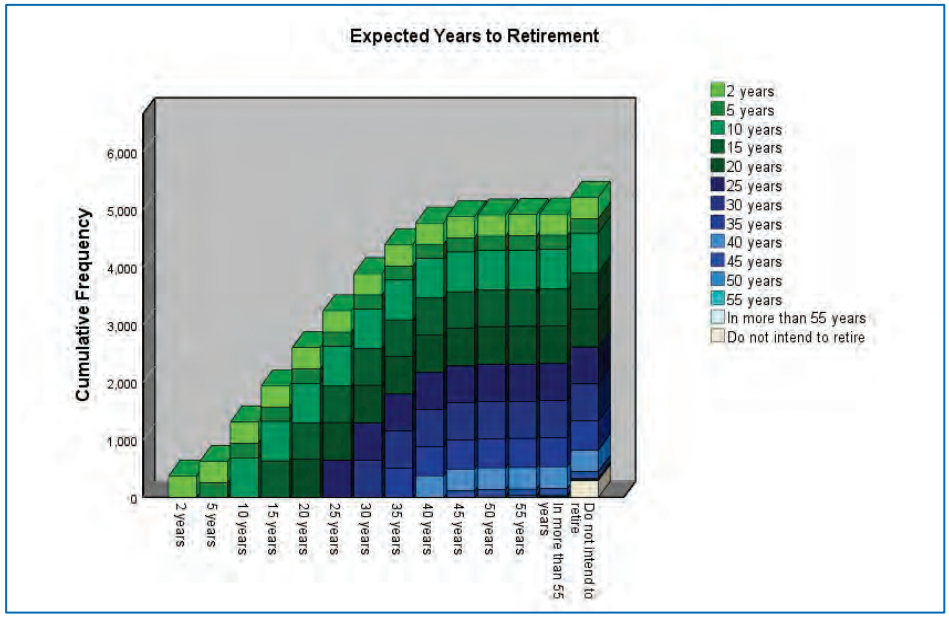
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	191	3%
Leave Virginia	187	2%
Decrease Patient Care Hours	298	3%
Decrease Teaching Hours	27	0%
Increase Participation		
Increase Patient Care Hours	566	6%
Increase Teaching Hours	356	4%
Pursue Additional Education	682	8%
Return to Virginia's Workforce	80	1%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacists. Only 7% of pharmacists plan on retiring in the next two years, while 25% plan on retiring in the next ten years. More than half of the current pharmacist workforce is expected to retire by 2048.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	369	7%	7%
5 years	249	5%	12%
10 years	689	13%	25%
15 years	633	12%	37%
20 years	659	13%	50%
25 years	640	12%	62%
30 years	646	12%	75%
35 years	505	10%	84%
40 years	375	7%	91%
45 years	115	2%	94%
50 years	24	0%	94%
55 years	4	0%	94%
In more than 55 years	13	0%	94%
Do not intend to retire	288	6%	100%
Total	**5,211**	**100%**	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce starting in 2033. Retirement will peak at 13% of the current workforce around 2043 before declining to under 10% of the current workforce again around 2063.

At a Glance:

FTEs

Total:	7,394
FTEs/1,000 Residents[2]:	0.856
Average:	0.85

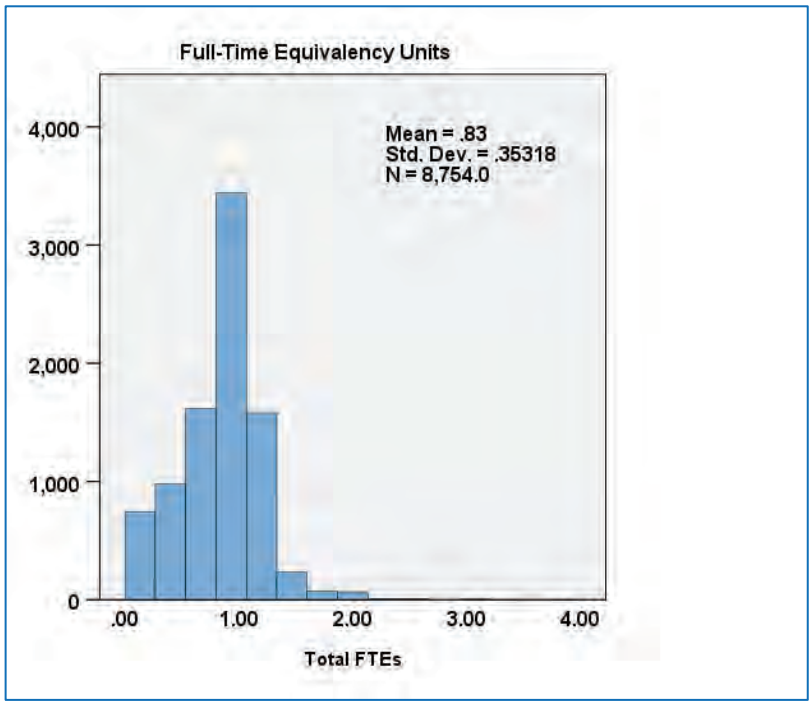
Age & Gender Effect

Age, Partial Eta[3]:	Small
Gender, Partial Eta[3]:	Negligible

Partial Eta[3] Explained:
Partial Eta[3] is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

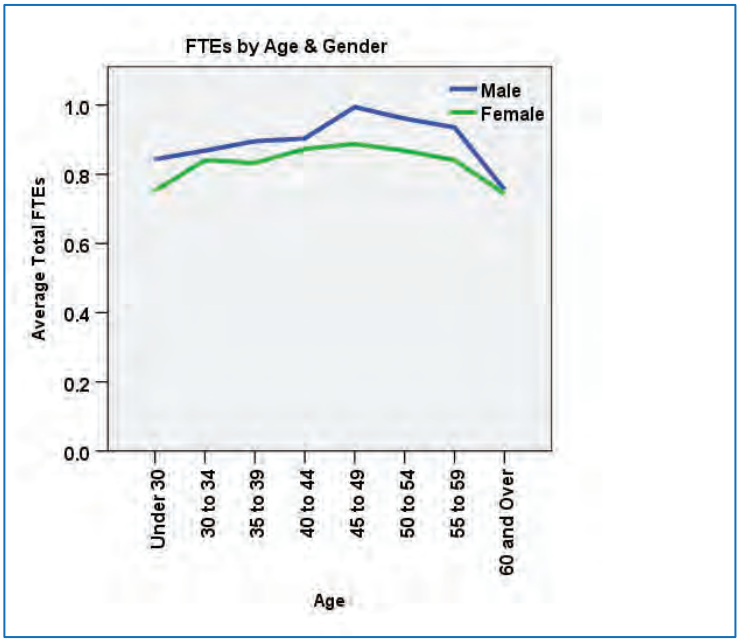


Source: Va. Healthcare Workforce Data Center

The typical pharmacist provided 0.85 FTEs in 2023, or about 34 hours per week for 52 weeks. Although FTEs appear to vary by both age and gender, statistical tests did not verify that a difference exists.[3]

Full-Time Equivalency Units		
	Average	Median
Under 30	0.76	0.74
30 to 34	0.82	0.84
35 to 39	0.85	0.84
40 to 44	0.84	0.81
45 to 49	0.91	0.88
50 to 54	0.91	0.96
55 to 59	0.86	0.82
60 and Over	0.69	0.55
Gender		
Male	0.88	0.96
Female	0.83	0.91

Source: Va. Healthcare Workforce Data Center

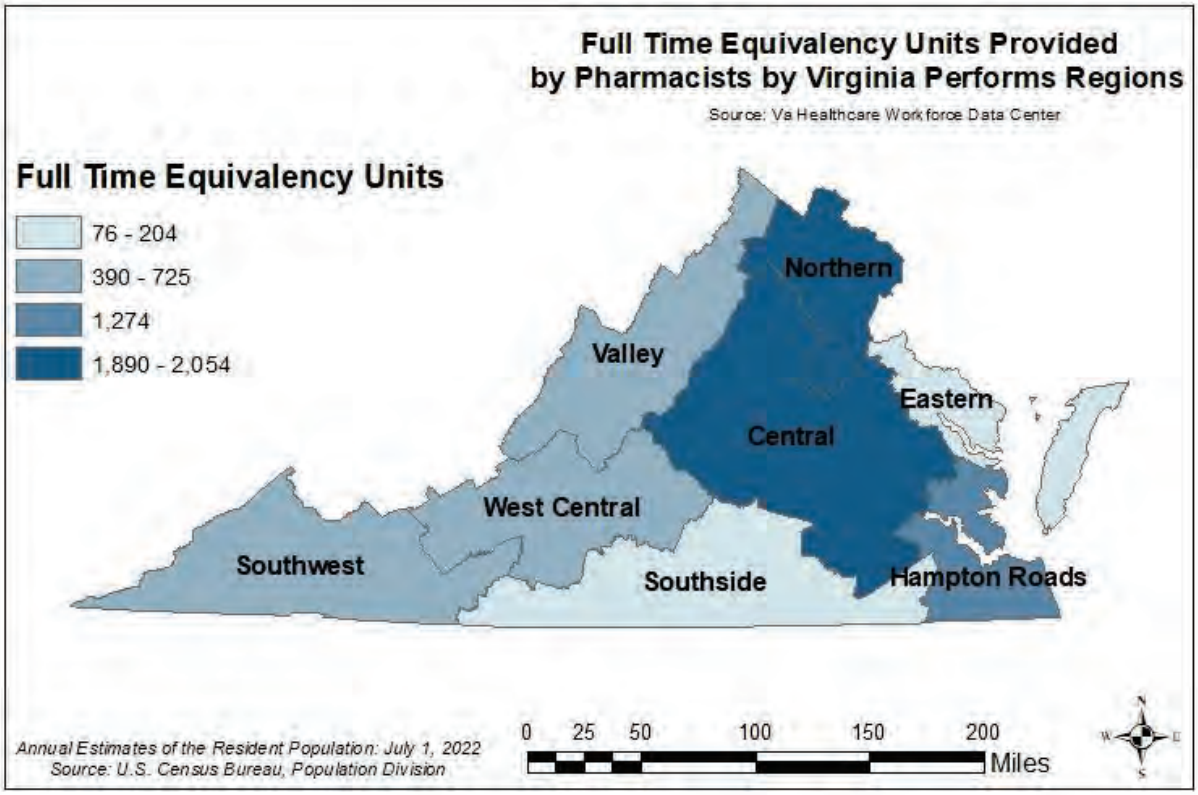


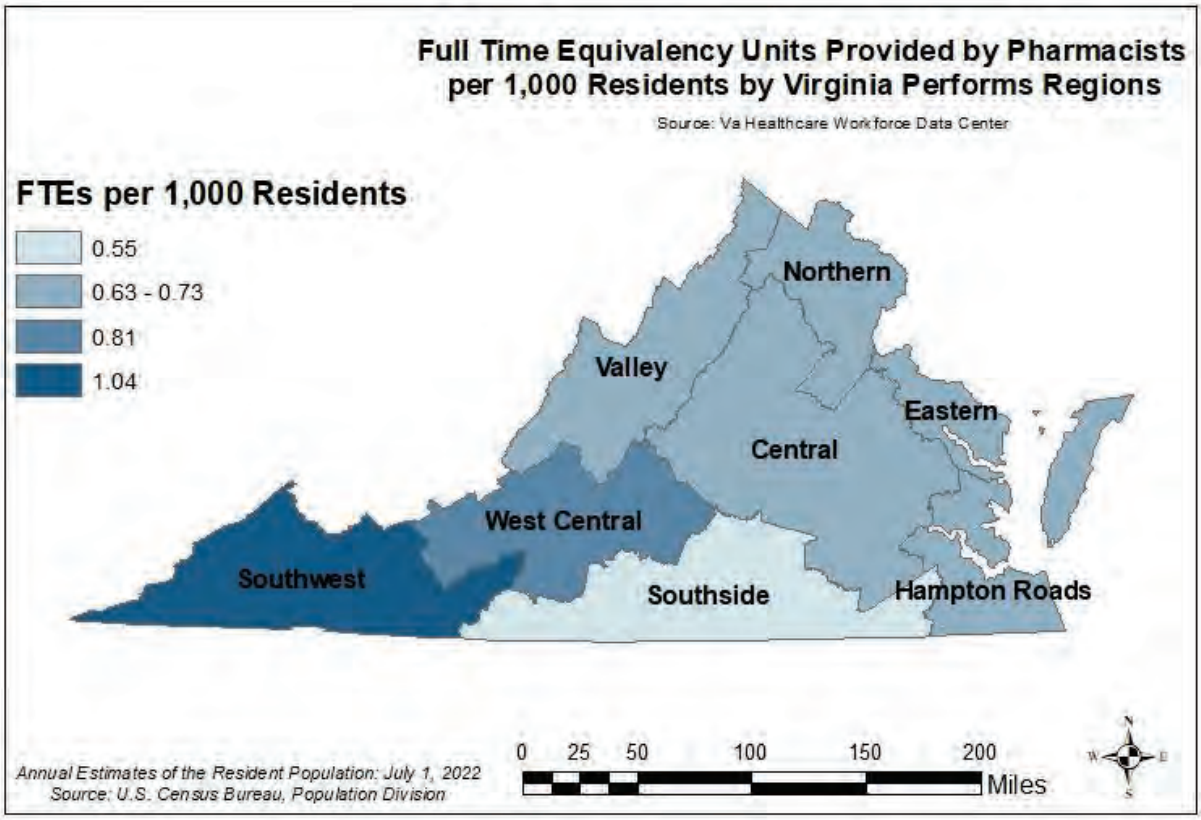
Source: Va. Healthcare Workforce Data Center

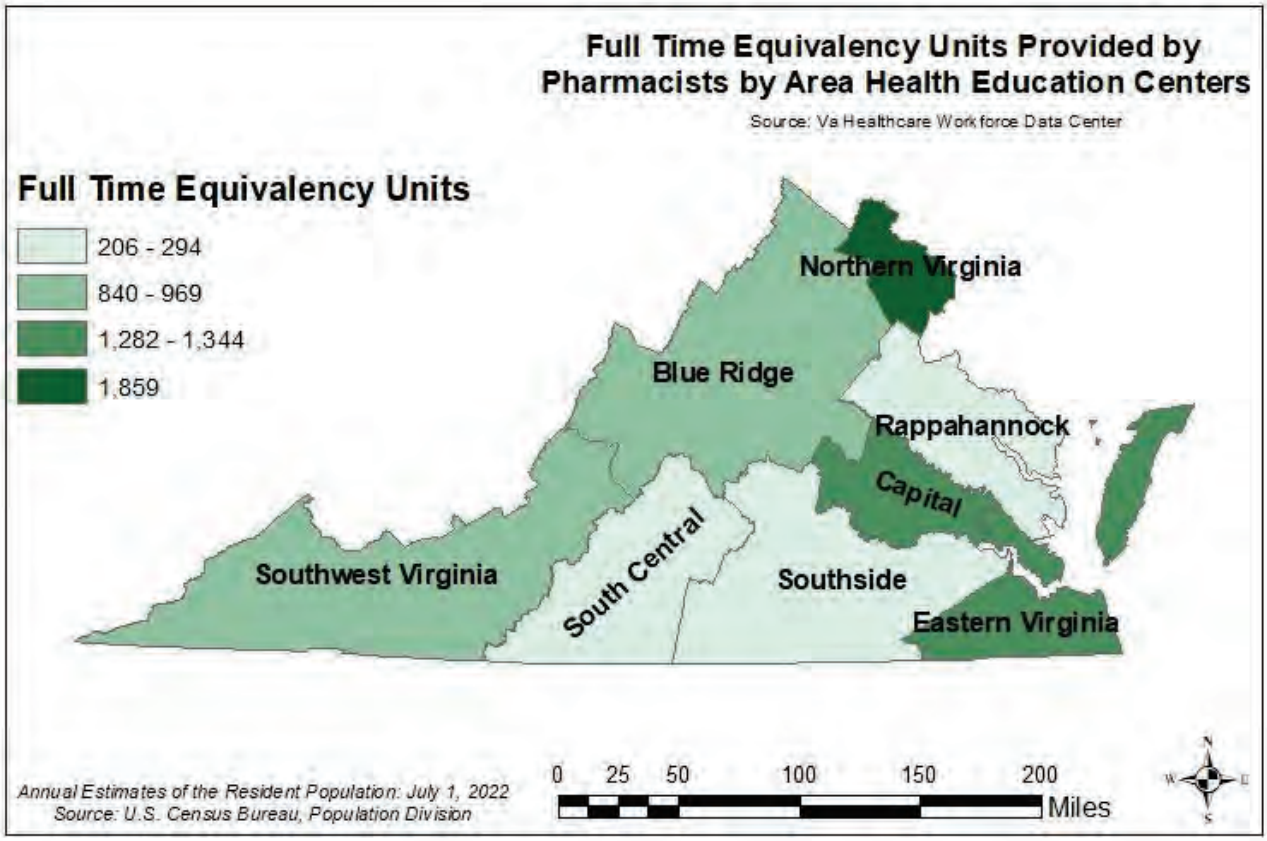
[2] Number of residents in 2022 was used as the denominator.
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

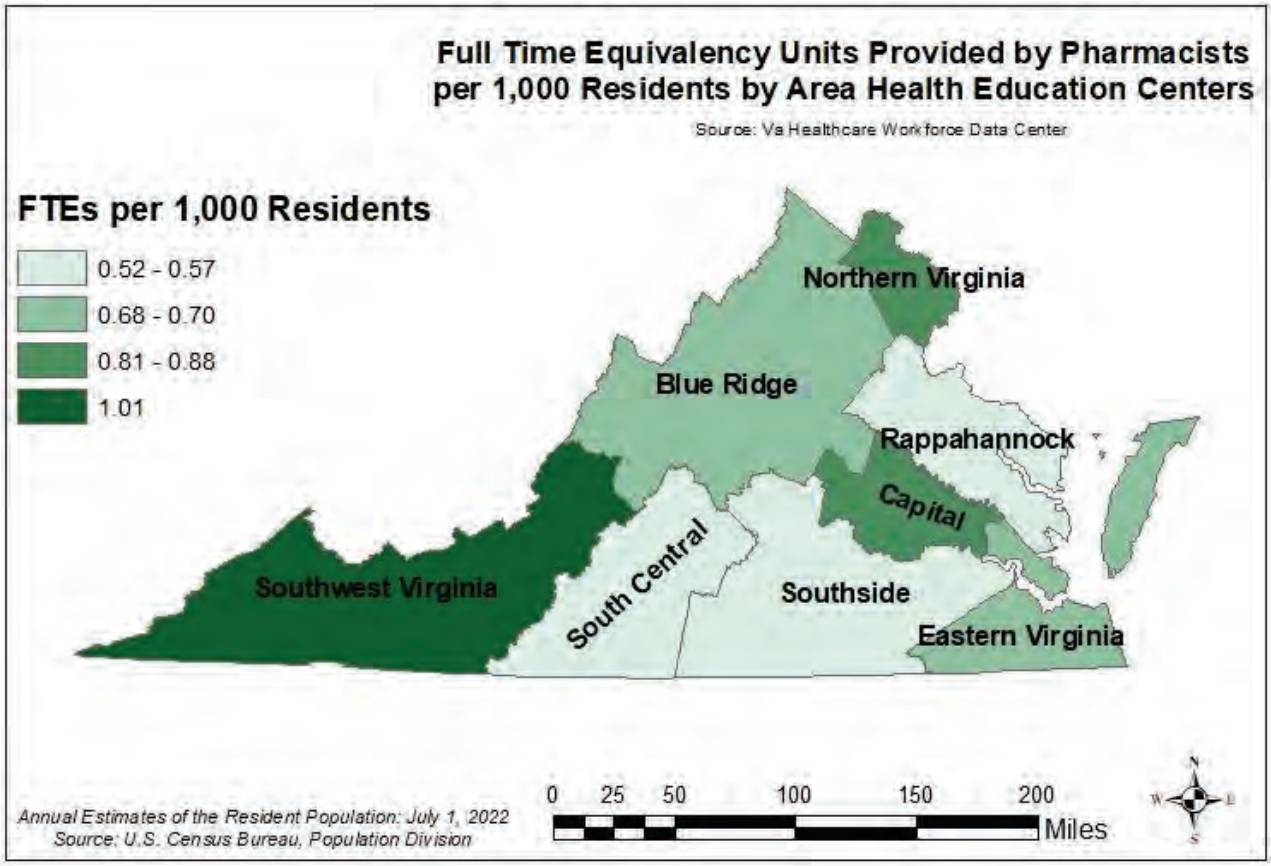
Maps

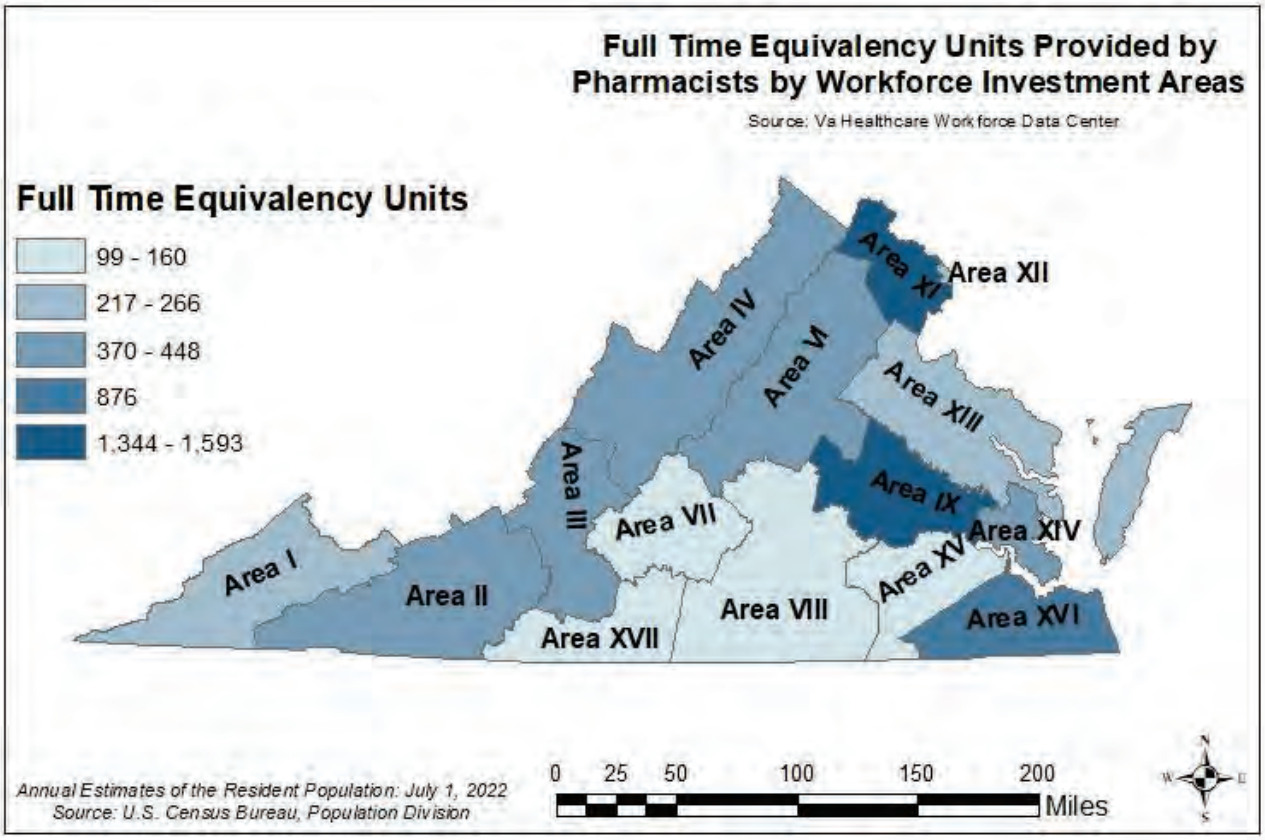
Virginia Performs Regions

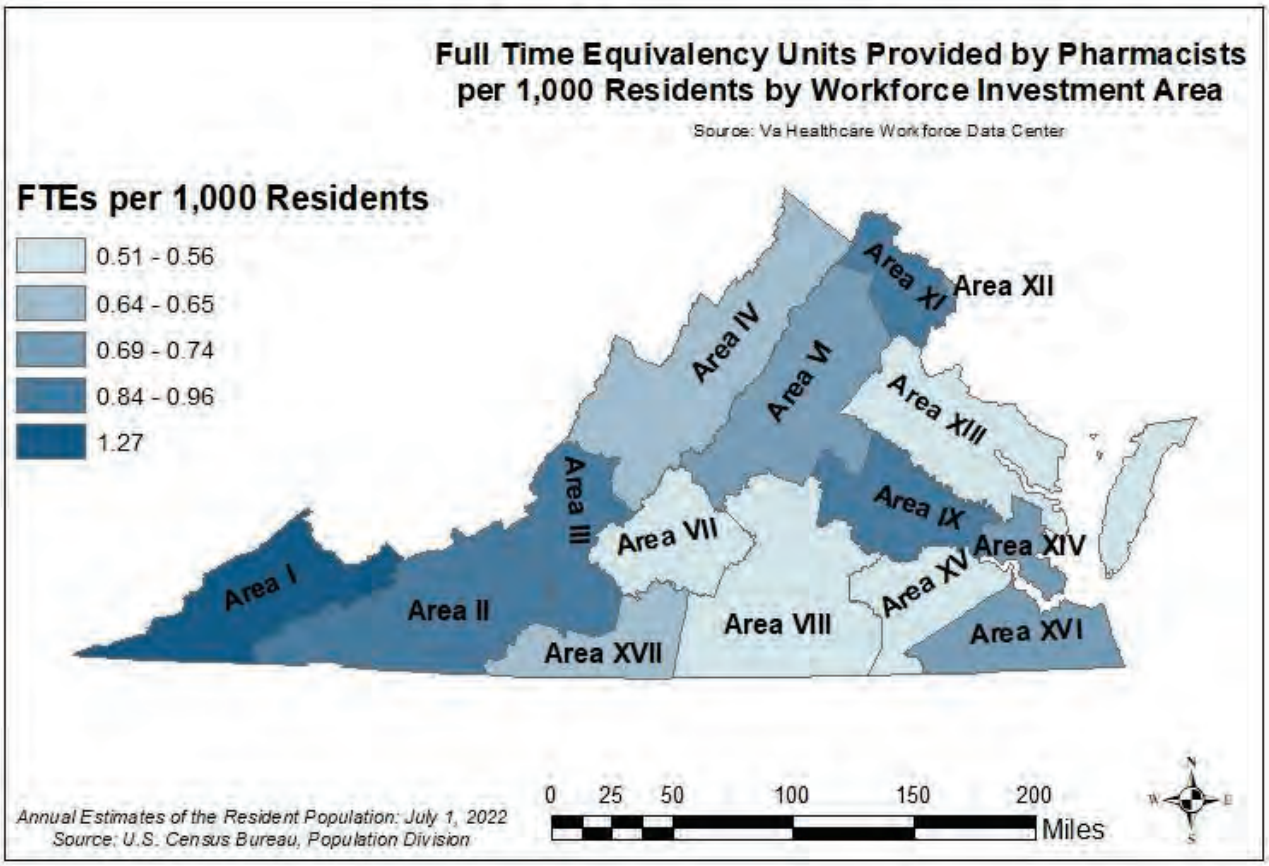


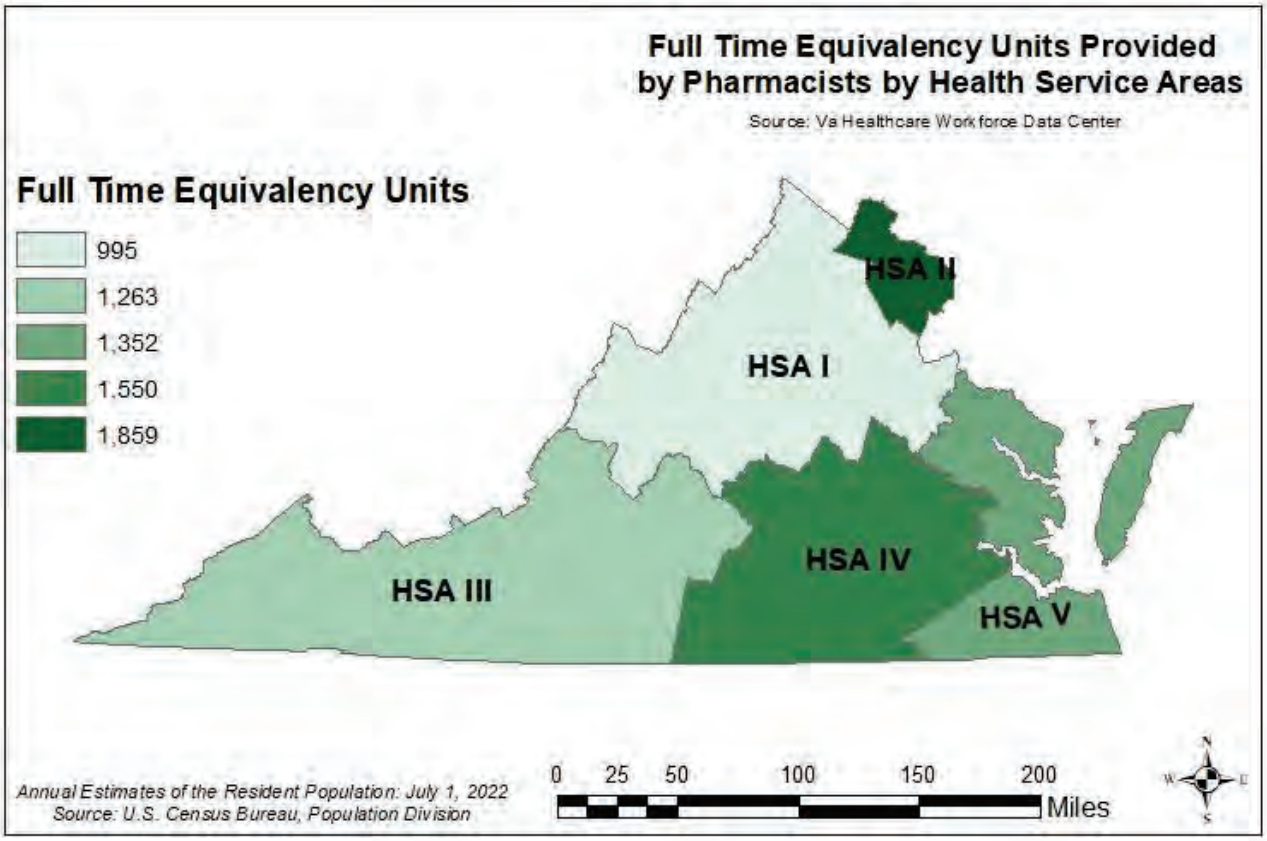


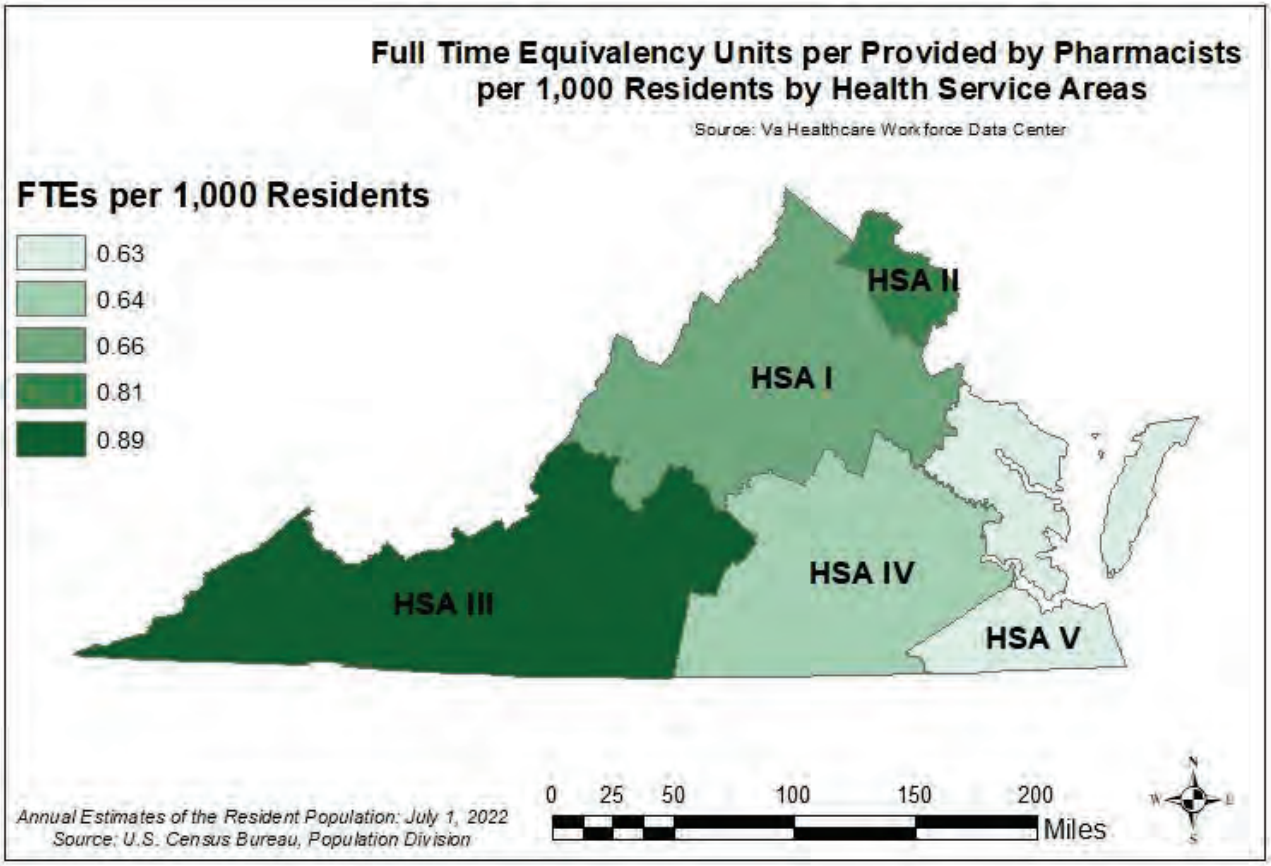

Full Time Equivalency Units Provided by Pharmacists by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
206 - 294
840 - 969
1,282 - 1,344
1,859
Northern Virginia
Blue Ridge
Rappahannock
Capital
South Central
Southwest Virginia
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

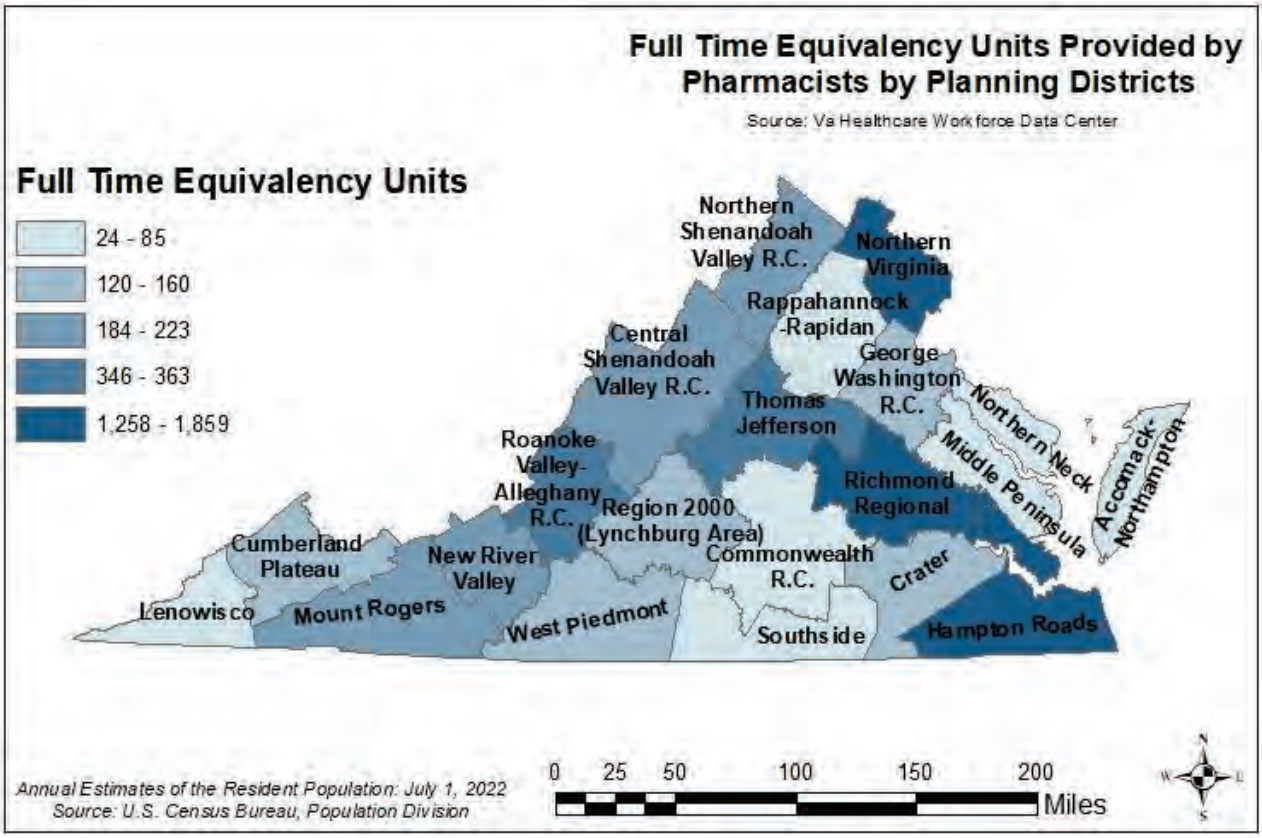

Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.52 - 0.57
0.68 - 0.70
0.81 - 0.88
1.01
Northern Virginia
Blue Ridge
Rappahannock
Capital
South Central
Southwest Virginia
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

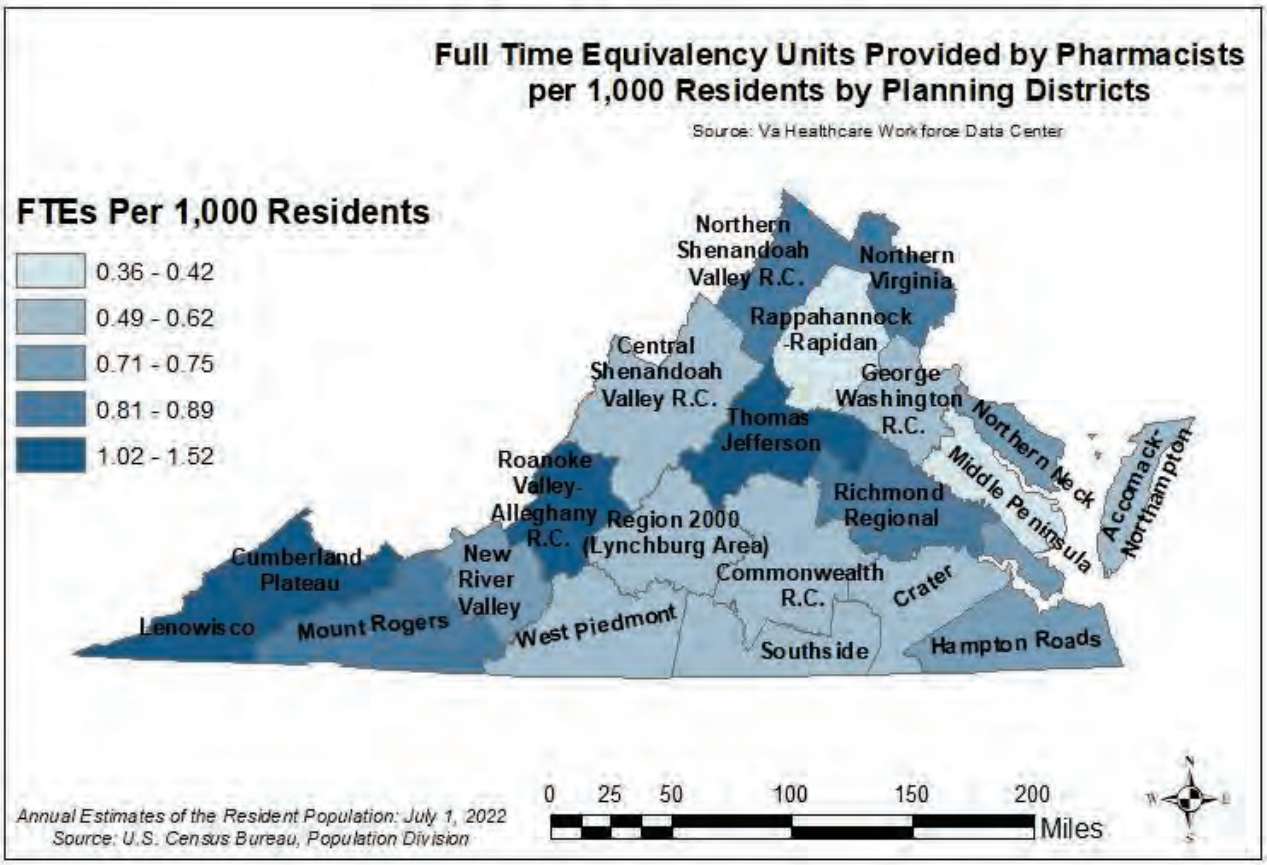

Full Time Equivalency Units Provided by Pharmacists by Workforce Investment Areas
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
99 - 160
217 - 266
370 - 448
876
1,344 - 1,593
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.51 - 0.56
0.64 - 0.65
0.69 - 0.74
0.84 - 0.96
1.27
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacists by Health Service Areas
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
995
1,263
1,352
1,550
1,859
HSA II
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units per Provided by Pharmacists per 1,000 Residents by Health Service Areas
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.63
0.64
0.66
0.81
0.89
HSA II
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacists by Planning Districts
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
24 - 85
120 - 160
184 - 223
346 - 363
1,258 - 1,859
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock -Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Accomack-Northampton
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Cumberland Plateau
New River Valley
Commonwealth R.C.
Crater
Lenowisco
Mount Rogers
West Piedmont
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Planning Districts
Source: Va Healthcare Workforce Data Center
FTEs Per 1,000 Residents
0.36 - 0.42
0.49 - 0.62
0.71 - 0.75
0.81 - 0.89
1.02 - 1.52
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock -Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Accomack-Northampton
Roanoke Valley-Alleghany R.C.
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Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

Appendix

Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 million+	6,760	93.43%	1.0703	1.0500	1.1241
Metro, 250,000 to 1 million	952	93.17%	1.0733	1.0529	1.1272
Metro, 250,000 or less	1,112	93.44%	1.0703	1.0499	1.1241
Urban pop 20,000+, Metro adj	119	94.12%	1.0625	1.0423	1.1159
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	358	92.74%	1.0783	1.0578	1.1325
Urban pop, 2,500-19,999, nonadj	302	92.05%	1.0863	1.0657	1.1409
Rural, Metro adj	242	90.91%	1.1000	1.0791	1.1553
Rural, nonadj	130	93.08%	1.0744	1.0540	1.1284
Virginia border state/DC	2,948	90.88%	1.1004	1.0795	1.1557
Other US State	3,748	88.37%	1.1316	1.1102	1.1885

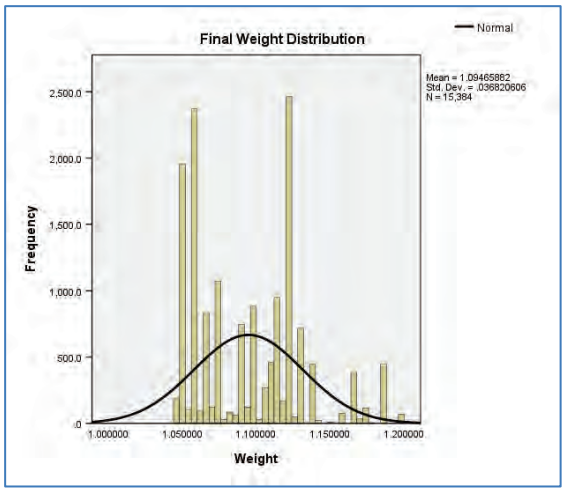
Source: Va. Healthcare Workforce Data Center

See the Methods section on the HWDC website for details on HWDC Methods: www.dhp.virginia.gov/hwdc/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate =
Final Weight.

Overall Response Rate: 0.9135



Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	807	87.36%	1.1447	1.1159	1.1885
30 to 34	2,448	92.03%	1.0866	1.0592	1.1282
35 to 39	2,906	93.22%	1.0727	1.0458	1.1138
40 to 44	2,354	92.69%	1.0788	1.0517	1.1202
45 to 49	1,956	93.25%	1.0724	1.0454	1.1134
50 to 54	1,888	93.27%	1.0721	1.0452	1.1132
55 to 59	1,514	93.53%	1.0692	1.0423	1.1102
60 and Over	2,798	87.42%	1.1439	1.1152	1.1877

Source: Va. Healthcare Workforce Data Center

DRAFT

Virginia's Pharmacy Technician Workforce: 2023

Healthcare Workforce Data Center

February 2024

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
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Henrico, VA 23233
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Get a copy of this report from:
https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/ProfessionReports/

Nearly 11,000 Pharmacy Technicians voluntarily participated in this survey. *Without their efforts, the work of the center would not be possible. The Department of Health Professions, the Healthcare Workforce Data Center, and the Board of Pharmacy express our sincerest appreciation for their ongoing cooperation.*

Thank You!

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Contents

The Pharmacy Technician Workforce At a Glance:

The Workforce

Registrants:	13,659
Virginia's Workforce:	12,535
FTEs:	9,754

Survey Response Rate

All Registrants:	79%
Renewing Practitioners:	99%

Demographics

Female:	85%
Diversity Index:	61%
Median Age:	37

Background

Rural Childhood:	40%
HS Degree in VA:	74%
% Work Non-Metro:	13%

Education

High School/GED:	56%
Associate Degree:	21%

Finances

Median Income:	$35k-$40k
Health Insurance:	59%
Under 40 w/ Ed. Debt:	46%

Current Employment

Employed in Prof.:	82%
Hold 1 Full-Time Job:	70%
Satisfied?:	90%

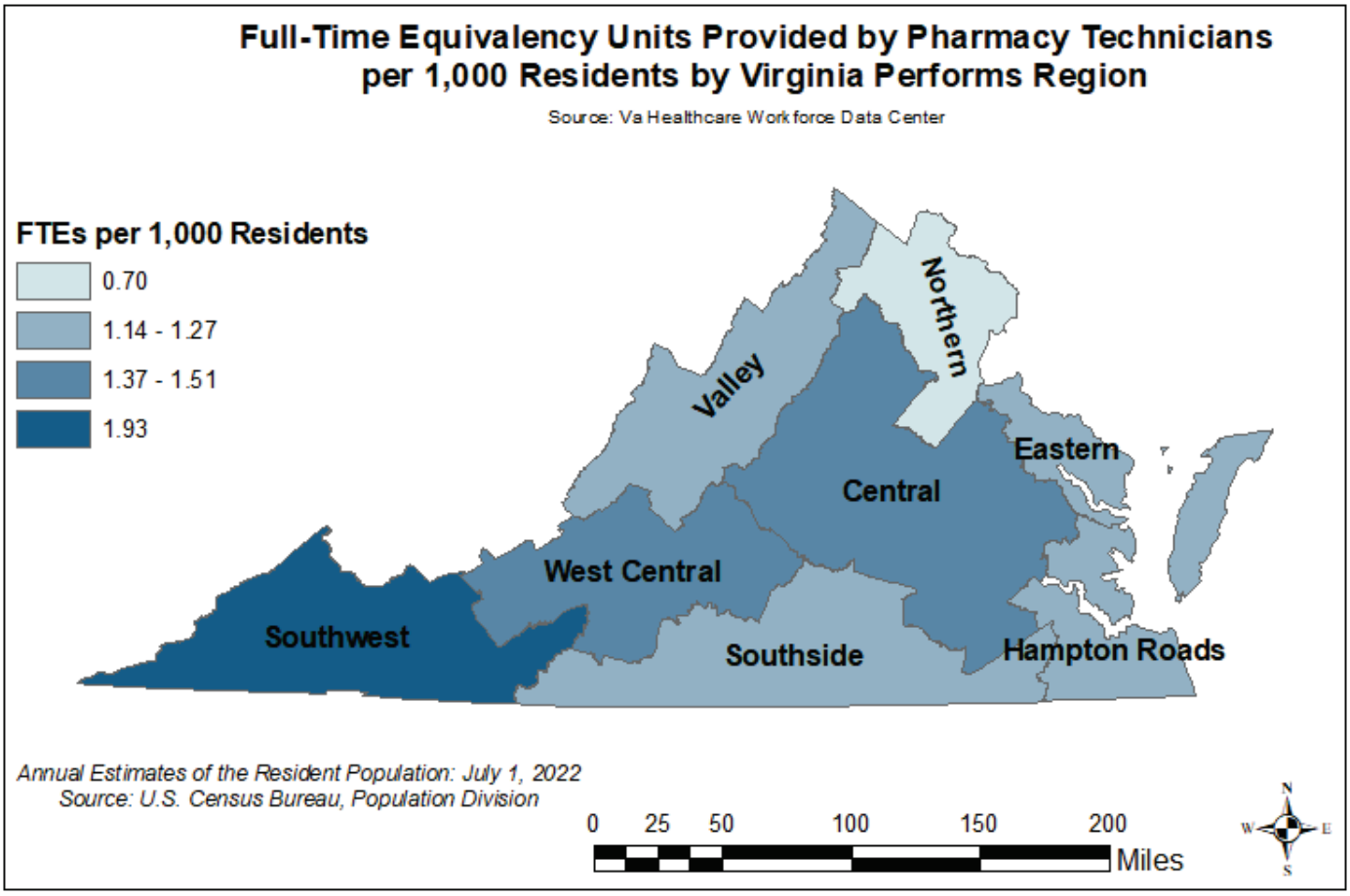
Job Turnover

Switched Jobs:	5%
Employed Over 2 Yrs.:	52%

Primary Roles

Medication Disp.:	54%
Administration:	6%
Supervision:	2%

Source: Va. Healthcare Workforce Data Center



Results in Brief

This report contains the results of the 2023 Pharmacy Technician Workforce survey. A total of 10,854 pharmacy technicians voluntarily participated in this survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the registration renewal process, which takes place every December for pharmacy technicians. These survey respondents represent 79% of the 13,659 pharmacy technicians who are registered in the state and 99% of renewing practitioners.

The HWDC estimates that 12,535 pharmacy technicians participated in Virginia's workforce during the survey period, which is defined as those who worked at least a portion of the year in the state or who live in the state and intend to return to work in the profession at some point in the future. Virginia's pharmacy technician workforce provided 9,754 "full-time equivalency units," which the HWDC defines simply as working 2,000 hours per year.

Among all pharmacy technicians, 85% are female. In addition, the median age of this workforce is 37. In a random encounter between two pharmacy technicians, there is a 61% chance that they would be of different races or ethnicities, a measure known as the diversity index. This diversity index increases to 65% for those pharmacy technicians who are under the age of 40. For Virginia's overall population, the comparable diversity index is 60%. Two out of every five pharmacy technicians grew up in a rural area, and 27% of pharmacy technicians who grew up in a rural area currently work in a non-metro area of Virginia. In total, 13% of all pharmacy technicians work in a non-metro area.

More than four out of every five pharmacy technicians are currently employed in the profession, 70% hold one full-time position, and 52% work between 40 and 49 hours per week. More than seven out of every ten pharmacy technicians work in the for-profit sector, and another 17% are employed in the non-profit sector. The median annual income for pharmacy technicians is between $35,000 and $40,000, and 90% of pharmacy technician receive this income in the form of an hourly wage. Nine out of every ten pharmacy technicians indicated that they are satisfied with their current work situation, including 49% who indicated that they are "very satisfied."

Summary of Trends

In this section, all statistics for the current year are compared to the 2013 pharmacy technician workforce. The number of registered pharmacy technicians has decreased by 4% (13,659 vs. 14,262). The size of Virginia's pharmacy technician workforce has fallen by 6% (12,535 vs. 13,404), while the number of FTEs provided by this workforce has fallen by 9% (9,754 vs. 10,703). Renewing pharmacy technicians are more likely to respond to the survey (99% vs. 91%).

The percentage of pharmacy technicians who are female has increased (85% vs. 84%), and the median age of this workforce has risen (37 vs. 34). The diversity index of this workforce has increased as well (61% vs. 57%), a trend that has also occurred among those who are under the age of 40 (65% vs. 61%). The percentage of pharmacy technicians who grew up in a rural area has declined (40% vs. 41%), and pharmacy technicians who grew up in a rural area are less likely to work in a non-metro area (27% vs. 28%). In total, the percentage of all pharmacy technicians who work in a non-metro county has declined (13% vs. 15%). Pharmacy technicians are relatively more likely to hold either an associate degree (21% vs. 20%) or a baccalaureate degree (19% vs. 18%) as their highest professional degree than a high school degree/GED (56% vs. 59%). Although pharmacy technicians are less likely to hold education debt (36% vs. 38%), the median outstanding balance among those with education debt has increased ($18k-$20k vs. $10k-$12k).

Pharmacy technicians are more likely to work in the profession (82% vs. 79%), hold one full-time position (70% vs. 61%), and work between 40 and 49 hours per week (52% vs. 39%). Pharmacy technicians are relatively more likely to work in the non-profit sector (17% vs. 13%) than in the for-profit sector (72% vs. 76%). In addition, pharmacy technicians are relatively more likely to work in the inpatient or outpatient department of a hospital (25% vs. 18%) than in a large chain community pharmacy (29% vs. 35%). The median annual income of pharmacy technicians has increased ($35k-$40k vs. $20k-$22.5k), and pharmacy technicians are also more likely to receive at least one employer-sponsored benefit (78% vs. 74%). Pharmacy technicians are more likely to indicate that they are satisfied with their current work situation (90% vs. 89%), including those who indicated that they are "very satisfied" (49% vs. 47%).

A Closer Look:

Registrant Counts		
Registration Status	**#**	**%**
Renewing Practitioners	10,370	76%
New Registrants	1,346	10%
Non-Renewals	1,943	14%
All Registrants	**13,659**	**100%**

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. Among all renewing pharmacy technicians, 99% submitted a survey. These represent 79% of the 13,659 pharmacy technicians who were registered at some point in 2023.

Definitions

1. **The Survey Period:** The survey was conducted in December 2023.
2. **Target Population:** All professionals who held a Virginia registration at some point in 2023.
3. **Survey Population:** The survey was available to those who renewed their registration online. It was not available to those who did not renew, including some professionals newly registered in 2023.

Response Rates			
Statistic	**Non Respondents**	**Respondents**	**Response Rate**
By Age			
Under 30	1,155	2,615	69%
30 to 34	449	1,669	79%
35 to 39	360	1,546	81%
40 to 44	243	1,291	84%
45 to 49	166	1,019	86%
50 to 54	148	1,009	87%
55 to 59	100	758	88%
60 and Over	184	947	84%
Total	**2,805**	**10,854**	**80%**
New Registrations			
Issued in 2023	784	562	42%
Metro Status			
Non-Metro	332	1,608	83%
Metro	2,038	8,471	81%
Not in Virginia	435	775	64%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	**10,854**
Response Rate, All Registrants	**79%**
Response Rate, Renewals	**99%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Registered Pharmacy Tech.

Number:	13,659
New:	10%
Not Renewed:	14%

Survey Response Rates

All Registrants:	79%
Renewing Practitioners:	99%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Workforce

Pharmacy Tech. Workforce:	12,535
FTEs:	9,754

Utilization Ratios

Registrants in VA Workforce:	92%
Registrants per FTE:	1.40
Workers per FTE:	1.29

Source: Va. Healthcare Workforce Data Center

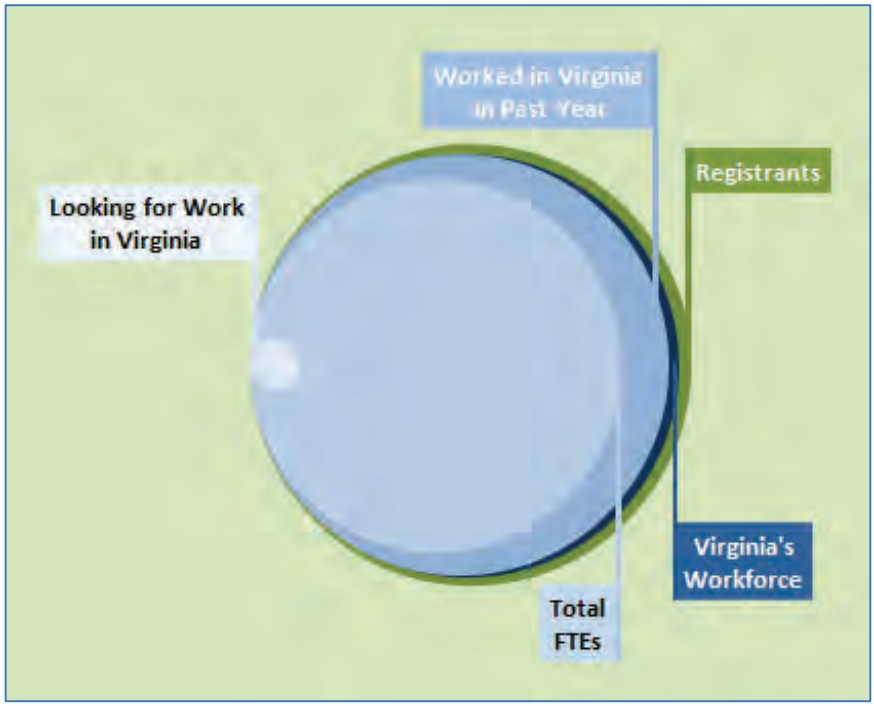
Definitions

1. **Virginia's Workforce:** A registrant with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
2. **Full-Time Equivalency Unit (FTE):** The HWDC uses 2,000 (40 hours for 50 weeks) as its baseline measure for FTEs.
3. **Registrants in VA Workforce:** The proportion of registrants in Virginia's Workforce.
4. **Registrants per FTE:** An indication of the number of registrants needed to create 1 FTE. Higher numbers indicate lower registrant participation.
5. **Workers per FTE:** An indication of the number of workers in Virginia's workforce needed to create 1 FTE. Higher numbers indicate lower utilization of available workers.

Pharmacy Tech. Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	12,343	98%
Looking for Work in Virginia	191	2%
Virginia's Workforce	**12,535**	**100%**
Total FTEs	**9,754**	
Registrants	**13,659**	

Source: Va. Healthcare Workforce Data Center

Weighting is used to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia workforce only. For more information on the HWDC's methodology, visit: https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	558	18%	2,610	82%	3,168	30%
30 to 34	264	16%	1,356	84%	1,620	16%
35 to 39	187	13%	1,220	87%	1,407	14%
40 to 44	136	12%	958	88%	1,094	11%
45 to 49	138	16%	723	84%	860	8%
50 to 54	98	12%	739	88%	837	8%
55 to 59	81	13%	549	87%	629	6%
60 and Over	97	12%	686	88%	783	8%
Total	**1,557**	**15%**	**8,840**	**85%**	**10,398**	**100%**

Source: Va. Healthcare Workforce Data Center

Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacy Tech.		Pharmacy Tech. Under 40	
	%	#	%	#	%
White	59%	5,949	57%	3,288	53%
Black	18%	2,342	22%	1,453	23%
Asian	7%	958	9%	556	9%
Other Race	1%	132	1%	76	1%
Two or More Races	5%	443	4%	340	5%
Hispanic	10%	668	6%	510	8%
Total	**100%**	**10,492**	**100%**	**6,223**	**100%**

*Population data in this chart is from the U.S. Census, Annual Estimates of the Resident Population by Sex, Race, and Hispanic Origin for the United States, States, and Counties: July 1, 2022.

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	85%
% Under 40 Female:	84%

Age

Median Age:	37
% Under 40:	60%
% 55 and Over:	14%

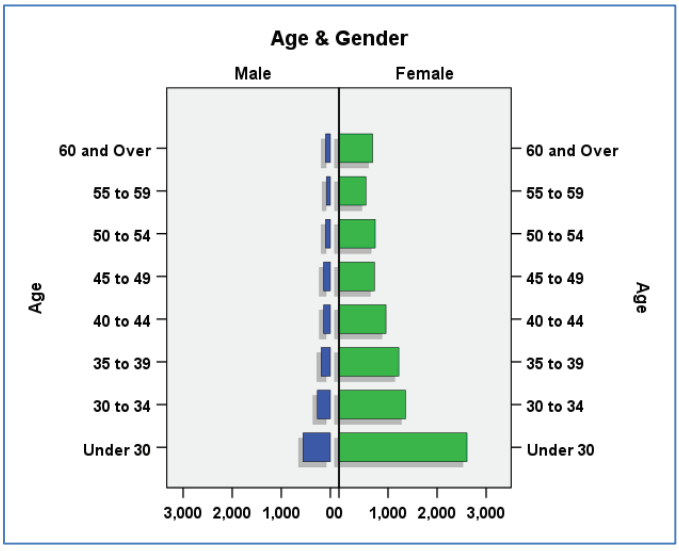
Diversity

Diversity Index:	61%
Under 40 Div. Index:	65%

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two professionals, there is a 61% chance that they would be of different races or ethnicities (a measure known as the diversity index). For Virginia's overall population, the comparable diversity index is 60%.

Among the 60% of pharmacy technicians who are under the age of 40, 84% are female. In addition, the diversity index among pharmacy technicians who are under the age of 40 is 65%.



Source: Va. Healthcare Workforce Data Center

At a Glance:

Childhood

Urban Childhood:	19%
Rural Childhood:	40%

Virginia Background

HS in Virginia:	74%
HS in VA, Past 5 Years:	71%

Location Choice

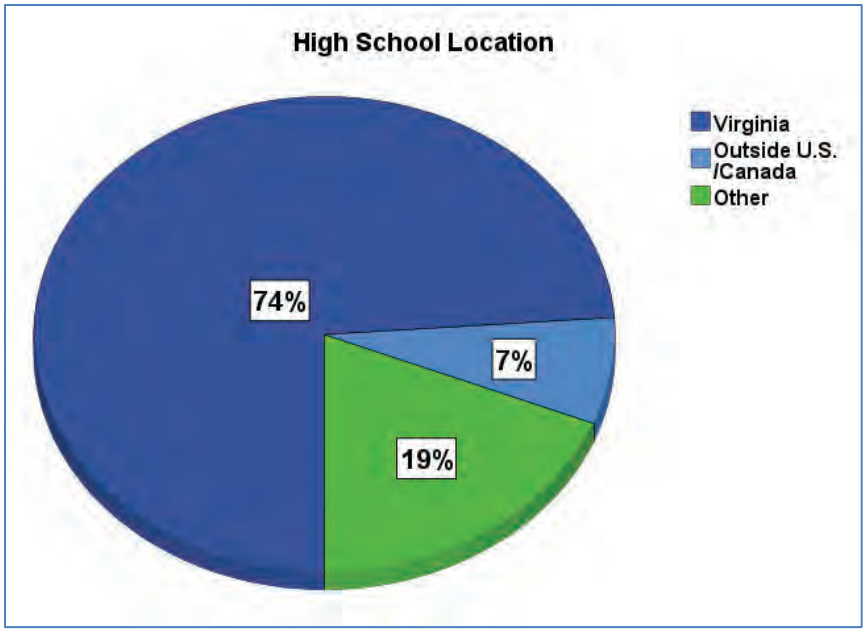
% Work Non-Metro:	13%
% Rural to Non-Metro:	27%
% Urban/Suburban to Non-Metro:	4%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 Million+	24%	52%	25%
2	Metro, 250,000 to 1 Million	58%	30%	12%
3	Metro, 250,000 or Less	63%	28%	10%
	Non-Metro Counties			
4	Urban, Pop. 20,000+, Metro Adjacent	64%	24%	12%
6	Urban, Pop. 2,500-19,999, Metro Adjacent	78%	17%	5%
7	Urban, Pop. 2,500-19,999, Non-Adjacent	93%	6%	1%
8	Rural, Metro Adjacent	87%	8%	5%
9	Rural, Non-Adjacent	75%	18%	8%
	Overall	**40%**	**42%**	**19%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 40% grew up in a self-described rural area, and 27% of pharmacy technicians who grew up in a rural area currently work in a non-metro county. In total, 13% of all pharmacy technicians are employed in a non-metro area of the state.

Top Ten States for Pharmacy Technician Recruitment

Rank	High School Location			
	All Pharmacy Technicians	#	Registered in the Past Five Years	#
1	Virginia	7,598	Virginia	2,801
2	Outside U.S./Canada	746	Outside U.S./Canada	273
3	Maryland	213	Maryland	118
4	North Carolina	166	North Carolina	87
5	New York	146	Florida	69
6	Florida	137	West Virginia	51
7	West Virginia	133	New York	51
8	Pennsylvania	118	California	46
9	California	111	Pennsylvania	46
10	New Jersey	85	Texas	45

Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 74% received their high school diploma in Virginia. Among those pharmacy technicians who obtained their initial registration in the past five years, 71% received their high school degree in the state.

In total, 8% of Virginia's registered pharmacy technicians did not participate in the state's workforce in 2023. However, 81% of these professionals worked at some point in the past year, including 63% who currently work as pharmacy technicians.

At a Glance:

Not in VA Workforce

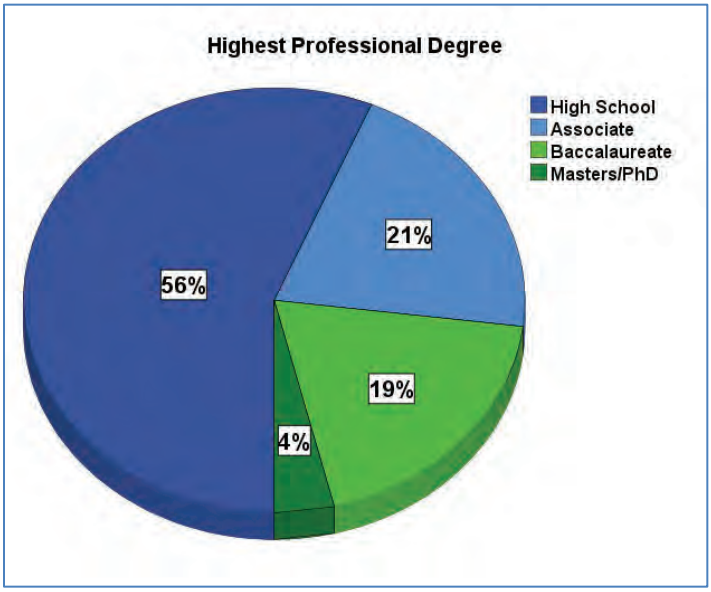
Total:	1,121
% of Registrants:	8%
Federal/Military:	4%
VA Border State/DC:	27%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	**#**	**%**
High School/GED	5,715	56%
Associate	2,091	21%
Baccalaureate	1,944	19%
Masters	348	3%
PhD	43	0%
Total	**10,141**	**100%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

More than one-third of all pharmacy technicians currently carry education debt, including 46% of those pharmacy technicians who are under the age of 40. For those pharmacy technicians with education debt, the median outstanding balance is between $18,000 and $20,000.

At a Glance:

Education

High School/GED: 56%
Associate Degree: 21%

Education Debt

Carry Debt: 36%
Under Age 40 w/ Debt: 46%
Median Debt: $18k-$20k

Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 56% hold either a high school degree or a GED as their highest professional degree.

Education Debt				
Amount Carried	**All Pharm. Tech.**		**Pharm. Tech. Under 40**	
	#	**%**	**#**	**%**
None	4,951	64%	2,488	54%
Less than $10,000	877	11%	687	15%
$10,000-$19,999	575	7%	433	9%
$20,000-$29,999	424	5%	324	7%
$30,000 or More	917	12%	636	14%
Total	**7,744**	**100%**	**4,568**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Certifications

PTCB:	64%
ExCPT:	12%
Total w/ Cert.:	76%

National Certifications

Required:	63%
Pay Raise w/ Cert.:	46%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Professional Certifications		
Certification	**#**	**% of Workforce**
Pharmacy Technician Certification Board (PTCB)	7,974	64%
Exam for Certification of Pharmacy Technicians (ExCPT)	1,500	12%
Total with Certification	**9,474**	**76%**

Source: Va. Healthcare Workforce Data Center

More than three-quarters of Virginia's pharmacy technician workforce holds a professional certification, including 64% who hold a Pharmacy Technician Certification Board (PTCB) credential.

Among all pharmacy technicians, 63% work for an employer that requires a national certification as a condition of employment. In addition, 46% of pharmacy technicians have received an increase in pay after having obtained a national certification.

National Certifications		
Required for Employment?	**#**	**%**
Yes	6,281	63%
No	3,766	37%
Pay Raise with Certification?	**#**	**%**
Yes	4,291	46%
No	4,634	50%
No Certification Held	423	5%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Employment

Employed in Profession: 82%
Involuntarily Unemployed: 1%

Positions Held

1 Full-Time: 70%
2 or More Positions: 9%

Weekly Hours:

40 to 49: 52%
60 or More: 3%
Less than 30: 14%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	**#**	**%**
Employed, Capacity Unknown	18	< 1%
Employed in a Pharmacy Technician-Related Capacity	8,321	82%
Employed, NOT in a Pharmacy Technician-Related Capacity	1,472	15%
Not Working, Reason Unknown	0	0%
Involuntarily Unemployed	73	1%
Voluntarily Unemployed	245	2%
Retired	38	< 1%
Total	**10,167**	**100%**

Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 82% are currently employed in the profession, 70% hold one full-time job, and 52% work between 40 and 49 hours per week.

Current Positions		
Positions	**#**	**%**
No Positions	356	4%
One Part-Time Position	1,710	17%
Two Part-Time Positions	136	1%
One Full-Time Position	7,010	70%
One Full-Time Position & One Part-Time Position	705	7%
Two Full-Time Positions	27	0%
More than Two Positions	34	0%
Total	**9,978**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	**#**	**%**
0 Hours	356	4%
1 to 9 Hours	242	2%
10 to 19 Hours	475	5%
20 to 29 Hours	689	7%
30 to 39 Hours	2,260	23%
40 to 49 Hours	5,036	52%
50 to 59 Hours	358	4%
60 to 69 Hours	103	1%
70 to 79 Hours	68	1%
80 or More Hours	151	2%
Total	**9,738**	**100%**

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Annual Income		
Income Level	**#**	**%**
Volunteer Work Only	77	2%
Less than $10,000	314	7%
$10,000-$14,999	170	4%
$15,000-$19,999	183	4%
$20,000-$24,999	282	6%
$25,000-$29,999	353	8%
$30,000-$34,999	568	13%
$35,000-$39,999	613	14%
$40,000-$44,999	641	15%
$45,000-$49,999	454	10%
$50,000 or More	722	17%
Total	**4,377**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $35k-$40k

Benefits
Health Insurance: 59%
Retirement: 56%

Satisfaction
Satisfied: 90%
Very Satisfied: 49%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	**#**	**%**
Very Satisfied	4,880	49%
Somewhat Satisfied	4,093	41%
Somewhat Dissatisfied	719	7%
Very Dissatisfied	288	3%
Total	**9,980**	**100%**

Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician earns between $35,000 and $40,000 per year. In addition, 78% of all pharmacy technicians receive at least one employer-sponsored benefit, including 59% who have access to health insurance.

Employer-Sponsored Benefits			
Benefit	**#**	**%**	**% of Wage/Salary Employees**
Paid Leave	5,356	64%	61%
Health Insurance	4,945	59%	56%
Dental Insurance	4,819	58%	54%
Retirement	4,699	56%	53%
Group Life Insurance	2,875	35%	32%
Signing/Retention Bonus	695	8%	8%
At Least One Benefit	**6,472**	**78%**	**73%**

*From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Employment Instability in the Past Year		
In The Past Year, Did You . . .?	**#**	**%**
Experience Involuntary Unemployment?	106	1%
Experience Voluntary Unemployment?	378	3%
Work Part-Time or Temporary Positions, but Would Have Preferred a Full-Time/Permanent Position?	309	2%
Work Two or More Positions at the Same Time?	1,210	10%
Switch Employers or Practices?	627	5%
Experience At Least One?	**2,225**	**18%**

Source: Va. Healthcare Workforce Data Center

Only 1% of pharmacy technicians were involuntarily unemployed at some point in the past year. By comparison, Virginia's average monthly unemployment rate was 2.9%.[1]

Location Tenure				
Tenure	**Primary**		**Secondary**	
	#	**%**	**#**	**%**
Not Currently Working at This Location	244	3%	211	13%
Less than 6 Months	873	9%	216	13%
6 Months to 1 Year	1,145	12%	225	13%
1 to 2 Years	2,252	24%	335	20%
3 to 5 Years	2,117	23%	299	18%
6 to 10 Years	1,238	13%	182	11%
More than 10 Years	1,524	16%	205	12%
Subtotal	**9,394**	**100%**	**1,674**	**100%**
Did Not Have Location	538		10,639	
Item Missing	2,603		222	
Total	**12,535**		**12,535**	

Source: Va. Healthcare Workforce Data Center

Nine out of every ten pharmacy technicians receive an hourly wage at their primary work location.

At a Glance:

Unemployment Experience

Involuntarily Unemployed: 1%
Underemployed: 2%

Turnover & Tenure

Switched Jobs: 5%
New Location: 26%
Over 2 Years: 52%
Over 2 Yrs., 2nd Location: 41%

Employment Type

Hourly Wage: 90%
Salary/Commission: 9%

Source: Va. Healthcare Workforce Data Center

More than half of all pharmacy technicians have worked at their primary work location for more than two years.

Employment Type		
Primary Work Site	**#**	**%**
Salary/Commission	694	9%
Hourly Wage	7,311	90%
By Contract/Per Diem	46	1%
Business/Practice Income	12	0%
Unpaid	55	1%
Subtotal	**8,118**	**100%**

Source: Va. Healthcare Workforce Data Center

[1] As reported by the U.S. Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate fluctuated between a low of 2.5% and a high of 3.3%. The unemployment rate from December 2023 was still preliminary at the time of publication.

At a Glance:

Concentration

Top Region:	24%
Top 3 Regions:	68%
Lowest Region:	2%

Locations

2 or More (Past Year):	20%
2 or More (Now*):	16%

Source: Va. Healthcare Workforce Data Center

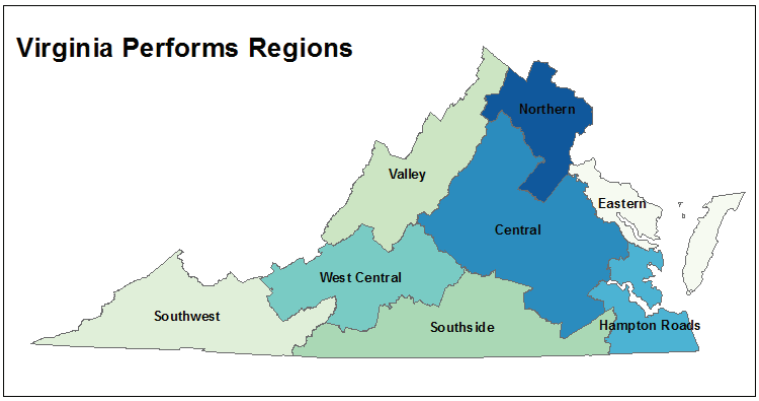
More than two-thirds of all pharmacy technicians work in Central Virginia, Northern Virginia, and Hampton Roads.

A Closer Look:

Regional Distribution of Work Locations

Virginia Performs Region	Primary Location		Secondary Location	
	#	%	#	%
Central	2,257	24%	364	20%
Eastern	184	2%	40	2%
Hampton Roads	2,027	22%	424	24%
Northern	2,057	22%	415	23%
Southside	384	4%	70	4%
Southwest	673	7%	108	6%
Valley	590	6%	85	5%
West Central	1,068	11%	216	12%
Virginia Border State/D.C.	22	0%	22	1%
Other U.S. State	30	0%	48	3%
Outside of the U.S.	1	0%	2	0%
Total	**9,293**	**100%**	**1,794**	**100%**
Item Missing	2,704		102	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Number of Work Locations

Locations	Work Locations in Past Year		Work Locations Now*	
	#	%	#	%
0	190	2%	355	4%
1	7,473	78%	7,687	81%
2	1,228	13%	1,005	11%
3	525	6%	429	5%
4	41	0%	25	0%
5	18	0%	11	0%
6 or More	56	1%	21	0%
Total	**9,532**	**100%**	**9,532**	**100%**

*At the time of survey completion, December 2023.

Source: Va. Healthcare Workforce Data Center

Among all pharmacy technicians, 16% currently have multiple work locations, while 20% have had multiple work locations over the past year.

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	6,391	72%	1,119	73%
Non-Profit	1,514	17%	256	17%
State/Local Government	588	7%	101	7%
Veterans Administration	81	1%	9	1%
U.S. Military	147	2%	31	2%
Other Federal Gov't	108	1%	23	1%
Total	**8,829**	**100%**	**1,539**	**100%**
Did Not Have Location	538		10,639	
Item Missing	3,168		358	

Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Sector

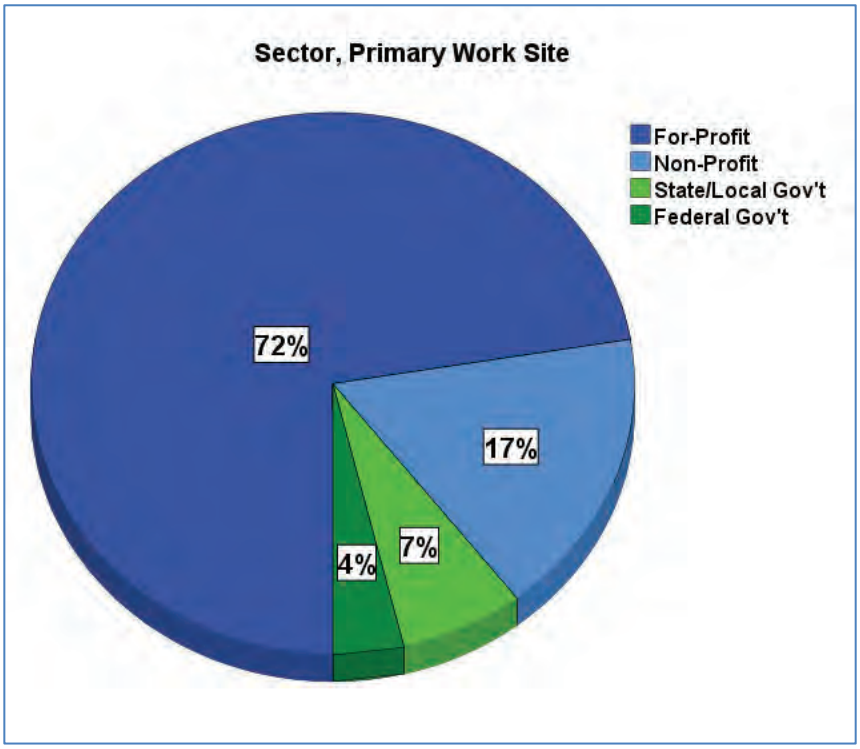
For-Profit: 72%
Federal: 4%

Top Establishments

Large Chain Pharmacy (11+ Stores): 29%
Hospital/Health System: (Inpatient) 16%
Independent Community Pharmacy (1-4 Stores): 10%

Source: Va. Healthcare Workforce Data Center

Nine out of every ten pharmacy technicians work in the private sector, including 72% who work in the for-profit sector. Another 7% of pharmacy technicians work for a state or local government.



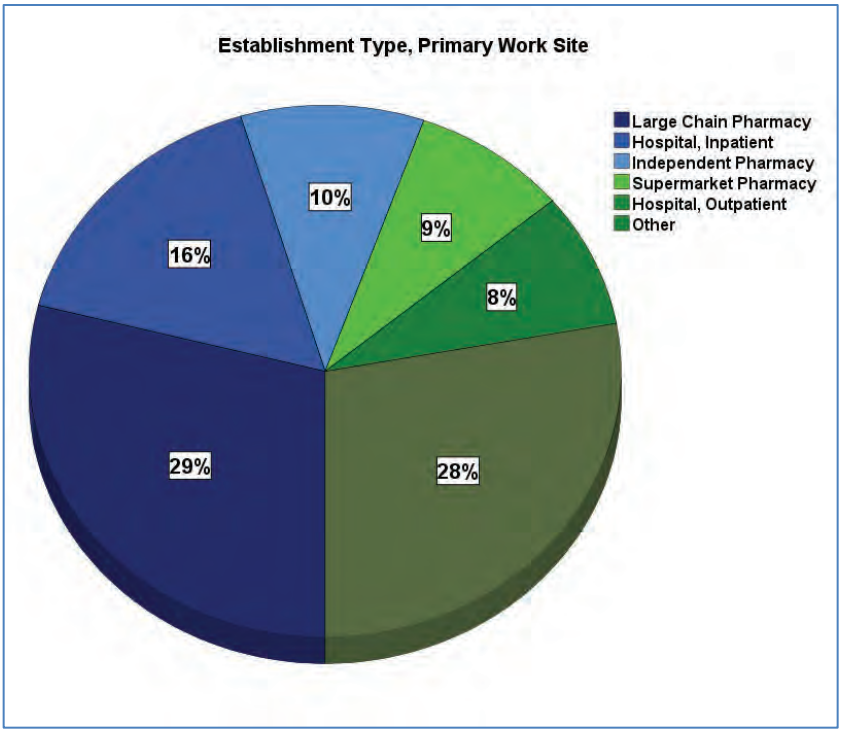
Source: Va. Healthcare Workforce Data Center

Location Type				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy (11+ Stores)	2,537	29%	504	34%
Hospital/Health System, Inpatient Department	1,435	16%	200	14%
Independent Community Pharmacy (1-4 Stores)	877	10%	130	9%
Supermarket Pharmacy	745	9%	131	9%
Hospital/Health System, Outpatient Department	717	8%	74	5%
Mass Merchandiser (i.e., Big Box Store)	320	4%	54	4%
Nursing Home/Long-Term Care	316	4%	45	3%
Pharmacy Benefit Administration (e.g., PBM, Managed Care)	280	3%	17	1%
Clinic-Based Pharmacy	263	3%	37	2%
Mail Service Pharmacy	168	2%	29	2%
Home Health/Infusion	133	2%	17	1%
Small Chain Community Pharmacy (5-10 Stores)	102	1%	21	1%
Academic Institution	72	1%	27	2%
Other	786	9%	195	13%
Total	**8,751**	**100%**	**1,481**	**100%**
Did Not Have Location	538		10,639	

Source: Va. Healthcare Workforce Data Center

Nearly three out of every ten pharmacy technicians in Virginia work in a large chain community pharmacy, while another 16% work in the inpatient department of a hospital.

For pharmacy technicians who also have a secondary work location, 34% work in a large chain community pharmacy, while 14% work in the inpatient department of a hospital.



Source: Va. Healthcare Workforce Data Center

At a Glance:
(Primary Locations)

Languages Offered

Spanish:	17%
Arabic:	8%
Vietnamese:	7%

Means of Communication

Virtual Translation:	38%
Other Staff Member:	32%
Respondent:	32%

Source: Va. Healthcare Workforce Data Center

Nearly one out of every five pharmacy technicians are employed at a primary work location that offers Spanish language services for patients.

A Closer Look:

Languages Offered		
Language	**#**	**% of Workforce**
Spanish	2,093	17%
Arabic	954	8%
Vietnamese	905	7%
Hindi	849	7%
Chinese	848	7%
Korean	838	7%
French	826	7%
Tagalog/Filipino	813	6%
Persian	648	5%
Urdu	645	5%
Amharic, Somali, or Other Afro-Asiatic Languages	534	4%
Pashto	532	4%
Others	413	3%
At Least One Language	**2,867**	**23%**

Source: Va. Healthcare Workforce Data Center

Means of Language Communication		
Provision	**#**	**% of Workforce with Language Services**
Virtual Translation Service	1,078	38%
Other Staff Member is Proficient	915	32%
Respondent is Proficient	906	32%
Onsite Translation Service	617	22%
Other	201	7%

Source: Va. Healthcare Workforce Data Center

Nearly two out of every five pharmacy technicians who are employed at a primary work location that offers language services for patients provide it by means of a virtual translation service.

At a Glance:
(Primary Locations)

Typical Time Allocation

Medication Disp.:	60%-69%
Administration:	10%-19%
Teaching:	1%-9%

Roles

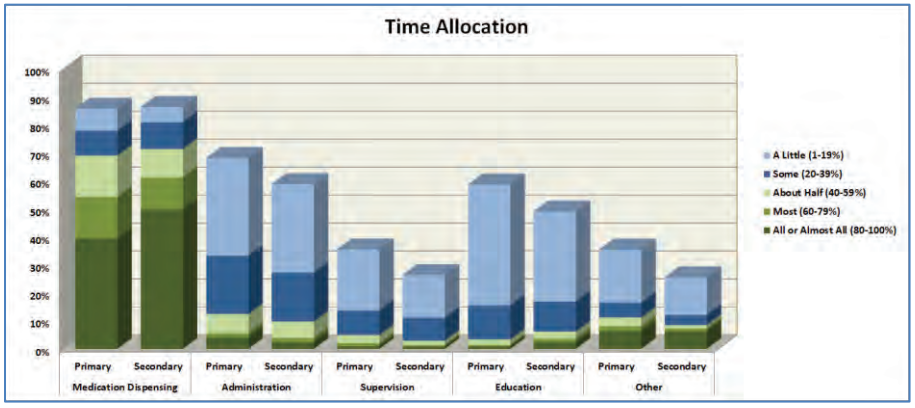
Medication Disp.:	54%
Administration:	6%
Supervision:	2%
Education:	1%

Patient Care Pharm. Tech.

Median Admin. Time:	1%-9%
Avg. Admin. Time:	1%-9%

Source: Va. Healthcare Workforce Data Center

A Closer Look:



Source: Va. Healthcare Workforce Data Center

More than half of all pharmacy technicians fill a medication dispensing and customer service role, defined as spending 60% or more of their time in that activity.

Time Allocation										
Time Spent	Medication Disp.		Admin.		Supervision		Education		Other	
	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site	Pri. Site	Sec. Site
All or Almost All (80-100%)	40%	50%	4%	2%	1%	1%	1%	2%	6%	6%
Most (60-79%)	15%	11%	1%	1%	1%	1%	0%	1%	2%	1%
About Half (40-59%)	15%	10%	7%	6%	3%	2%	2%	3%	3%	1%
Some (20-39%)	9%	10%	21%	17%	9%	8%	12%	11%	5%	4%
A Little (1-19%)	8%	5%	35%	32%	22%	15%	43%	32%	19%	13%
None (0%)	14%	14%	32%	41%	64%	74%	41%	51%	64%	74%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		50 and Over	
	#	%	#	%
Under Age 50	1,685	22%	-	-
50 to 54	404	5%	23	1%
55 to 59	448	6%	104	6%
60 to 64	1,234	16%	395	23%
65 to 69	1,973	26%	695	41%
70 to 74	536	7%	234	14%
75 to 79	145	2%	52	3%
80 and Over	105	1%	28	2%
I Do Not Intend to Retire	999	13%	150	9%
Total	**7,529**	**100%**	**1,681**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacy Technicians

Under 65:	50%
Under 60:	34%

Pharm. Tech. 50 and Over

Under 65:	31%
Under 60:	8%

Time Until Retirement

Within 2 Years:	5%
Within 10 Years:	15%
Half the Workforce:	By 2048

Source: Va. Healthcare Workforce Data Center

One half of all pharmacy technicians expect to retire by the age of 65. Among pharmacy technicians who are age 50 and over, 31% expect to retire by the age of 65.

Within the next two years, 19% of all pharmacy technicians expect to pursue additional educational opportunities, and 6% expect to increase their patient care hours.

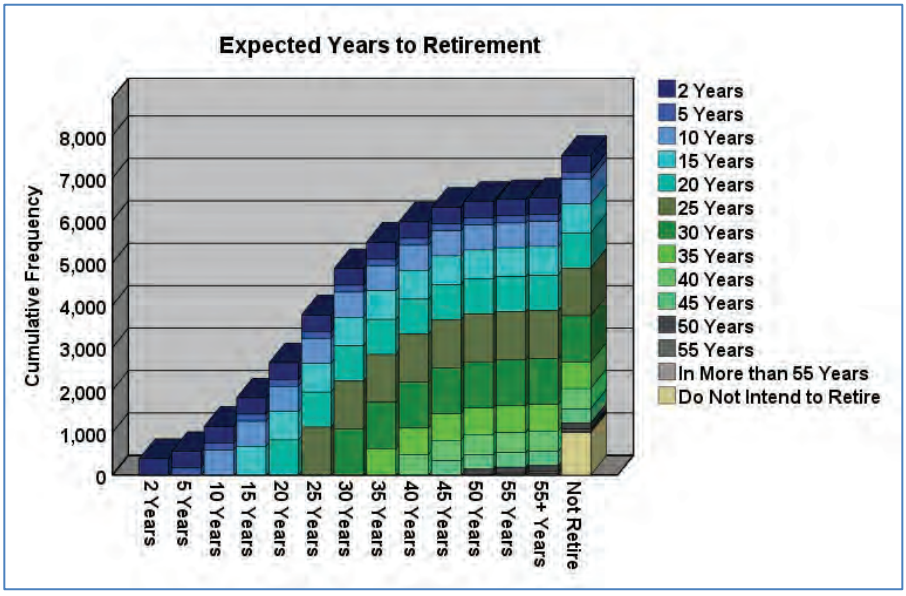
Future Plans		
Two-Year Plans:	#	%
Decrease Participation		
Leave Profession	991	8%
Leave Virginia	462	4%
Decrease Patient Care Hours	224	2%
Decrease Teaching Hours	134	1%
Increase Participation		
Increase Patient Care Hours	803	6%
Increase Teaching Hours	699	6%
Pursue Additional Education	2,410	19%
Return to the Workforce	103	1%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacy technicians. While 5% of pharmacy technicians expect to retire in the next two years, 15% expect to retire within the next ten years. Half of the current workforce expect to retire by 2048.

Time to Retirement			
Expect to Retire Within. . .	**#**	**%**	**Cumulative %**
2 Years	388	5%	5%
5 Years	167	2%	7%
10 Years	587	8%	15%
15 Years	679	9%	24%
20 Years	825	11%	35%
25 Years	1,129	15%	50%
30 Years	1,089	14%	65%
35 Years	626	8%	73%
40 Years	478	6%	79%
45 Years	340	5%	84%
50 Years	138	2%	86%
55 Years	49	1%	86%
In More than 55 Years	34	0%	87%
Do Not Intend to Retire	999	13%	100%
Total	**7,529**	**100%**	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirement will begin to reach 10% of the current workforce every five years by 2043. Retirement will peak at 15% of the current workforce around 2048 before declining to below 10% of the current workforce again around 2058.

At a Glance:

FTEs

Total:	9,754
FTEs/1,000 Residents[2]:	1.123
Average:	0.81

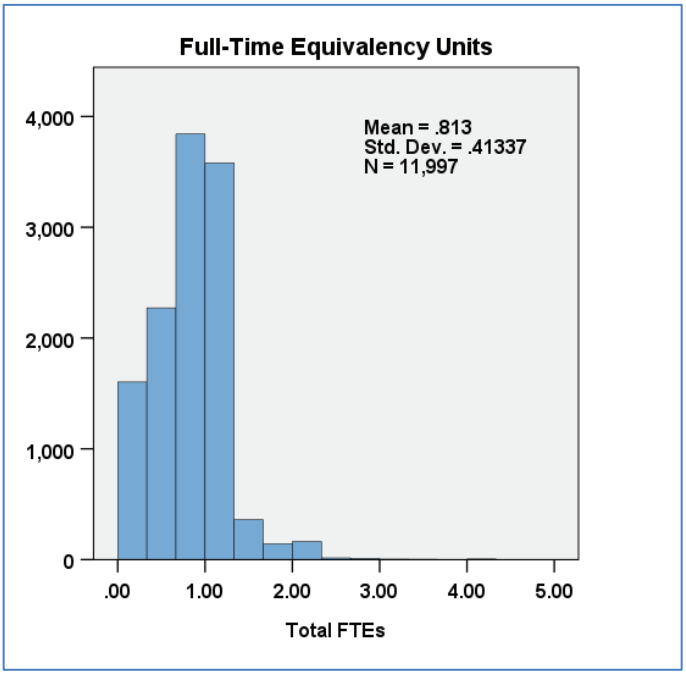
Age & Gender Effect

Age, *Partial Eta*^{2}:	Small
Gender, *Partial Eta*^{2}:	Negligible

Partial Eta^2 *Explained:*
Partial Eta^2 is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

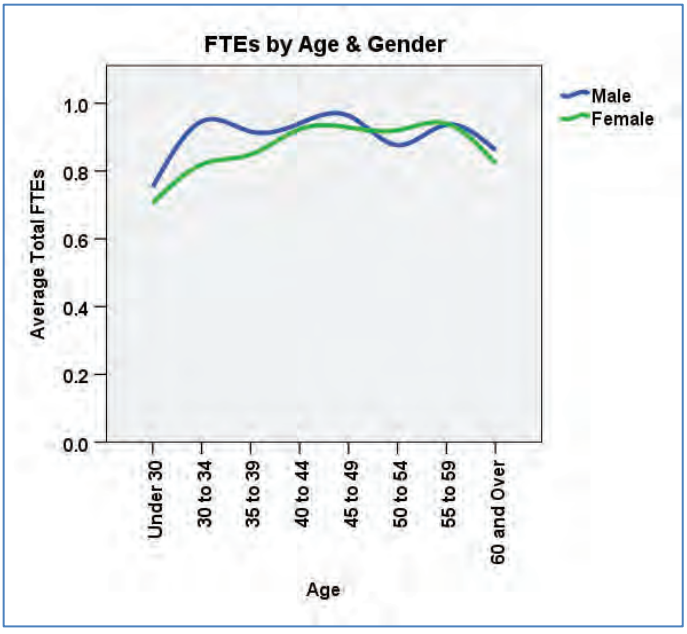


Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.83 FTEs in 2023, or approximately 33 hours per week for 50 weeks. Although FTEs appear to vary by age and gender, statistical tests did not verify that a difference exists.[3]

Full-Time Equivalency Units		
	Average	Median
Age		
Under 30	0.70	0.63
30 to 34	0.82	0.77
35 to 39	0.83	0.78
40 to 44	0.94	1.01
45 to 49	0.86	0.91
50 to 54	0.87	0.90
55 to 59	0.92	0.93
60 and Over	0.80	0.74
Gender		
Male	0.86	0.93
Female	0.83	0.91

Source: Va. Healthcare Workforce Data Center

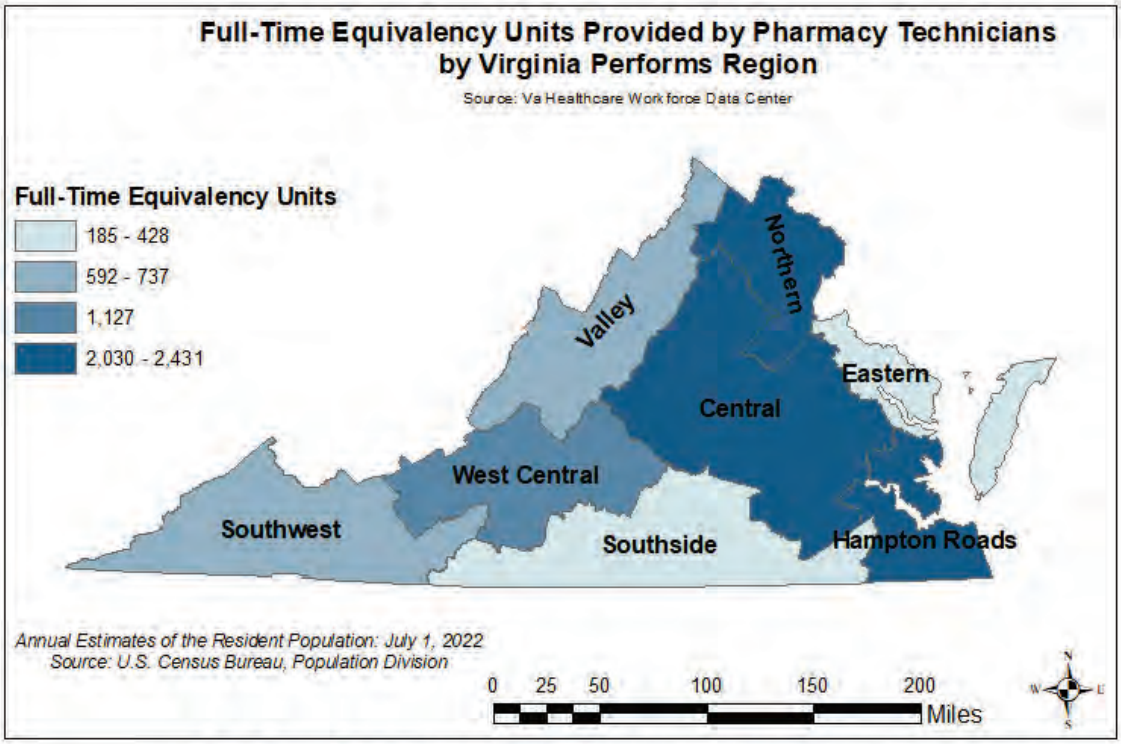


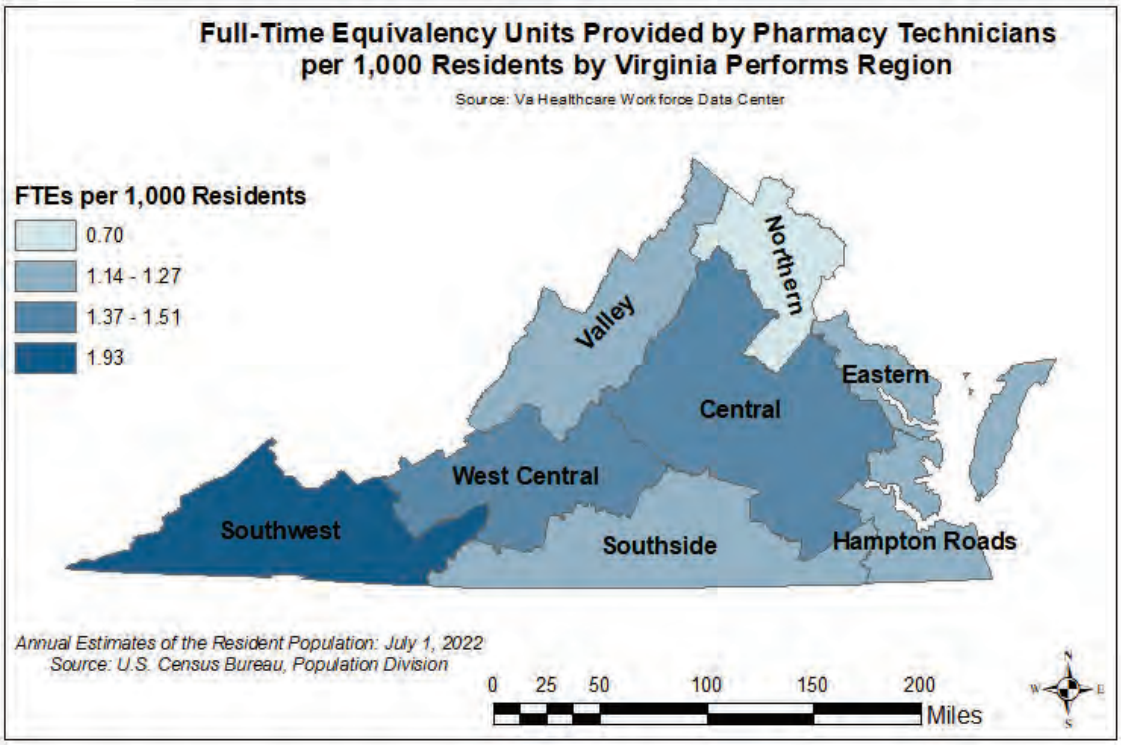
Source: Va. Healthcare Workforce Data Center

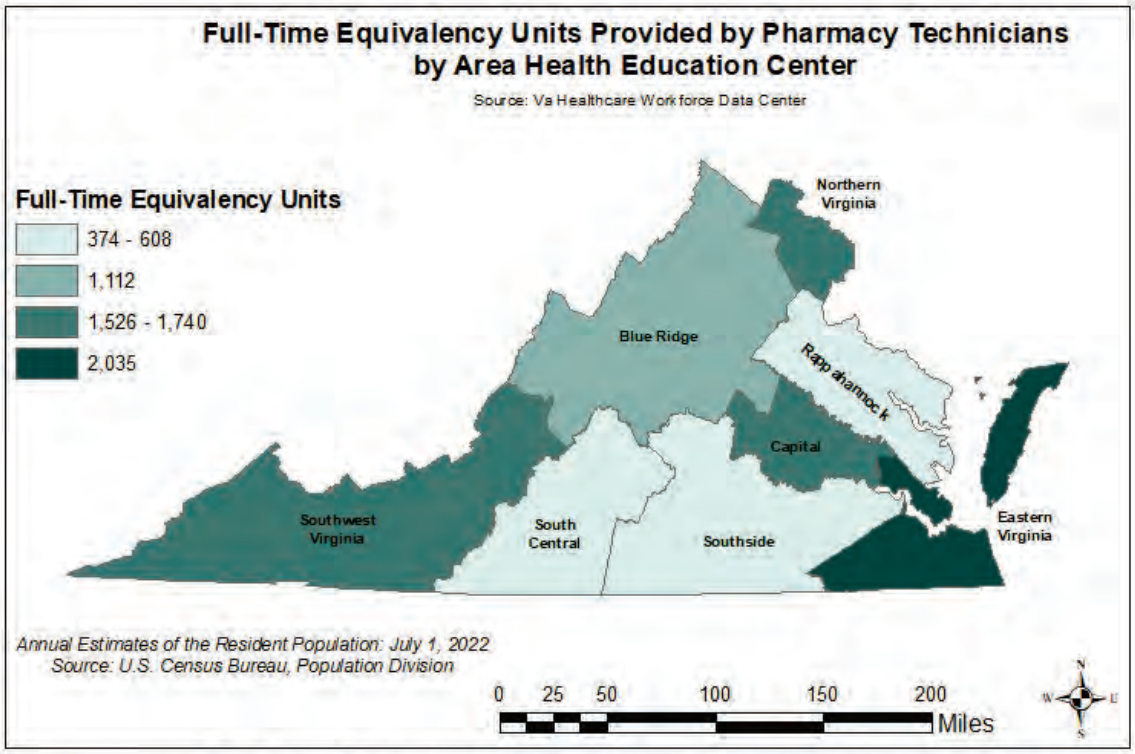
[2] Number of residents in 2022 was used as the denominator.
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test was significant).

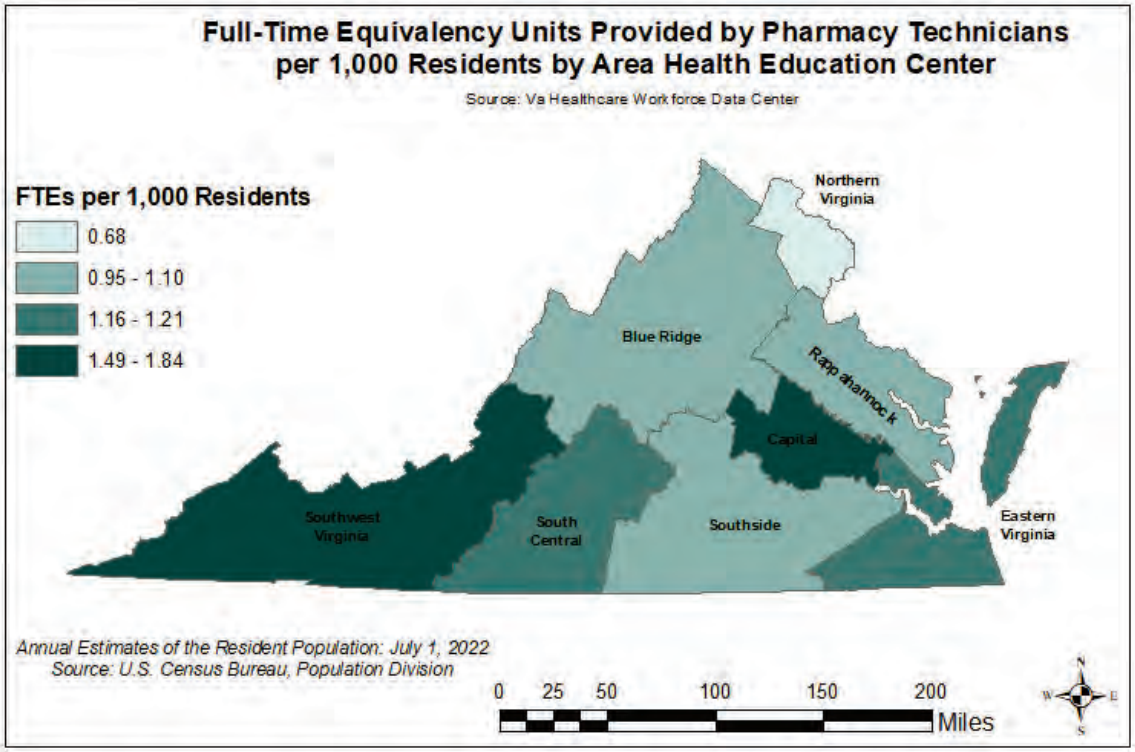
Maps

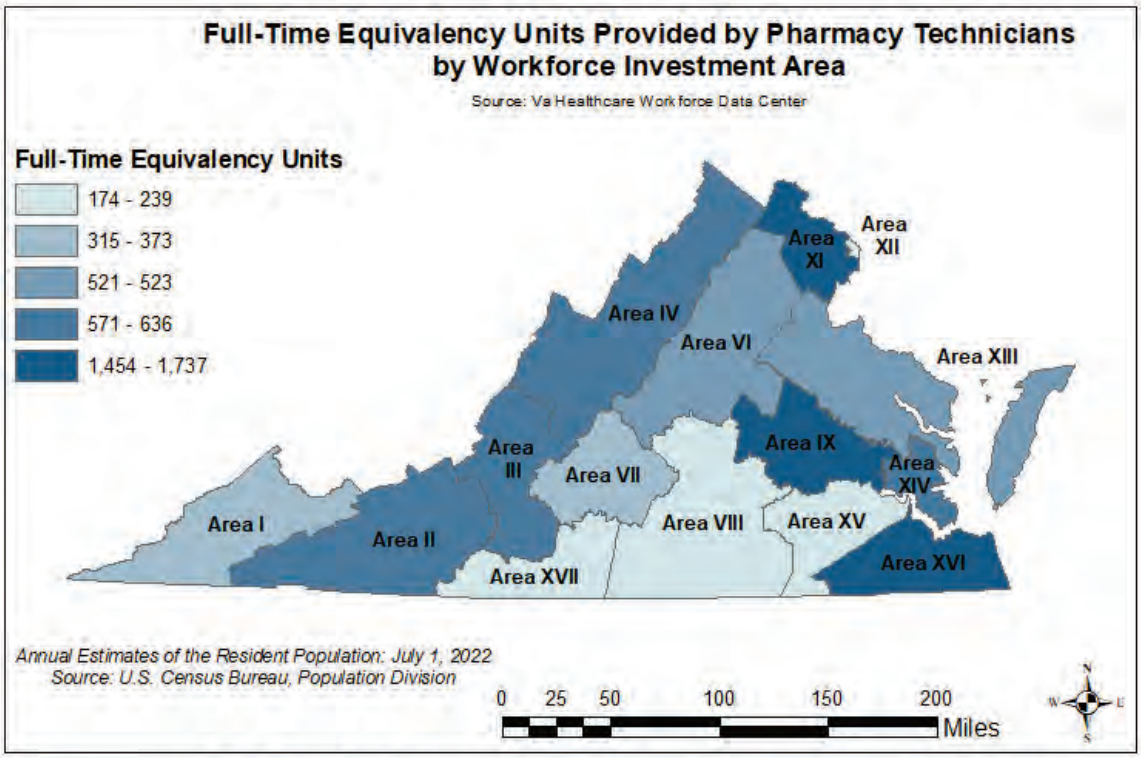
Virginia Performs Regions

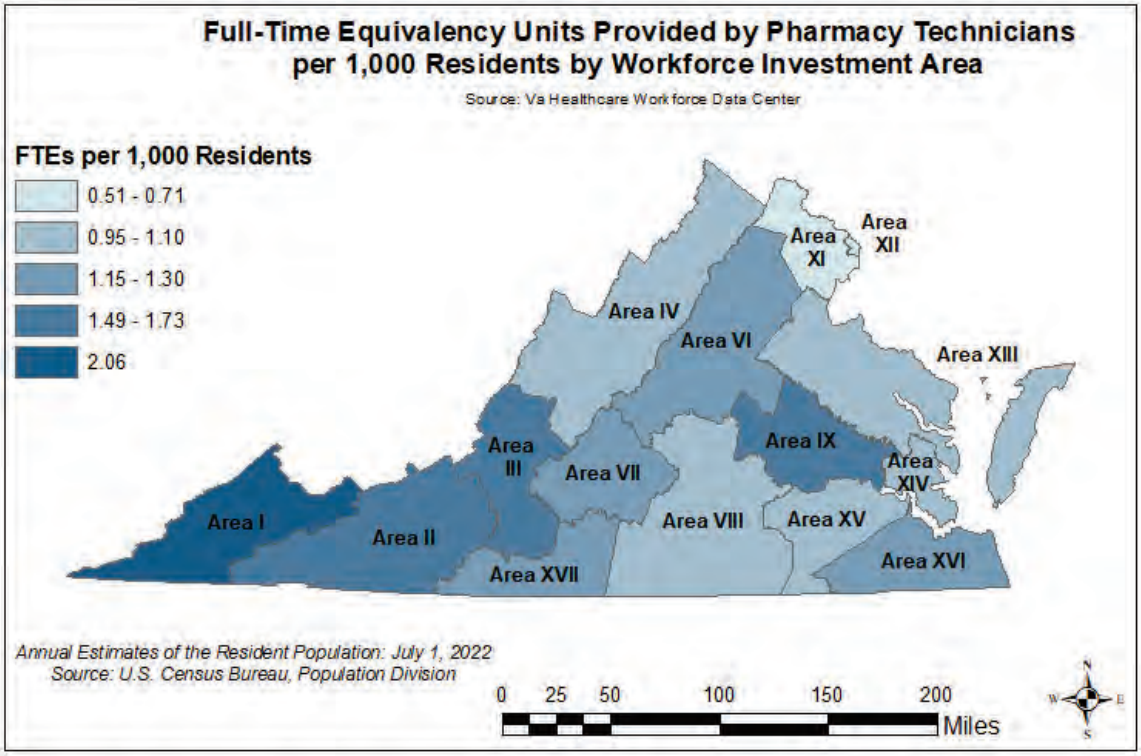


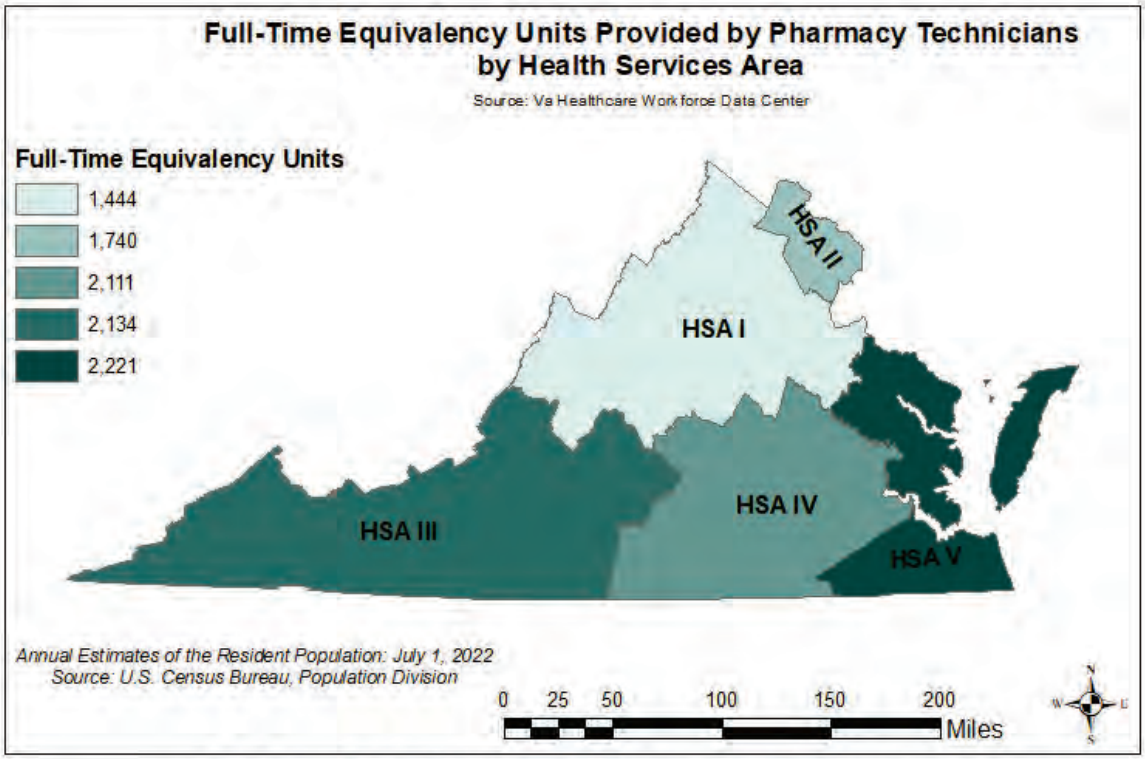


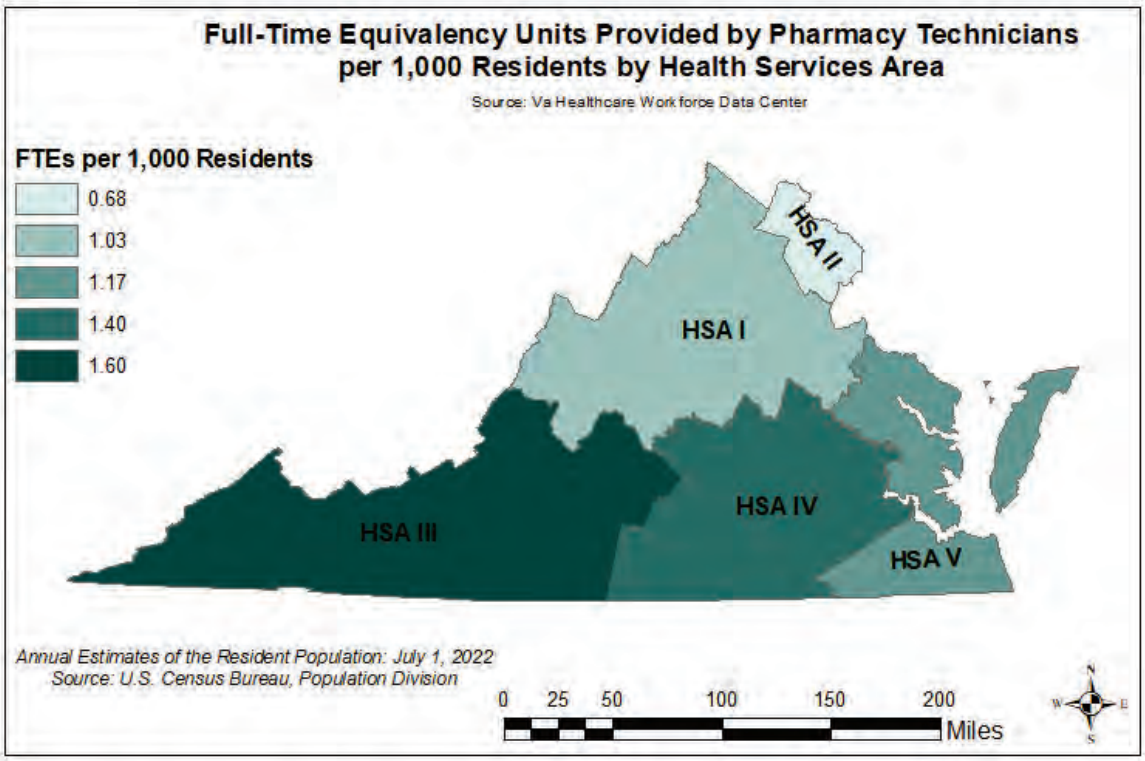

Full-Time Equivalency Units Provided by Pharmacy Technicians
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
374 - 608
1,112
1,526 - 1,740
2,035
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

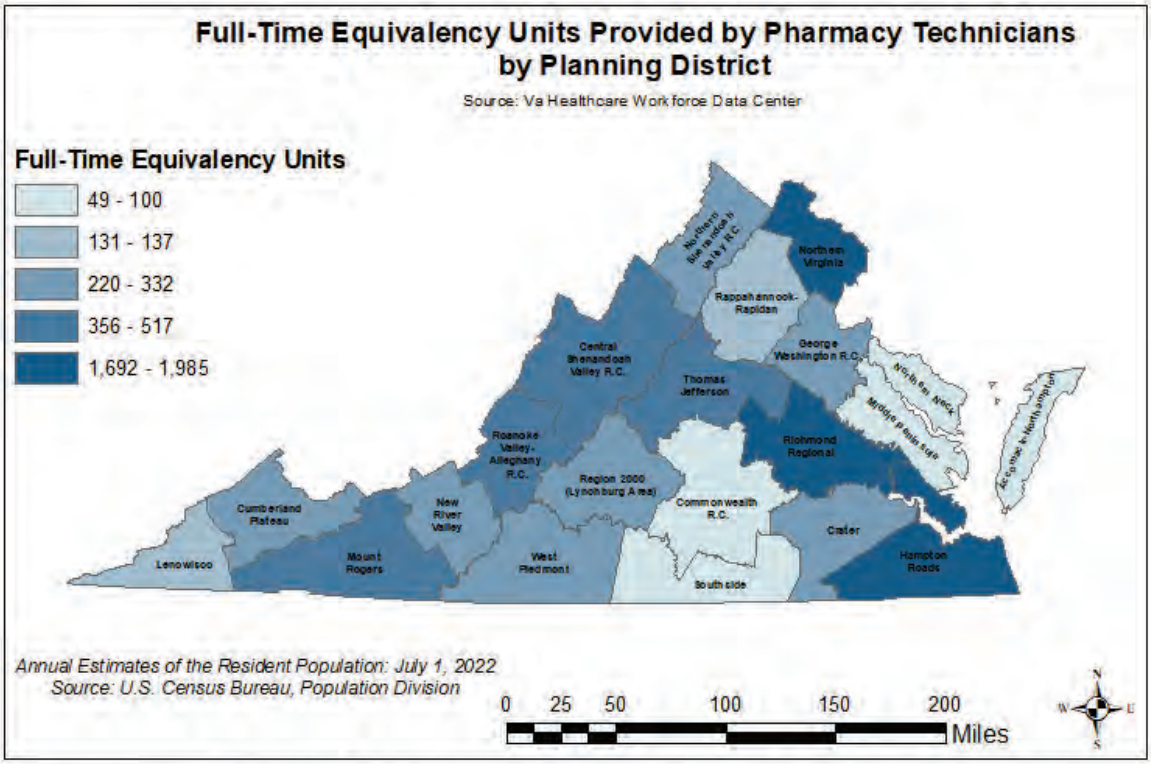

Full-Time Equivalency Units Provided by Pharmacy Technicians
per 1,000 Residents by Area Health Education Center
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.68
0.95 - 1.10
1.16 - 1.21
1.49 - 1.84
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

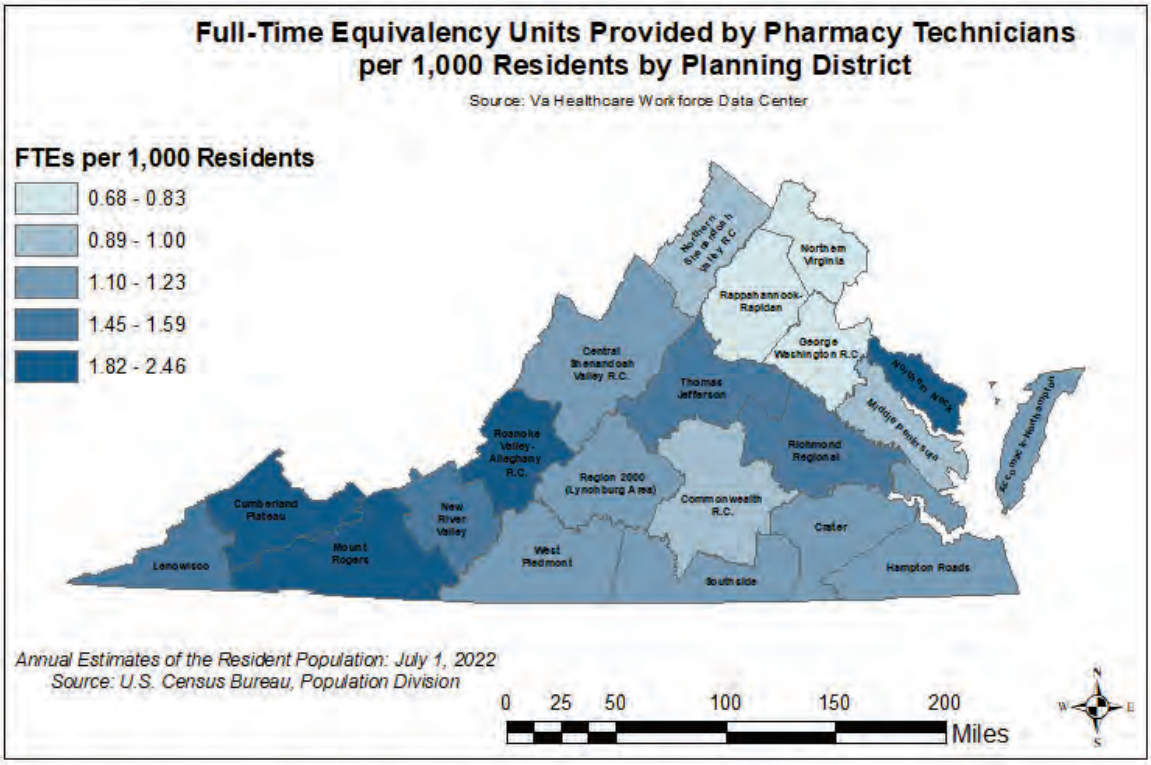

Full-Time Equivalency Units Provided by Pharmacy Technicians by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
174 - 239
315 - 373
521 - 523
571 - 636
1,454 - 1,737
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full-Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.51 - 0.71
0.95 - 1.10
1.15 - 1.30
1.49 - 1.73
2.06
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full-Time Equivalency Units Provided by Pharmacy Technicians by Health Services Area
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
1,444
1,740
2,111
2,134
2,221
HSA II
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full-Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Health Services Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.68
1.03
1.17
1.40
1.60
HSA II
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles


Full-Time Equivalency Units Provided by Pharmacy Technicians by Planning District
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
49 - 100
131 - 137
220 - 332
356 - 517
1,692 - 1,985
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Central Shenandoah Valley R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Accomack-Northampton
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Cumberland Plateau
New River Valley
Mount Rogers
West Piedmont
Lenowisco
South side
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles
N
W
E
S


Full-Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Planning District
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.68 - 0.83
0.89 - 1.00
1.10 - 1.23
1.45 - 1.59
1.82 - 2.46
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Central Shenandoah Valley R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Accomack-Northampton
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Cumberland Plateau
New River Valley
Mount Rogers
West Piedmont
Lenowisco
South side
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2022
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles
N
W
E
S

Appendix

Weights

Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min.	Max.
Metro, 1 Million+	8,055	80.10%	1.248	1.123	1.430
Metro, 250,000 to 1 Million	1,222	82.82%	1.208	1.086	1.383
Metro, 250,000 or Less	1,232	81.74%	1.223	1.100	1.402
Urban, Pop. 20,000+, Metro Adj.	295	84.07%	1.190	1.070	1.363
Urban, Pop. 20,000+, Non-Adj.	0	NA	NA	NA	NA
Urban, Pop. 2,500-19,999, Metro Adj.	661	84.72%	1.180	1.062	1.352
Urban, Pop. 2,500-19,999, Non-Adj.	499	80.76%	1.238	1.114	1.419
Rural, Metro Adj.	297	81.14%	1.232	1.108	1.412
Rural, Non-Adj.	188	82.98%	1.205	1.084	1.381
Virginia Border State/D.C.	791	67.64%	1.479	1.330	1.694
Other U.S. State	419	57.28%	1.746	1.570	2.000

Source: Va. Healthcare Workforce Data Center

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min.	Max.
Under 30	3,770	69.36%	1.442	1.352	2.000
30 to 34	2,118	78.80%	1.269	1.190	1.761
35 to 39	1,906	81.11%	1.233	1.156	1.710
40 to 44	1,534	84.16%	1.188	1.115	1.648
45 to 49	1,185	85.99%	1.163	1.091	1.613
50 to 54	1,157	87.21%	1.147	1.076	1.591
55 to 59	858	88.34%	1.132	1.062	1.570
60 and Over	1,131	83.73%	1.194	1.120	1.657

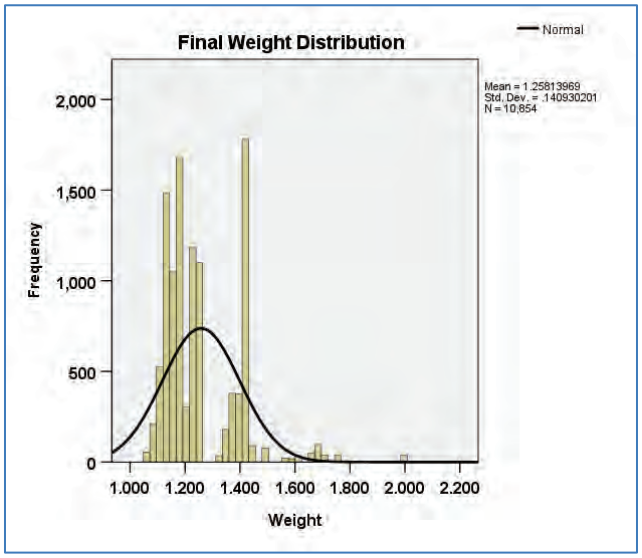
Source: Va. Healthcare Workforce Data Center

See the Methods section on the HWDC website for details on HWDC methods: https://www.dhp.virginia.gov/PublicResources/HealthcareWorkforceDataCenter/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.

Overall Response Rate: **0.794641**



Source: Va. Healthcare Workforce Data Center

Virginia Board of Pharmacy
March 28, 2024
Licenses Issued

	8/1/22 - 10/31/22	11/1/22 - 1/31/23	2/1/23 - 4/30/23	5/1/23 - 7/31/23	8/1/23 - 10/31/23	11/1/23 - 1/31/24	License Count 3/10/2024
Business CSR	32	25	26	38	29	20	1,362
CE Courses	0	0	0	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	6
Medical Equipment Supplier	3	3	6	12	2	4	203
Non-restricted Manufacturer	1	1	1	0	0	0	32
Outsourcing Facility	0	1	0	0	0	0	1
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	252	164	144	237	273	131	16,106
Pharmacist Volunteer Registration	2	1	0	4	1	0	0
Pharmacy	10	11	11	11	11	13	1,745
Pharmacy Intern	96	179	91	71	133	74	1,035
Pharmacy Technician	430	311	339	469	327	327	12,142
Pharmacy Technician Trainee	1,226	1,185	789	1,074	1,069	1,085	7,888
Physician Selling Controlled Substances	27	43	16	15	37	23	537
Limited Use Practitioner Dispensing	1	0	0	0	1	2	6
Nonresident Manufacturer	6	6	9	2	7	8	226
Nonresident Medical Equipment Supplier	11	4	11	6	10	15	334
Nonresident Outsourcing Facility	2	1	1	0	0	0	31
Nonresident Pharmacy	18	21	23	21	27	23	935
Nonresident Third Party Logistics Provider	11	10	15	11	12	6	231
Nonresident Warehouser	8	7	7	3	10	4	122
Nonresident Wholesale Distributor	9	2	11	12	12	8	598
Physician Selling Drugs Location	2	3	3	5	3	5	126
Pilot Programs	1	0	0	2	1	1	15
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	32
Third Party Logistics Provider	0	0	0	0	0	0	5
Warehouser	0	2	3	1	2	2	124
Limited Use Facility Dispensing	0	2	1	0	0	1	4
Wholesale Distributor	0	0	0	0	2	1	58
Total	**2,148**	**1,982**	**1,507**	**1,994**	**1,969**	**1,753**	**43,915**

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 2 - Fiscal Year 2024

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	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	CURRENT Q2 2024
Audiology/Speech Pathology	5,527	5,662	5,114	5,432	5,605	5,756	5,894	5,671	5,809	5,975	6,117	5,963	6,108
Counseling	35,176	34,246	31,769	33,693	35,020	36,141	37,436	36,097	37,512	38,791	40,118	39,278	40,239
Dentistry	15,133	15,286	14,768	15,171	15,290	15,284	15,238	15,421	15,275	15,037	15,186	15,190	15,126
Funeral Directing	3,205	3,190	3,114	3,187	3,247	3,295	3,182	3,254	3,308	3,379	3,287	3,351	3,390
Long-Term Care Administrators	2,226	2,274	2,152	2,226	2,293	2,352	2,146	2,232	2,288	2,345	2,159	2,225	2,278
Medicine	74,654	75,929	76,642	78,312	79,452	80,957	82,857	83,193	83,804	85,497	87,470	88,629	89,957
Nurse Aide	50,753	51,820	49,909	50,322	49,967	49,911	50,189	50,085	50,216	50,278	50,817	51,449	51,594
Nursing	170,050	172,380	172,263	174,791	174,984	176,169	177,138	179,221	179,997	181,279	181,581	183,596	184,003
Optometry	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871	1,903
Pharmacy	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374	46,935
Pharmaceutical Processing	9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238	10,362
Physical Therapy	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411	14,571
Psychology	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168	6,282
Social Work	11,443	11,805	11,302	11,868	12,405	12,799	13,138	12,952	13,598	14,241	14,913	15,089	15,535
Veterinary Medicine	7,894	8,181	8,442	8,615	8,723	8,429	8,648	8,826	8,947	8,711	9,016	9,192	9,297
Agency Total	441,815	457,898	464,278	482,398	494,685	505,753	518,191	514,037	512,996	505,591	499,117	495,024	497,580

Virginia Department of Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 2 - Fiscal Year 2024

Current licenses by board and occupation as of the last day of the quarter.

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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

BOARD	Occupation	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	CURRENT Q2 2024
Optometry	Optometrist	87	88	77	77	77	78	65	65	65	65	49	50	51
	Optometrist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	-	1	-
	Professional Designation	-	-	-	-	-	-	-	-	-	-	-	-	-
	TPA Certified Optometrist	1,693	1,720	1,680	1,716	1,736	1,749	1,708	1,758	1,784	1,808	1,777	1,820	1,852
	Total	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871	1,903
Pharmacy	Business CSR	1,458	1,378	1,461	1,478	1,510	1,399	1,463	1,507	1,529	1,423	1,465	1,508	1,533
	CE Courses	9	9	9	9	9	9	9	9	9	9	9	9	9
	Humane Society	-	-	-	-	-	-	-	-	-	-	-	-	-
	Limited Use Facility Dispensing	-	-	-	-	-	-	-	-	1	2	3	3	3
	Limited Use Pharmacy Technician	7	8	8	8	8	7	7	7	7	7	7	7	7
	Limited Use Practitioner Dispensing	-	-	-	-	-	1	2	2	3	3	3	4	6
	Medical Equipment Supplier	233	224	223	230	229	209	217	223	226	213	220	226	224
	Non-Resident Manufacturer	200	194	202	209	215	206	213	218	224	217	226	231	236
	Non-Resident Medical Equipment Supplier	375	322	349	363	373	331	354	361	369	346	355	367	379
	Non Resident Outsourcing facility	33	33	33	34	33	30	29	32	33	35	33	32	31
	Non Resident Pharmacy	841	866	874	876	885	882	898	910	911	924	923	923	934
	Non-Resident Wholesale Distributor	634	604	635	644	660	624	634	643	641	610	624	635	641
	Non Restricted Manufacturer	32	28	28	29	30	31	32	34	34	35	35	35	35
	Non-Resident Third Party Logistics Prov.	161	169	182	186	191	181	181	194	206	207	219	229	238
	Non Resident Warehouser	78	79	91	96	101	98	99	105	115	109	114	123	130
	Outsourcing Facility	-	-	-	-	-	-	-	-	-	1	1	1	1
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	15,326	15,668	15,865	16,210	16,445	15,858	16,079	16,414	16,619	16,064	16,273	16,606	16,796
	Pharmacist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	1	-	-
	Pharmacy	1,769	1,772	1,771	1,770	1,767	1,773	1,768	1,765	1,765	1,762	1,755	1,751	1,738
	Pharmacy Intern	1,368	1,464	1,489	1,499	1,457	1,247	1,312	1,267	1,352	1,166	1,235	1,213	1,274
	Pharmacy Technician	11,838	12,751	13,248	13,689	14,042	12,421	12,924	13,522	13,875	12,312	12,871	13,310	13,640
	Pharmacy Technician Trainee	-	831	2,406	3,309	4,628	5,930	6,258	6,977	8,041	8,581	8,178	8,190	8,063

Virginia Department of Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 2 - Fiscal Year 2024

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

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

BOARD	Occupation	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2023	CURRENT Q2 2024
Pharmacy	Pharmacy Technician Training Program	119	126	136	138	133	128	126	-	-	-	-	-	-
	Physician Selling Controlled Substances	526	558	571	614	631	537	571	600	645	543	565	596	632
	Physician Selling Drugs Location	139	163	165	168	167	160	160	160	164	125	131	135	139
	Pilot Programs	24	24	24	17	20	18	25	23	20	15	15	13	14
	Registered Physician for CBD/THC-A Oil	-	-	-	-	-	-	-	-	-	-	-	-	-
	Repackaging Training Program	2	2	2	2	2	2	2	2	2	2	2	2	2
	Restricted Manufacturer	43	39	41	41	41	36	36	36	36	33	32	32	32
	Third Party Logistics Provider	6	7	7	7	7	8	7	7	7	6	6	6	6
	Warehouser	115	119	120	121	122	117	121	121	122	123	125	127	129
	Wholesale Distributor	67	64	65	66	66	60	62	64	63	60	60	60	63
	Total	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374	46,935
Pharmaceutical Processing	Pharmaceutical Processor Permit	4	4	4	4	4	4	4	4	4	4	4	4	4
	Registered Agent For Medical Cannabis	20	65	103	141	162	180	179	181	166	158	137	109	79
	Registered Practitioner for CBD/THC-A Oil	633	685	797	920	997	720	873	1,059	1,164	938	1,051	1,051	1,051
	Registered Par/Guard For Medical Cannab	77	136	183	212	235	258	262	210	163	133	74	38	28
	Registered Patient For Medical Cannabis	8,754	17,257	26,136	33,204	39,468	47,466	52,903	45,434	38,071	29,214	16,201	7,547	5,282
	Registered Product	59	216	372	568	842	1,178	1,566	1,949	2,271	2,770	3,158	3,489	3,918
		9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238	10,362
Physical Therapy	Direct Access Certification	1,323	1,333	1,345	1,376	1,384	1,396	1,406	1,420	1,427	1,437	1,448	1,250	1,257
	Physical Therapist	8,372	8,603	8,901	9,161	9,245	9,382	9,634	9,906	10,022	8,878	9,146	9,403	9,523
	Physical Therapist Assistant	3,574	3,641	3,714	3,816	3,852	3,901	3,969	4,061	4,093	3,615	3,676	3,758	3,791
	Total	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411	14,571
Psychology	Applied Psychologist	29	29	24	26	27	27	28	25	25	25	25	23	24
	Clinical Psychologist	4,042	4,130	3,888	4,082	4,224	4,325	4,418	4,230	4,360	4,461	4,573	4,517	4,607
	Resident in School Psychology	11	11	11	12	13	13	13	21	24	26	27	29	33
	Resident In Training	370	373	368	376	376	380	380	397	395	392	392	404	397
	School Psychologist	97	102	90	97	98	99	100	96	96	100	103	98	99
	School Psychologist-Limited	633	648	560	622	640	658	673	550	569	583	598	577	592
	Sex Offender Treatment Provider	442	447	414	433	437	444	455	421	427	439	450	441	450
	SOTP Trainee	131	135	131	125	110	99	100	95	97	79	78	79	80
	Total	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168	6,282

Enforcement Division Inspections Report:
Prepared for the March 28, 2024 - Board of Pharmacy Meeting

Quarterly Inspection Completed Review – Date Range: 10/01/2023 - 12/31/2023
Numbers of Inspections Completed by License Type:

Insp Status	License Type	Change of Location	Compliance	New	Reinspection	Remodel	**Routine**	Grand Total
Completed	Business CSR	8		17	2	6	**95**	128
	Cannabis Dispensing Facility						**7**	7
	Medical Equipment Supplier	2		2		1	**11**	16
	Pharmaceutical Processor Permit						**1**	1
	Pharmacy	4	1	13	5	21	**94**	138
	Physician Selling Drugs Location			5		1	**2**	8
	Warehouser			1	1		**5**	7
	Wholesale Distributor			2	1		**4**	7
Completed Total		14	1	40	9	29	**219**	312
Completed Virtual	Business CSR			6	1	2	**6**	15
	Pharmacy			1	3	4		8
	Physician Selling Drugs Location			1				1
Completed Virtual Total				8	4	6	**6**	24
Grand Total		14	1	48	13	35	**225**	336

Enforcement Division Inspections Report:
Prepared for the March 28, 2024 - Board of Pharmacy Meeting

Quarterly Routine Deficiency Review Date Range: 07/01/2023 - 09/30/2023
Routine Inspections - Deficiencies by License Type:

License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR		37		64	101
Cannabis Dispensing Facility		5		2	7
Medical Equipment Supplier		4		7	11
Pharmaceutical Processor Permit		1			1
Pharmacy		31	33	30	94
Physician Selling Drugs Location		1		1	2
Warehouser		1		4	5
Wholesale Distributor	1	1		2	4
Grand Total	1	81	33	110	225

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

Enforcement Division Inspections Report:
Prepared for the March 28, 2024 - Board of Pharmacy Meeting

Categories of Deficiencies for Occurrences Date Range: 10/01/2023 - 12/31/2023
Routine Inspections - Recorded >20 Times with Examples:

Description	Number of times for occurrence
54.1-3404	*21*

Deficiency 13: No biennial inventory, or over 30 days late
Deficiency 16: Theft/unusual loss of drugs not reported to the Board as required.
Deficiency 148: Theft/unusual loss of drugs reported to board, but report not maintained by pharmacy.
Records of receipt of CII-V drugs does not include the date of receipt.
No Biennial Inventory completed.
Invoices not dated with actual date of receipt.

Description	Number of times for occurrence
54.1-3410.2	*73*

Two (2) of these 73 Occurrences related to 800 Assessment of Risk that had not been performed.
AS of 11/1/23 – This "warning" was no longer given and if the facility had not performed a risk assessment the deficiency was marked. My next report will not have this data separated.

Deficiency 130: Required compounding records not complete and properly maintained.
Deficiency 130a. Compounded products not properly labeled.
Deficiency 131. Required ?other documents? for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained.
Deficiency 132: Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements.
Deficiency 147: Smoke pattern testing not performed under dynamic conditions.
Deficiency 20b: Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products.
Deficiency 27: Compounding using ingredients in violation of §54.1-3410.2.
Deficiency 32: Have clean room, but not all physical standards in compliance.

Enforcement Division Inspections Report:
Prepared for the March 28, 2024 - Board of Pharmacy Meeting

Two Year Inspection Completed Review Date Range: 10/01/2021 - 10/01/2023
Number of Inspections Completed by License Type:

License Type	Audit	Change of Location	Change of Owner	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Business CSR		50			1	246	2	17	46	879	1241
Cannabis Dispensing Facility						18		5		5	28
Limited Use Facility Dispensing						3		1			4
Medical Equipment Supplier		20				29				143	192
Non-resident Medical Equipment Supplier						2					2
Non-restricted Manufacturer		1				8		7	2	2	20
Outsourcing Facility						1		1			2
Pharmaceutical Processor Permit		2						1	11	10	24
Pharmacy	1	36	1	7	4	93		89	409	1393	2033
Physician Selling Drugs Location		6		3	1	31		6	2	125	174
Pilot Programs							8				8
Restricted Manufacturer										1	1
Third Party Logistics Provider		1				2				5	8
Warehouser		5				12		3	3	90	113
Wholesale Distributor		5				2		1	5	36	49
Grand Total	1	126	1	10	6	447	10	131	478	2689	3899

NOTE: 201 of these inspections were completed virtually.

Reports Extracted: 03/06/2024 from My License Office (MLO) database

- Data extrapolated from MLO / Inspection Completed Detail Reports /Inspection Result Detail Reports

A few items to note: Recruitment underway for 4 vacancies – Additional Senior Inspector vacancy pending (retirement in May)

- Southwest & Central Region Senior Inspectors interviews completed moving forward to hire selected candidates.
- Wage Tidewater Pharmacy Inspectors recruitment underway and Southwest Region Pharmacy Inspector will be posted soon.

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

Discipline Program Report

Open Cases as of 2/14/24:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	TOTALS
Patient Care Cases	78	12	93	0	4	1	0	6	194
Non-Patient Care Cases	81	14	48	3	27	1	12	3	189
						TOTAL:			**383**

Staffing Update:

- Agency Subordinate
- New Discipline Specialist position

Upcoming Disciplinary Proceedings:

April 9, 2024	Garvin/Nash	Informal Conferences
April 23, 2024	All members	Formal Hearings
April 24, 2024	Yuan/Richards-Spruill	Informal Conferences
May 8, 2024	Garvin/Kocot	Informal Conferences
May 9, 2024	All members	Formal Hearings
May 22, 2024	Garvin/Kocot	Informal Conferences
June 5, 2024	Dowdy/Kocot	Informal Conferences
June 18, 2024	St. Clair/Yuan	Pilot Committee
June 25, 2024	All members	Full Board Meeting/Formal Hearings

Virginia Department of Health Professions

Arne W. Owens
Director

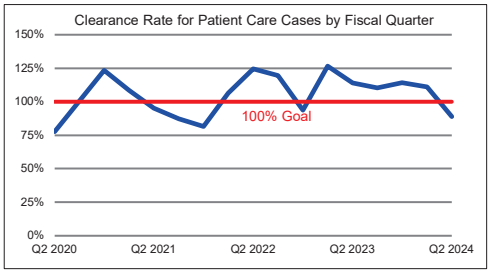
Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q2 2020 - Q2 2024

"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."

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 the case was in the continuance activity.

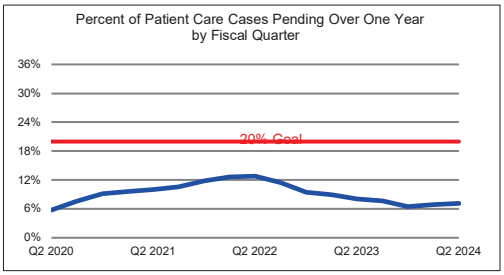
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 89%, with 1,207 patient care cases received and 1,075 closed.



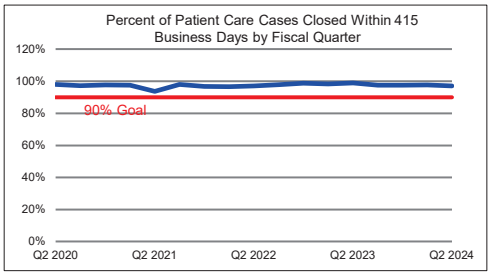
Age of Pending Caseload - the percent of open patient care cases over 415 business days old. This measure tracks the backlog of patient care cases older than 415 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

The current quarter shows 7% patient care cases pending over 415 business days with 3,539 patient care cases pending and 252 pending over 415 business days.



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

The current quarter shows 97% of patient care cases being resolved within 415 business days with 1,024 cases closed and 994 closed within 415 business days.



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

Medicine

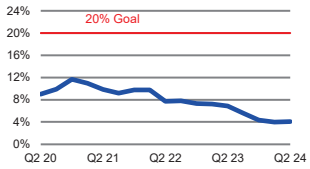
Clearance Rate: 85%
384 Cases Received
326 Cases Closed

Pending Caseload Over 415 Days: 4%
36 Cases Pending over 415 Days

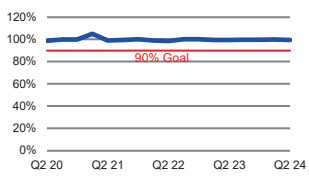
Time to Disposition Within 415 Days: 99%
319 Cases Closed within 415 Days

Clearance Rate

Age of Pending Caseload
(percent of cases pending over one year)



Time to Disposition

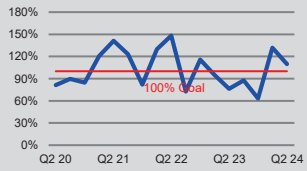


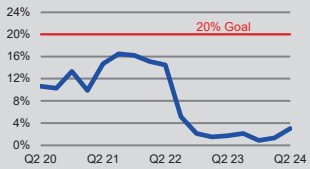
Dentistry

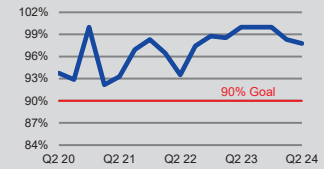
Clearance Rate: 110%
82 Cases Received
90 Cases Closed

Pending Caseload Over 415 Days: 3%
9 Cases Pending over 415 Days

Time to Disposition Within 415 Days: 98%
88 Cases Closed within 415 Days





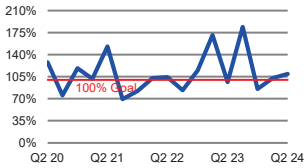


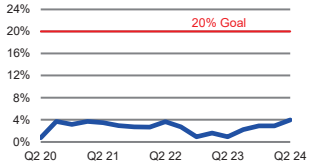
Pharmacy

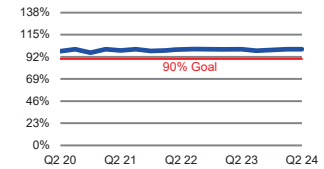
Clearance Rate: 109%
108 Cases Received
118 Cases Closed

Pending Caseload Over 415 Days: 4%
8 Cases Pending over 415 Days

Time to Disposition Within 415 Days: 100%
117 Cases 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.

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days Removed): Quarterly Performance Measurement, Q2 2020 - Q2 2024

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.

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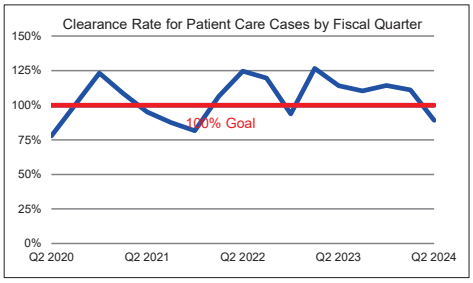
The current quarter's clearance rate is 89%, with 1,207 patient care cases received and 1,075 closed.

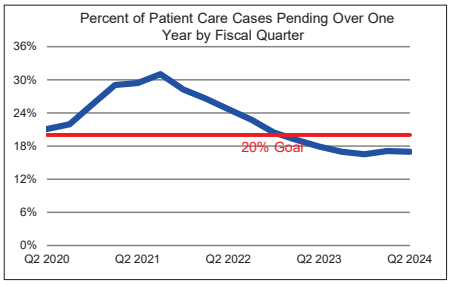
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

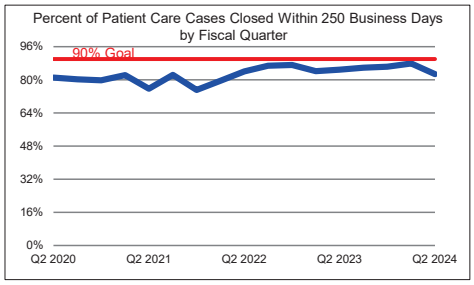
The current quarter shows 17% patient care cases pending over 250 business days with 3,539 patient care cases pending and 602 pending over 250 business days.

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 83% of patient care cases being resolved within 250 business days with 1,024 cases closed and 848 closed within 250 business days.







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

Medicine

Clearance Rate: 85%
384 Cases Received
326 Cases Closed

Pending Caseload: 10%
84 Cases Pending over 250 Days

Time to Disposition: 95%
305 Cases Closed within 250 Days

Dentistry

Clearance Rate: 110%
82 Cases Received
90 Cases Closed

Pending Caseload: 13%
39 Cases Pending over 250 Days

Time to Disposition: 87%
78 Cases Closed within 250 Days

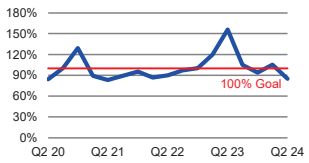
Pharmacy

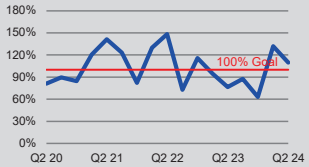
Clearance Rate: 109%
108 Cases Received
118 Cases Closed

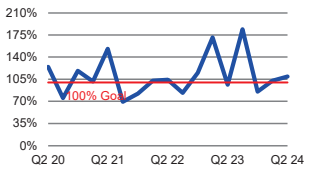
Pending Caseload: 11%
22 Cases Pending over 250 Days

Time to Disposition: 89%
104 Cases Closed within 250 Days

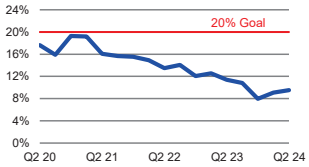
Clearance Rate

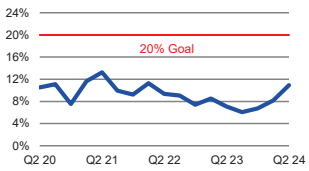




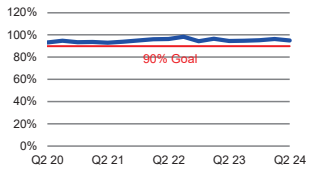


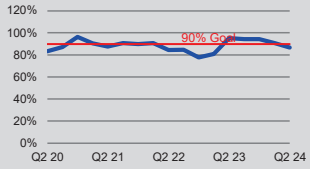
Age of Pending Caseload
(percent of cases pending over one year)

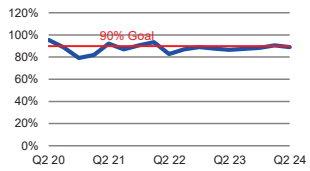




Time to Disposition







Submitted: 1/22/2024

Prepared by: Department of Health Professions

Patient Care Disciplinary Case Processing Times(with Continuance Days Removed)

Virginia Department of Health Professions

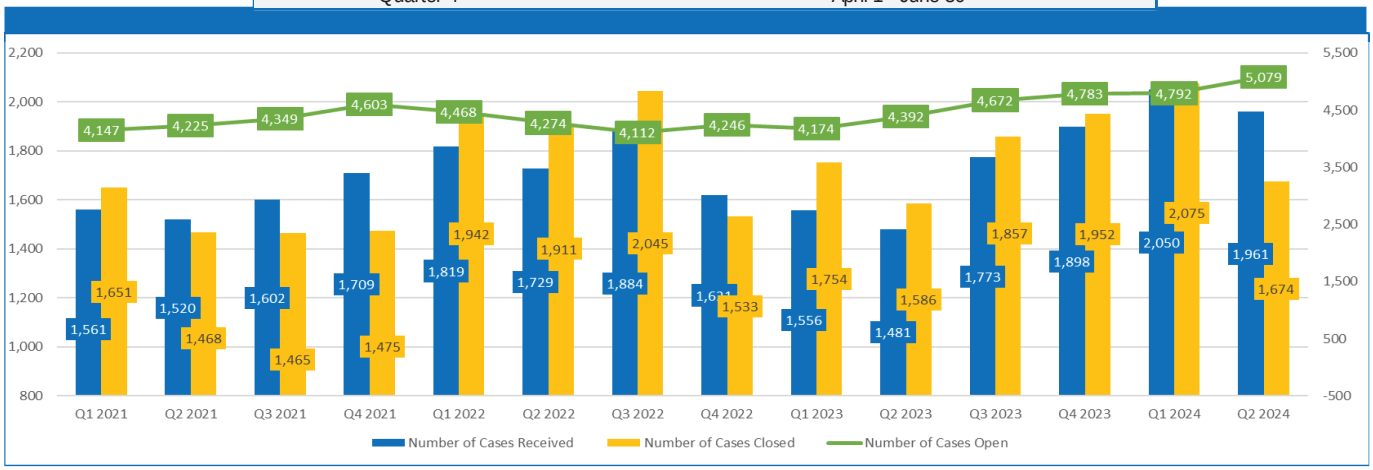
Cases Received, Open & Closed

Agency Summary

Quarter 2 – Fiscal Year 2024

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

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



Virginia Department of Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 2 – Fiscal Year 2024

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Quarter Date Ranges	
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Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

		Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	Q1 2024	CURRENT Q2 2024
Pharmacy	**Number of Cases Received**	138	145	160	212	208	220	185	215	210	204	249	206	179
	Number of Cases Open	263	300	332	350	329	399	409	416	437	384	442	390	372
	Number of Cases Closed	174	115	131	193	228	154	181	228	214	288	220	257	199
Physical Therapy	**Number of Cases Received**	12	12	20	11	9	15	3	15	13	10	4	10	27
	Number of Cases Open	29	33	47	46	47	46	39	35	34	36	35	31	55
	Number of Cases Closed	19	8	7	12	8	18	10	21	18	8	5	14	4
Psychology	**Number of Cases Received**	37	36	31	37	32	24	34	20	18	22	31	39	35
	Number of Cases Open	106	130	132	140	159	144	162	163	169	174	172	167	157
	Number of Cases Closed	26	13	32	29	13	39	22	26	16	24	49	44	43

Pharmaceutical Processors Report-March 28, 2024

Final Report

- The medical cannabis program was successfully transitioned to the Virginia Cannabis Control Authority (VCCA) on January 1, 2024.
  - All required records and documents have been transferred
  - The Medical Cannabis Program Portal has fully transitioned-all patient and product applications are being submitted to, and processed by, the VCCA.
  - Board staff have provided consultation to VCCA staff upon request. Requests have been minimal. Staff remain available to assist the VCCA if requested.
  - Board staff continue to share the VCCA contact information in response to inquiries from patients and practitioners to ensure they receive the most accurate and up to date information.
  - Transfer of remaining program funds should occur following the third fiscal quarter closeout.
  - Open enforcement actions have been transferred to the VCCA.
- 2020 RFA Application update: 17 of the 26 applicant refunds have been completed. Board and Finance staff continue to verify contact information for the remaining 9 applicants to facilitate the outstanding refunds.
- Staffing: all classified employees attached to the pharmaceutical processor program have transitioned to other agency positions.

Pharmaceutical Processors Program-By the Numbers
as of 1/1/2024

Registered Patients	5,188/69,000+ for program total
Registered Parents/Guardians	26/250+ for program total
Registered Agents	80/200+ for program total
Portal Issued Written Certifications	10,461
Portal Enrolled Practitioners	820
Registered Cannabis Products	3,918
Pharmaceutical Processor Permits	4
Cannabis Dispensing Facility Permits	18

Registration and Dispensing of Cannabis Products

The table below provides information on the product types and concentrations of THC/THC-A and cannabidiol/cannabidiol-A (CBD/CBDA) in the products approved by the Board during the administration of the medical cannabis program. The THC/THC-A concentration of vaped inhalations from oils, wax concentrates and bubble hash concentrates range up to 90.80%, 74.20% for tablets/capsules, and 36.74% for botanical cannabis.

Product Type	Combined THC/THC-A Range	Combined CBD/CBDA Range
Nasal Spray	3.46%	0.0%
Chewable/Edible	0.13% - 5.80%	0.00% - 6.90%
Suppository	0.68 - 0.95%	0.44% - 0.63%
Topical Gel/Lotion	0.12% - 57.87%	0.0% - 18.10%
Oral Oils	0.01% - 64.29%	0.00 - 21.02%
Vaped Inhalations from Oils, Wax Concentrates and Bubble Hash Concentrates	0.25% - 90.80%	0.00% - 57.42%
Tablet/Capsule	0.26% - 74.20%	0.12% - 4.05%
Lozenge	0.26% - 0.47%	0.26% - 0.68%
Botanical cannabis	7.57% - 36.74%	0.00% - 12.72%

Regarding the volume of dispensed medical cannabis products, the following data is derived from dispensing information within the Prescription Monitoring Program:

- Monthly unique patients receiving cannabis products increased over 13 times between January 2021 and September 2023, or 3,389 to 45,434, respectively.
- Monthly dispensations increased over 17 times between January 2021 and September 2023, or 17,992 to 308,380, respectively.
- Between January 2023 and September 2023, 2,447,862 dispensations resulted from written certifications issued by 930 practitioners.
- The average number of monthly dispensations per practitioner was 292; the median was 23.
- Half of the practitioners are associated with ≤23 dispensations per month (average).
- 76% of dispensations are attributable to top 5% of practitioners, which amounts to 46 practitioners.
    - Each of these 46 practitioners are associated with >1,000 dispensations per month (average).
- 37% of dispensations are attributable to the top 1% of practitioners.
    - Each of these nine practitioners have > 8,000 dispensation/month (average).
    - Three of the nine (33%) are out of state.

Executive Director's Report – March 28, 2024

New Staff:

- Glenn Bolyard, RPh – Agency Subordinate and Probable Cause Reviewer
- Terrance Carter – Discipline Program Specialist

Project:

- Impact Makers review of licensure processes

In-person or Virtual Meetings Recently Attended:

- SAMHSA Region 3 Access to Buprenorphine
- VACDS annual meeting - presenter
- Forensic Science Board Meeting
- EMS Medical Direction Committee – presenter
- Rappahannock EMS Council – presenter
- HIV Services in Community Pharmacies Initiative – NABP workgroup member
- NABP UPJE Steering Committee
- NABP Executive Directors meeting
- DSCSA Suspect Product Investigation Workshop – attended by Ms. O'Halloran
- Virginia Regional EMS Medication Kit Transition Workgroup Meeting
- VSHP Spring Seminar – presenter
- VPhA Annual Meeting
- DHP Monthly Executive Director Meeting and Executive Leadership Team Meeting
- RxPartnership Board Meeting

Upcoming Meetings:

- DHP SWOT Analysis meeting
- SAMHSA Region 3 Leaders' New Strategies Phase 2 Summit
- DHP New Member Training – March 26th
- Forensic Science Board Meeting
- DOE Pharmacy Technician Curriculum Review meeting
- Asembia's AXS24 Summit – panelist
- RxPartnership's 20th Anniversary Celebration
- NABP 120th Annual Meeting – Ft. Worth, TX, May 14-17th