## At a Glance:

**Concentration**

| | |
|---|---|
| Top Region: | 27% |
| Top 3 Regions: | 70% |
| Lowest Region: | 2% |

**Locations**

| | |
|---|---|
| 2 or more (2020): | 10% |
| 2 or more (Now*): | 12% |

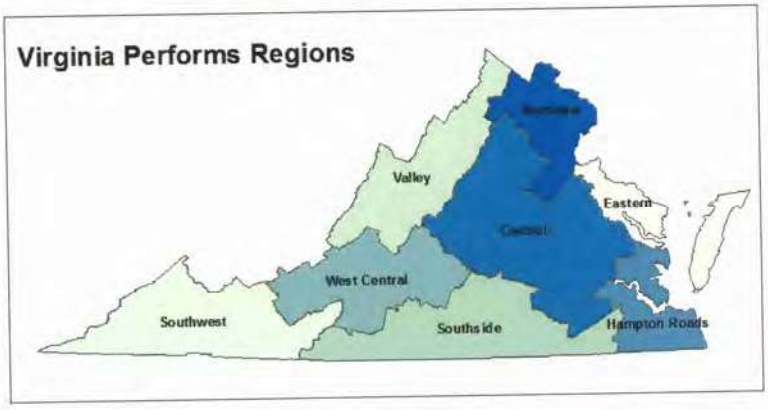
Source: Va. Healthcare Workforce Data Center

*Over half of all pharmacists in the state work in either Northern Virginia or Central Virginia.*

## A Closer Look:

| Regional Distribution of Work Locations | | | | |
|---|---|---|---|---|
| Virginia Performs Region | Primary Location | | Secondary Location | |
| | # | % | # | % |
| Central | 1,721 | 27% | 158 | 18% |
| Eastern | 110 | 2% | 20 | 2% |
| Hampton Roads | 1,185 | 18% | 144 | 17% |
| Northern | 1,610 | 25% | 203 | 23% |
| Southside | 212 | 3% | 26 | 3% |
| Southwest | 358 | 6% | 84 | 10% |
| Valley | 387 | 6% | 67 | 8% |
| West Central | 731 | 11% | 76 | 9% |
| Virginia Border State/DC | 45 | 1% | 30 | 3% |
| Other US State | 47 | 1% | 52 | 6% |
| Outside of the US | 2 | 0% | 4 | 0% |
| **Total** | **6,408** | **100%** | **864** | **100%** |
| Item Missing | 2,091 | | 22 | |

Source: Va. Healthcare Workforce Data Center




| Number of Work Locations | | | | |
|---|---|---|---|---|
| Locations | Work Locations in 2020 | | Work Locations Now* | |
| | # | % | # | % |
| 0 | 325 | 4% | 363 | 5% |
| 1 | 7,619 | 86% | 5,534 | 83% |
| 2 | 450 | 5% | 441 | 7% |
| 3 | 279 | 3% | 263 | 4% |
| 4 | 32 | 0% | 15 | 0% |
| 5 | 19 | 0% | 13 | 0% |
| 6 or More | 104 | 1% | 67 | 1% |
| **Total** | **8,827** | **100%** | **6,696** | **100%** |

*At the time of survey completion, December 2020. 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** | 3,832 | 64% | 560 | 70% |
| **Non-Profit** | 1,568 | 26% | 174 | 22% |
| **State/Local Government** | 231 | 4% | 34 | 4% |
| **Veterans Administration** | 129 | 2% | 5 | 1% |
| **U.S. Military** | 134 | 2% | 18 | 2% |
| **Other Federal Gov't** | 78 | 1% | 7 | 1% |
| **Total** | **5,972** | **100%** | **798** | **100%** |
| **Did not have location** | 328 | | 7,940 | |
| **Item Missing** | 2,529 | | 88 | |

*Source: Va. Healthcare Workforce Data Center*

### At a Glance:
**(Primary Locations)**

**Sector**

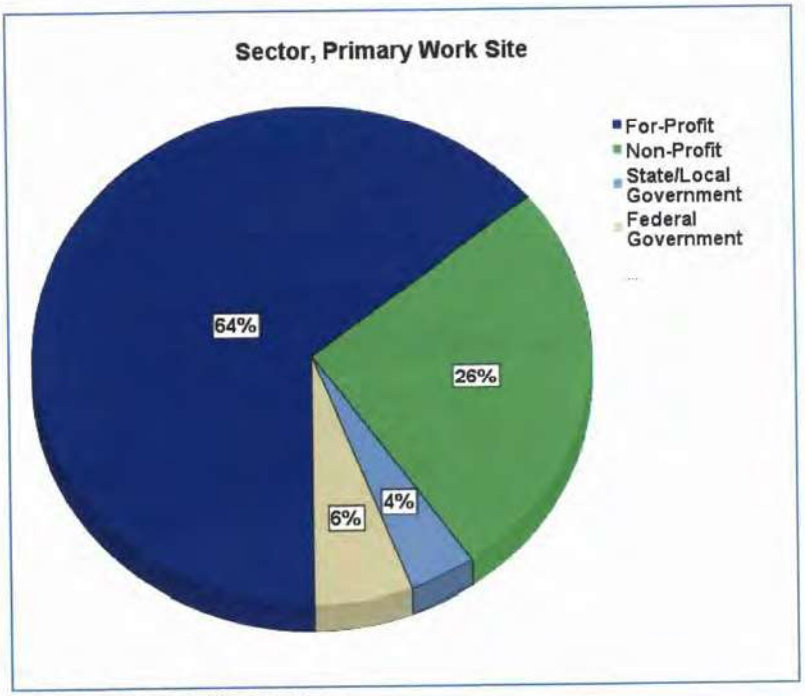
For Profit: 64%
Federal: 6%

**Top Establishments**

Large Chain Pharmacy (11+ Stores): 27%
Hospital/Health System (Inpatient): 25%
Independent Pharmacy (1-4 Stores): 9%

*Source: Va. Healthcare Workforce Data Center*

*91% of all pharmacists work in the private sector, including 64% who work at a for-profit company. Another 5% of pharmacists work for the federal government, while 4% work for a state or local government.*



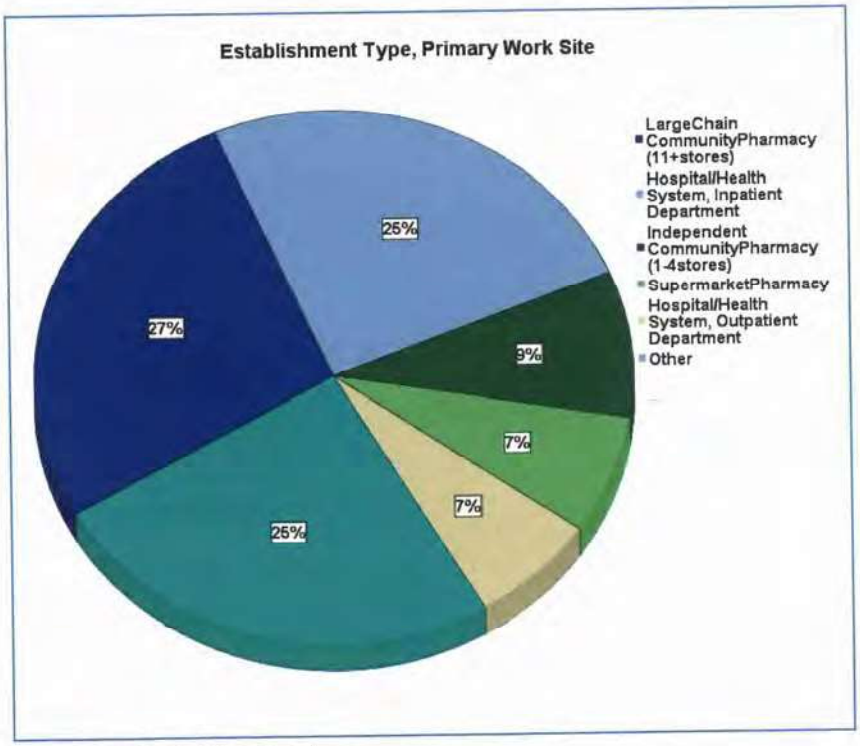

*Source: Va. Healthcare Workforce Data Center*

| Top Location Types | | | | |
|---|---|---|---|---|
| Establishment Type | Primary Location | | Secondary Location | |
| | # | % | # | % |
| Large Chain Community Pharmacy | 1,583 | 27% | 197 | 25% |
| Hospital/Health System, Inpatient Department | 1,473 | 25% | 140 | 18% |
| Independent Community Pharmacy | 523 | 9% | 105 | 13% |
| Supermarket Pharmacy | 420 | 7% | 32 | 4% |
| Hospital/Health System, Outpatient Department | 405 | 7% | 32 | 4% |
| Mass Merchandiser (i.e. Big Box Store) | 238 | 4% | 29 | 4% |
| Clinic-Based Pharmacy | 210 | 4% | 73 | 9% |
| Nursing Home/Long-Term Care | 176 | 3% | 30 | 4% |
| Benefit Administration | 151 | 3% | 11 | 1% |
| Academic Institution | 113 | 2% | 36 | 5% |
| Home Health/Infusion | 69 | 1% | 5 | 1% |
| Mail Service Pharmacy | 68 | 1% | 7 | 1% |
| Manufacturer | 52 | 1% | 3 | 0% |
| Small Chain Community Pharmacy | 28 | 0% | 5 | 1% |
| Wholesale Distributor | 10 | 0% | 1 | 0% |
| Other | 346 | 6% | 72 | 9% |
| **Total** | **5,865** | **100%** | **778** | **100%** |
| Did Not Have a Location | 328 | | 7,940 | |

*Source: Va. Healthcare Workforce Data Center*

*Large chain community pharmacies of more than 10 stores are 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 also 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**

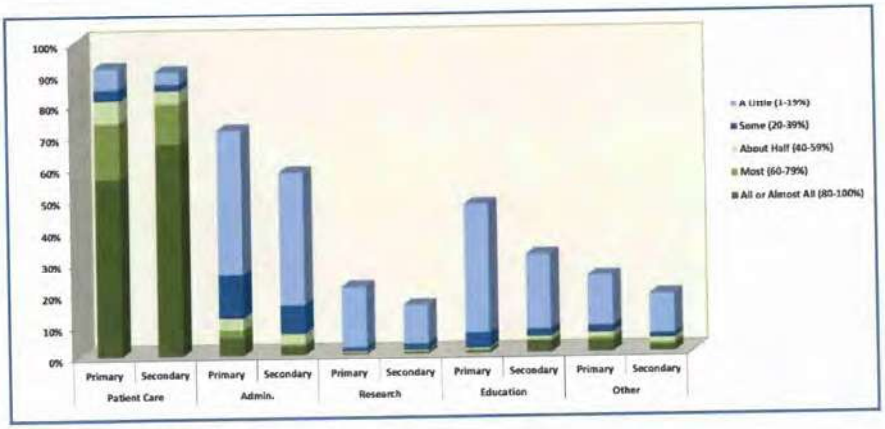
| | |
|---|---|
| Patient Care: | 74% |
| Administration: | 8% |
| Education: | 1% |

**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, about three-quarters of pharmacists fill a patient care role, defined as spending at least 60% of her 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% | 67% | 6% | 3% | 0% | 1% | 1% | 3% | 3% | 2% |
| Most (60-79%) | 18% | 13% | 2% | 1% | 0% | 0% | 0% | 0% | 1% | 1% |
| About Half (40-59%) | 7% | 5% | 4% | 3% | 0% | 0% | 1% | 1% | 1% | 2% |
| Some (20-39%) | 4% | 2% | 14% | 9% | 1% | 2% | 5% | 2% | 2% | 1% |
| A Little (1-20%) | 7% | 4% | 46% | 42% | 19% | 12% | 41% | 24% | 16% | 12% |
| None (0%) | 8% | 10% | 29% | 42% | 79% | 84% | 53% | 69% | 76% | 82% |

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

| Retirement Expectations | | | | |
|---|---|---|---|---|
| Expected Retirement Age | All | | Over 50 | |
| | # | % | # | % |
| Under age 50 | 220 | 4% | - | - |
| 50 to 54 | 241 | 4% | 0 | 0% |
| 55 to 59 | 628 | 11% | 122 | 6% |
| 60 to 64 | 1,431 | 26% | 549 | 26% |
| 65 to 69 | 1,931 | 35% | 859 | 41% |
| 70 to 74 | 572 | 10% | 315 | 15% |
| 75 to 79 | 155 | 3% | 91 | 4% |
| 80 or over | 87 | 2% | 44 | 2% |
| I do not intend to retire | 318 | 6% | 117 | 6% |
| **Total** | **5,582** | **100%** | **2,097** | **100%** |

Source: Va. Healthcare Workforce Data Center

### At a Glance:

**Retirement Expectations**

**All Pharmacists**

Under 65: 45%

Under 60: 20%

**Pharmacists 50 and over**

Under 65: 32%

Under 60: 6%

**Time until Retirement**

Within 2 years: 7%

Within 10 years: 23%

Half the workforce: By 2045

Source: Va. Healthcare Workforce Data Center

*45% of Virginia's pharmacists expect to retire before the age of 65, while 21% plan on working until at least age 70. Among pharmacists who are age 50 and over, 32% still plan on retiring by age 65, while over a quarter expect to work until at least age 70.*

*Within the next two years, 2% of Virginia's pharmacists plan on leaving the profession and 3% expect to leave the state. Meanwhile, 9% of pharmacists expect to pursue additional educational opportunities, and 8% plan on increasing the number of hours that they devote to patients.*

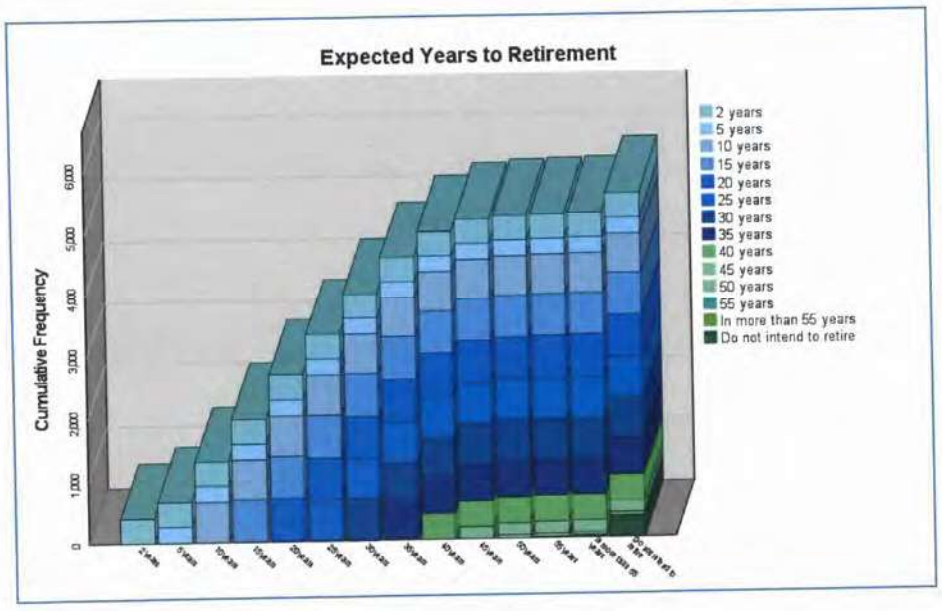
| Future Plans | | |
|---|---|---|
| 2 Year Plans: | # | % |
| **Decrease Participation** | | |
| Leave Profession | 169 | 2% |
| Leave Virginia | 229 | 3% |
| Decrease Patient Care Hours | 249 | 3% |
| Decrease Teaching Hours | 28 | 0% |
| **Increase Participation** | | |
| Increase Patient Care Hours | 705 | 8% |
| Increase Teaching Hours | 418 | 5% |
| Pursue Additional Education | 817 | 9% |
| Return to Virginia's Workforce | 120 | 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 23% plan on retiring in the next ten years. Half of the current pharmacist workforce expect to retire by 2045.*

| Time to Retirement | | | |
|---|---|---|---|
| **Expect to retire within. . .** | # | % | Cumulative % |
| **2 years** | 396 | 7% | 7% |
| **5 years** | 261 | 5% | 12% |
| **10 years** | 647 | 12% | 23% |
| **15 years** | 682 | 12% | 36% |
| **20 years** | 700 | 13% | 48% |
| **25 years** | 651 | 12% | 60% |
| **30 years** | 655 | 12% | 72% |
| **35 years** | 588 | 11% | 82% |
| **40 years** | 407 | 7% | 89% |
| **45 years** | 196 | 4% | 93% |
| **50 years** | 49 | 1% | 94% |
| **55 years** | 18 | 0% | 94% |
| **In more than 55 years** | 13 | 0% | 94% |
| **Do not intend to retire** | 318 | 6% | 100% |
| **Total** | **5,582** | **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 2030. Retirement will peak at 13% of the current workforce around 2040 before declining to under 10% of the current workforce again around 2060.*

## At a Glance:

**FTEs**

| | |
|---|---|
| Total: | 7,142 |
| FTEs/1,000 Residents[2]: | 0.836 |
| Average: | 0.85 |

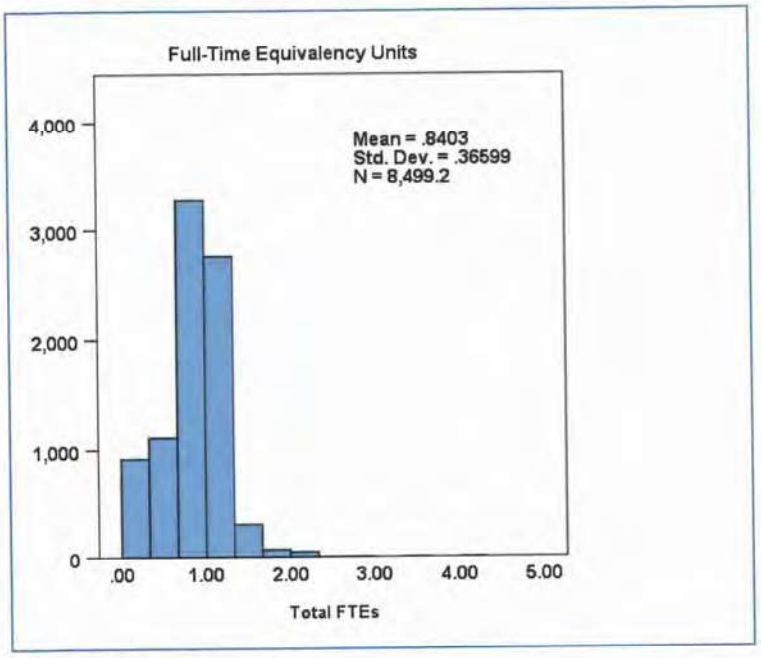
**Age & Gender Effect**

| | |
|---|---|
| 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:

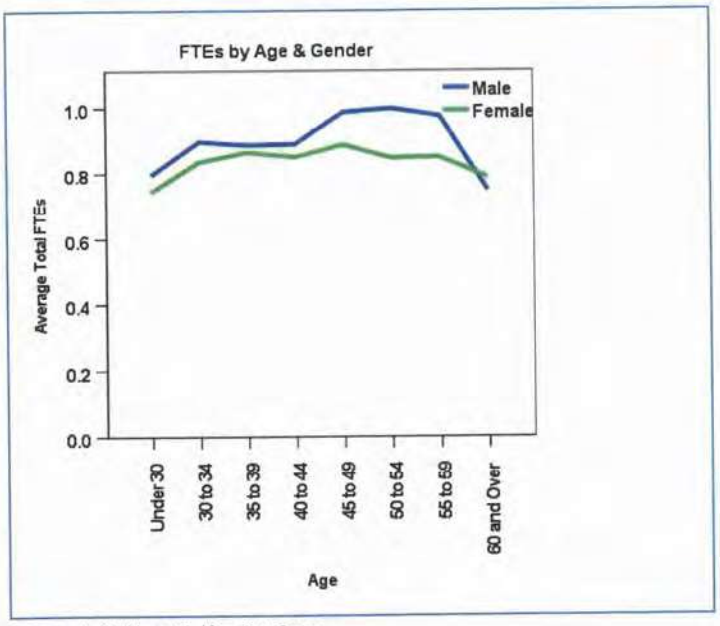



Source: Va. Healthcare Workforce Data Center

*The typical pharmacist provided 0.85 FTEs in 2020, 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]*

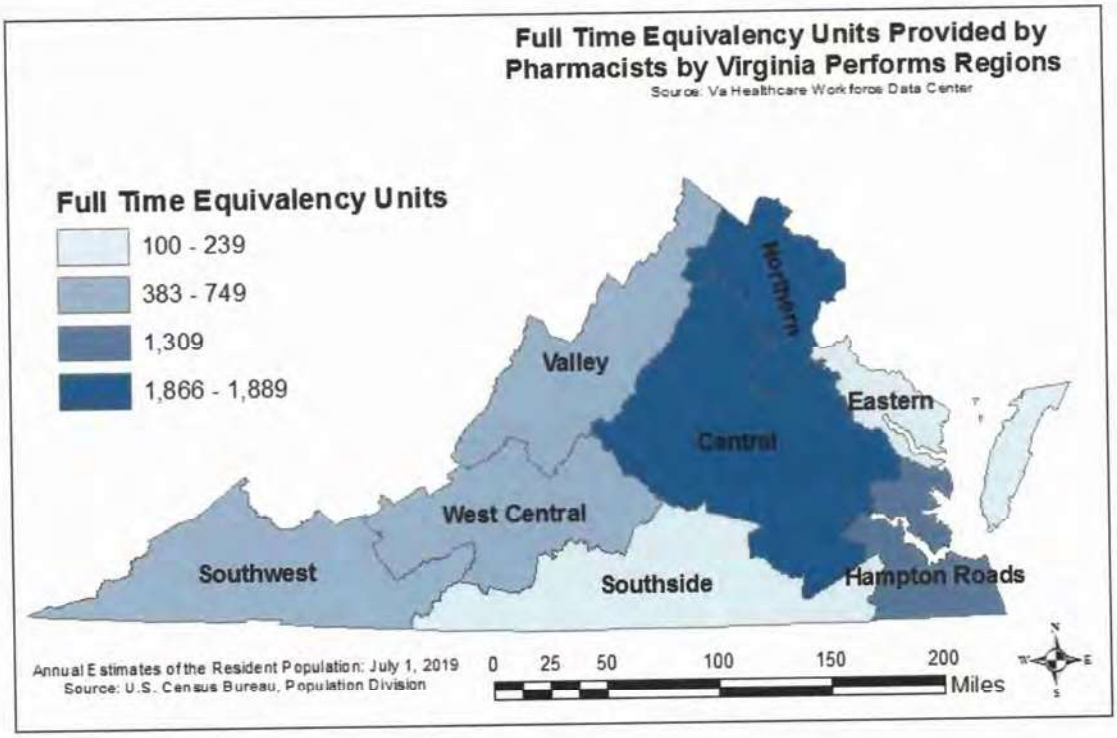
| Full-Time Equivalency Units | | |
|---|---|---|
| **Age** | | |
| | Average | Median |
| Under 30 | 0.77 | 0.83 |
| 30 to 34 | 0.84 | 0.86 |
| 35 to 39 | 0.83 | 0.84 |
| 40 to 44 | 0.81 | 0.80 |
| 45 to 49 | 0.99 | 1.09 |
| 50 to 54 | 0.87 | 0.83 |
| 55 to 59 | 0.88 | 0.83 |
| 60 and Over | 0.76 | 0.72 |
| **Gender** | | |
| Male | 0.88 | 0.96 |
| Female | 0.84 | 0.93 |

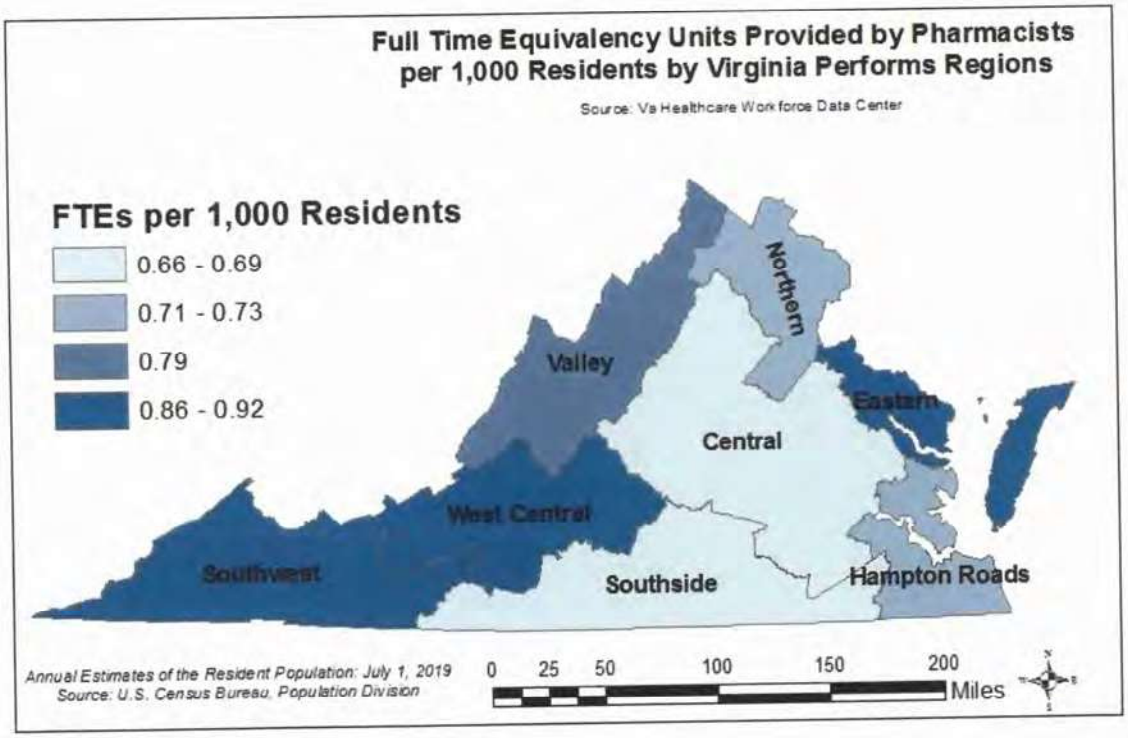
Source: Va. Healthcare Workforce Data Center

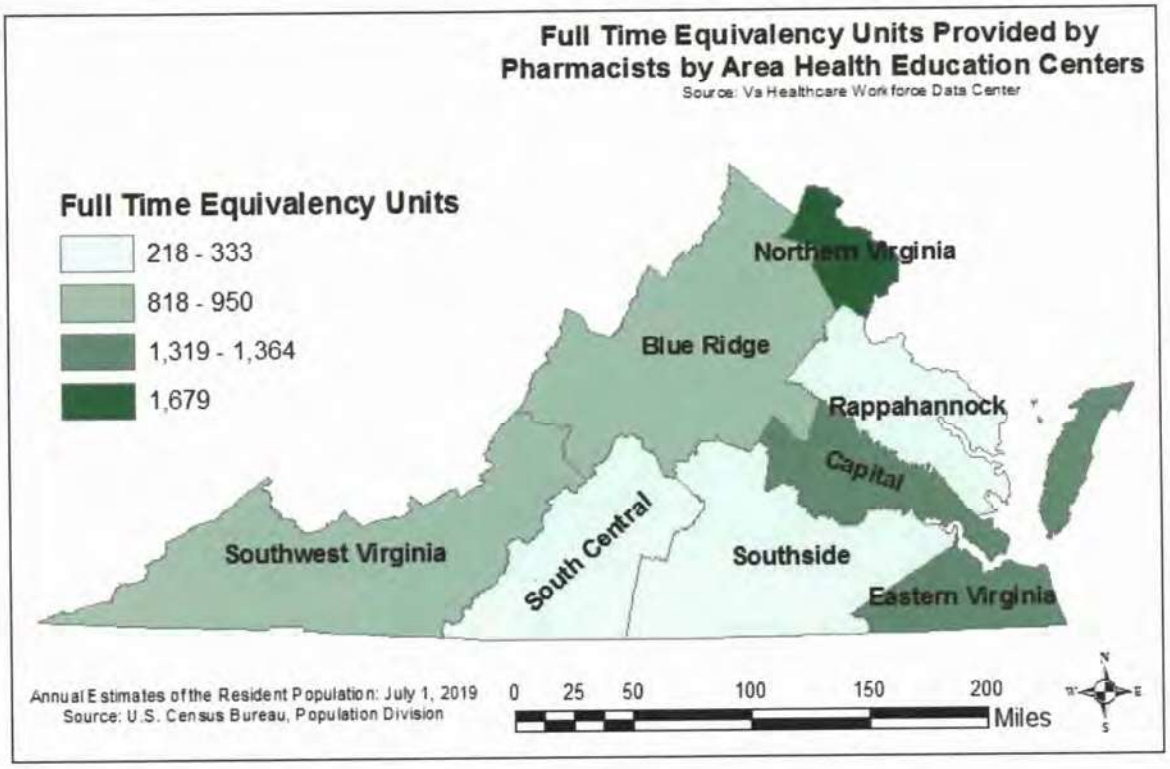


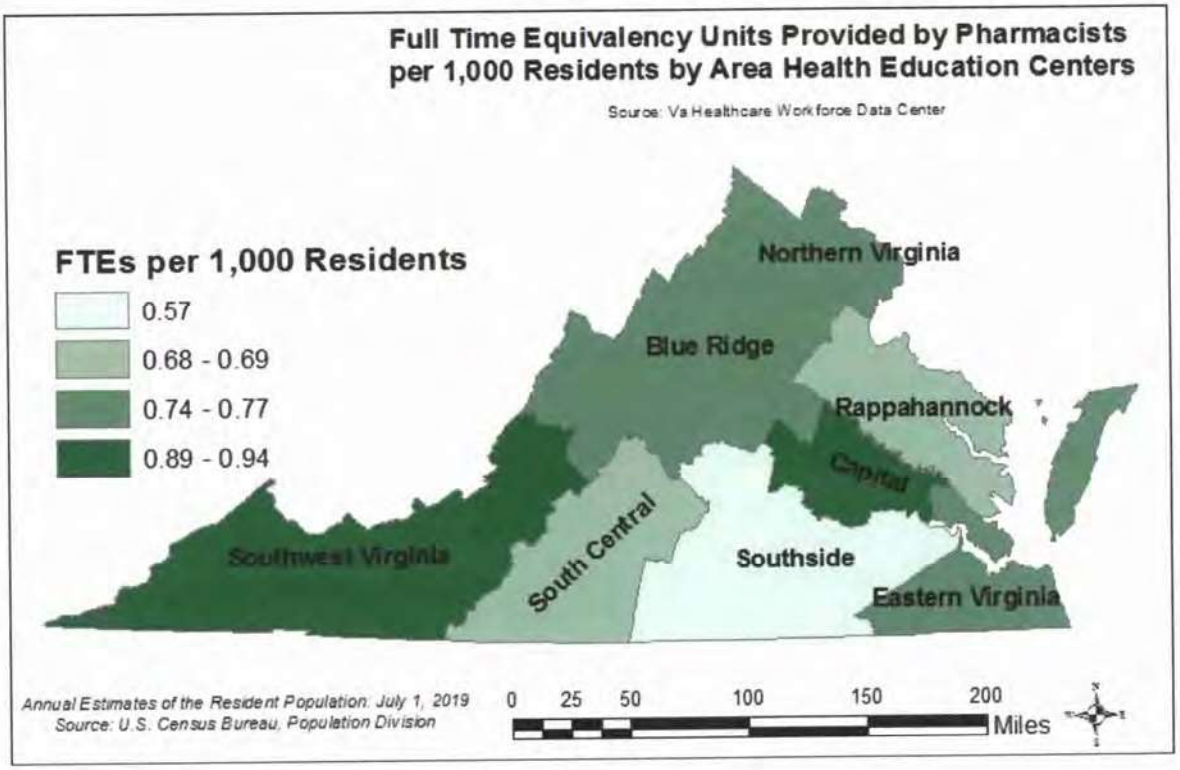

Source: Va. Healthcare Workforce Data Center

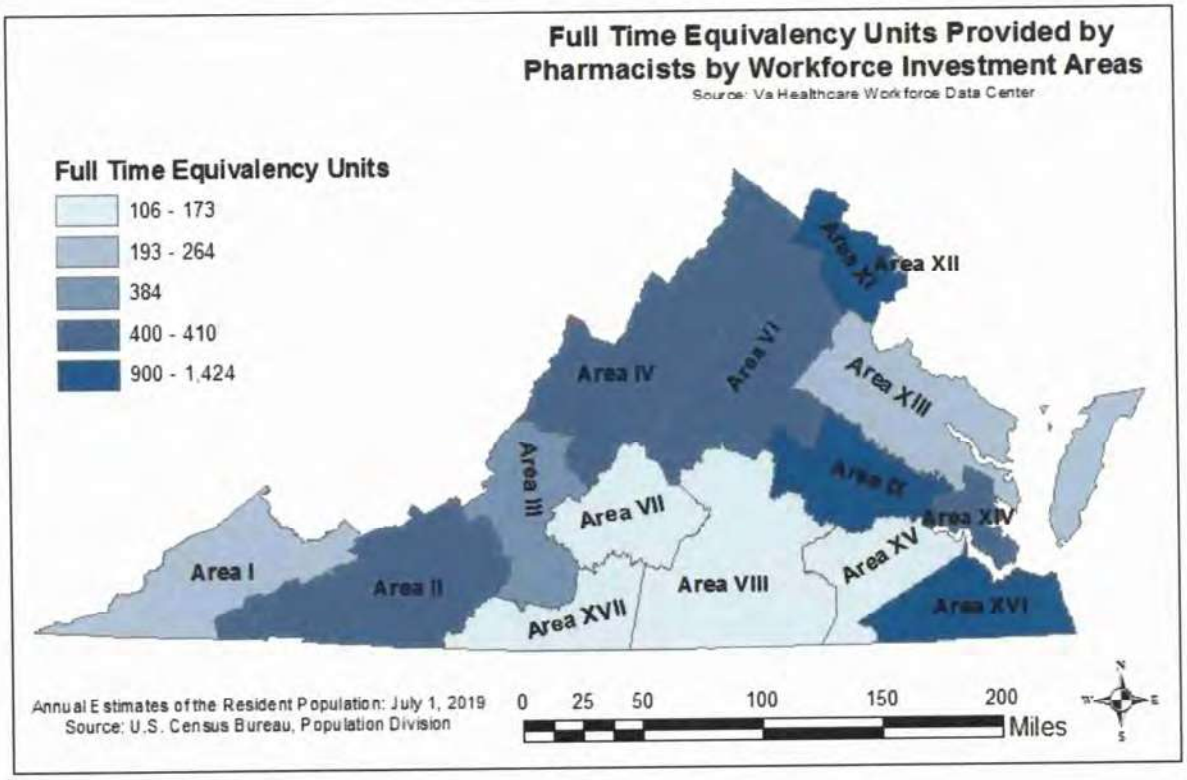
[2] Number of residents in 2019 was used as the denominator.
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

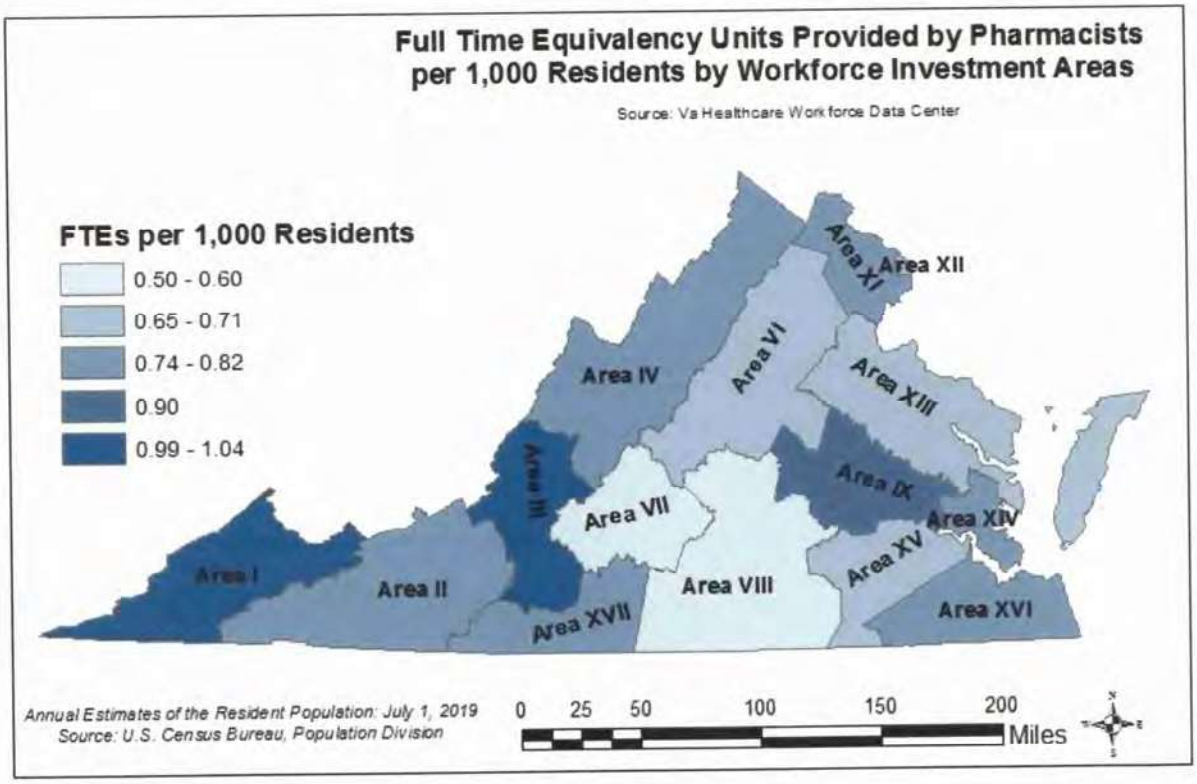

Full Time Equivalency Units Provided by Pharmacists by Virginia Performs Regions
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
100 - 239
383 - 749
1,309
1,866 - 1,889
Northern
Valley
Eastern
Central
West Central
Southwest
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

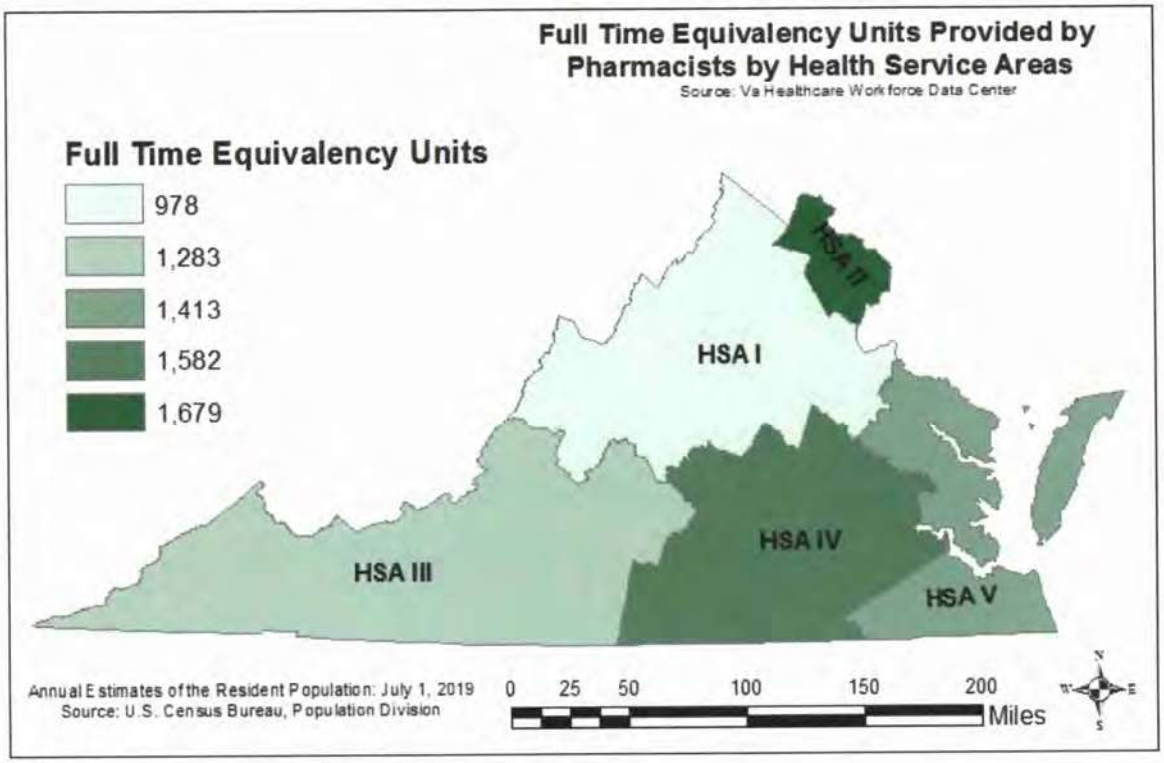

Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Virginia Performs Regions
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.66 - 0.69
0.71 - 0.73
0.79
0.86 - 0.92
Northern
Valley
Eastern
Central
West Central
Southwest
Southside
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

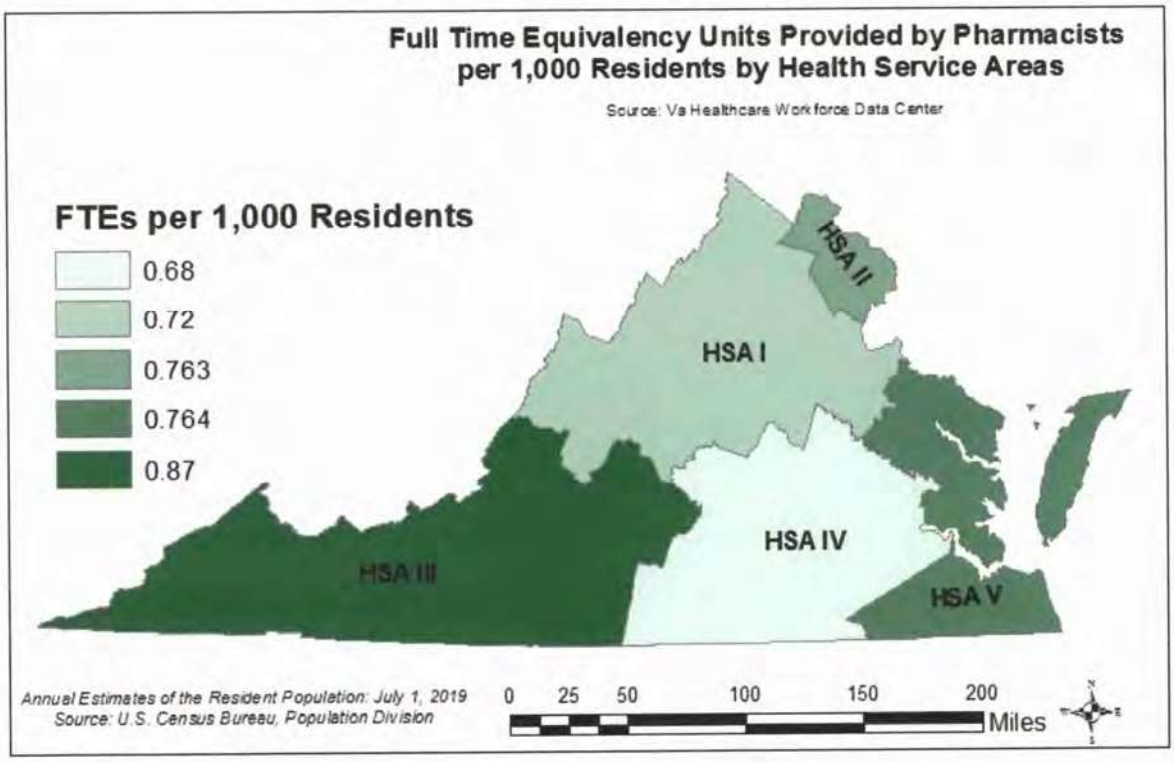

Full Time Equivalency Units Provided by Pharmacists by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
218 - 333
818 - 950
1,319 - 1,364
1,679
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

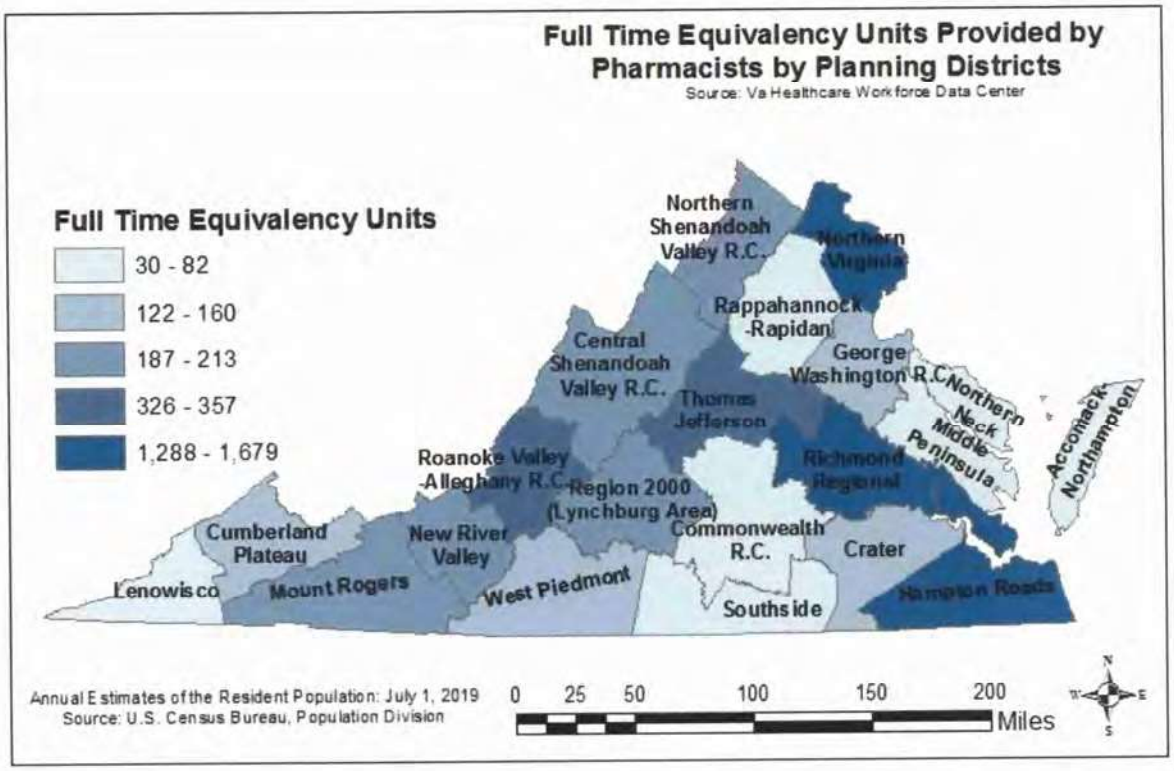

Full Time Equivalency Units Provided by Pharmacists per 1,000 Residents by Area Health Education Centers
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.57
0.68 - 0.69
0.74 - 0.77
0.89 - 0.94
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

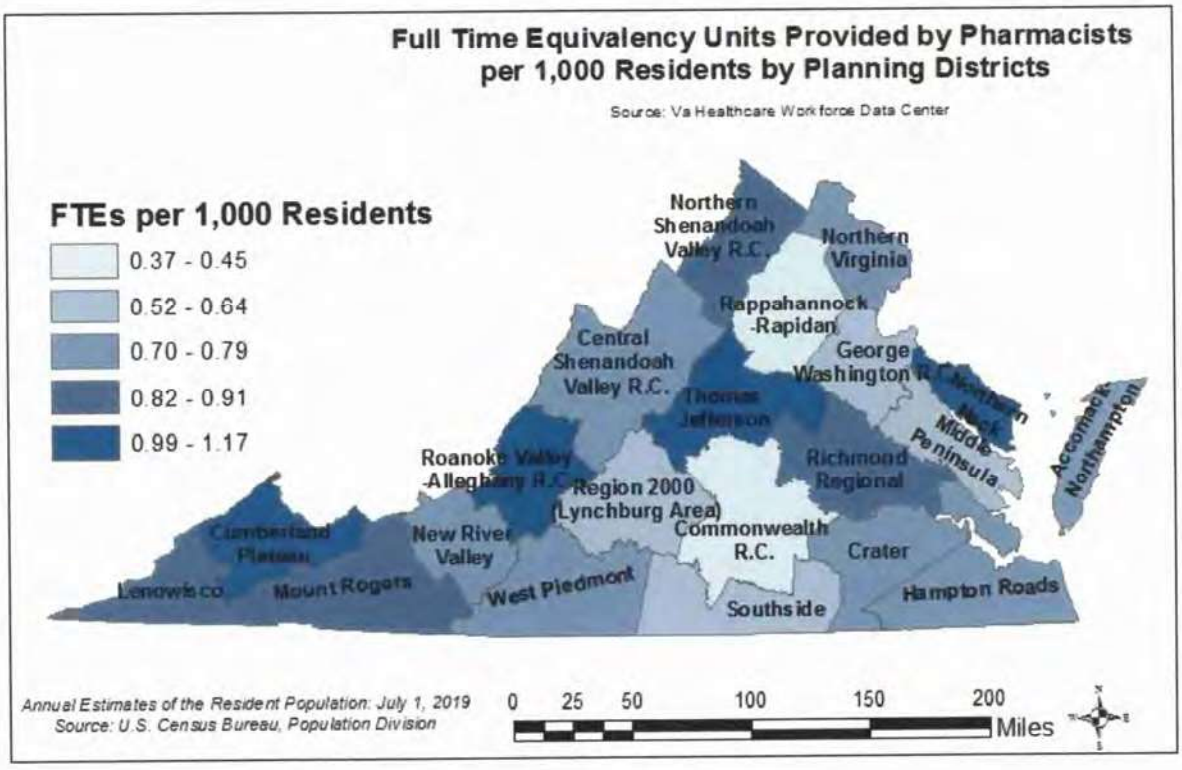

Full Time Equivalency Units Provided by Pharmacists by Workforce Investment Areas
Source: Va Healthcare Workforce Data Center
Full Time Equivalency Units
106 - 173
193 - 264
384
400 - 410
900 - 1,424
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2019
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 Areas
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.50 - 0.60
0.65 - 0.71
0.74 - 0.82
0.90
0.99 - 1.04
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, 2019
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
978
1,283
1,413
1,582
1,679
HSA I
HSA II
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2019
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 Health Service Areas
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.68
0.72
0.763
0.764
0.87
HSA I
HSA II
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2019
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
30 - 82
122 - 160
187 - 213
326 - 357
1,288 - 1,679
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.
Region 2000 (Lynchburg Area)
Richmond Regional
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, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles
N
W
E
S


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
0.37 - 0.45
0.52 - 0.64
0.70 - 0.79
0.82 - 0.91
0.99 - 1.17
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.
Region 2000 (Lynchburg Area)
Richmond Regional
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, 2019
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+ | 6,646 | 92.88% | 1.0766 | 1.0500 | 1.1378 |
| Metro, 250,000 to 1 million | 936 | 92.84% | 1.0771 | 1.0505 | 1.1383 |
| Metro, 250,000 or less | 1,070 | 93.18% | 1.0732 | 1.0467 | 1.1342 |
| Urban pop 20,000+, Metro adj | 118 | 88.14% | 1.1346 | 1.1066 | 1.1991 |
| Urban pop 20,000+, nonadj | 0 | NA | NA | NA | NA |
| Urban pop, 2,500-19,999, Metro adj | 361 | 89.47% | 1.1176 | 1.0900 | 1.1812 |
| Urban pop, 2,500-19,999, nonadj | 296 | 93.58% | 1.0686 | 1.0422 | 1.1293 |
| Rural, Metro adj | 241 | 88.38% | 1.1315 | 1.1035 | 1.1957 |
| Rural, nonadj | 133 | 91.73% | 1.0902 | 1.0632 | 1.1521 |
| Virginia border state/DC | 2,857 | 90.34% | 1.1069 | 1.0796 | 1.1698 |
| Other US State | 3,547 | 87.74% | 1.1398 | 1.1116 | 1.2045 |

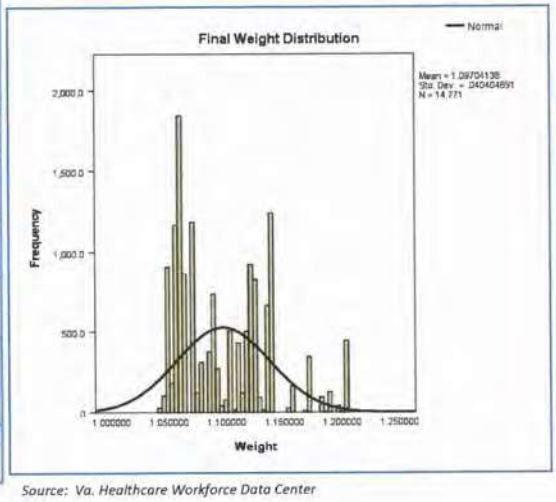
*Source: Va. Healthcare Workforce Data Center*

See the Methods section on the HWDC website for details on HWDC Methods:
www.vhdp.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:** 0.91151




*Source: Va. Healthcare Workforce Data Center*

| Age | Age Weight | | | Total Weight | |
|---|---|---|---|---|---|
| | # | Rate | Weight | Min | Max |
| Under 30 | 997 | 87.26% | 1.1460 | 1.1162 | 1.1906 |
| 30 to 34 | 2,523 | 91.52% | 1.0927 | 1.0643 | 1.1352 |
| 35 to 39 | 2,631 | 92.74% | 1.0783 | 1.0503 | 1.1202 |
| 40 to 44 | 2,107 | 92.88% | 1.0766 | 1.0487 | 1.1186 |
| 45 to 49 | 1,896 | 93.46% | 1.0700 | 1.0422 | 1.1116 |
| 50 to 54 | 1,815 | 92.40% | 1.0823 | 1.0542 | 1.1244 |
| 55 to 59 | 1,436 | 92.69% | 1.0789 | 1.0509 | 1.1209 |
| 60 and Over | 2,800 | 86.25% | 1.1594 | 1.1293 | 1.2045 |

*Source: Va. Healthcare Workforce Data Center*

# *Virginia's Pharmacy Technician Workforce: 2020*

Healthcare Workforce Data Center

February 2021

Virginia Department of Health Professions
Healthcare Workforce Data Center
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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 your ongoing cooperation.*

## *Thank You!*


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# The Pharmacy Technician Workforce At a Glance:

| The Workforce | |
|---|---|
| Licensees: | 14,158 |
| Virginia's Workforce: | 13,021 |
| FTEs: | 10,203 |

| Survey Response Rate | |
|---|---|
| All Licensees: | 77% |
| Renewing Practitioners: | 98% |

| Demographics | |
|---|---|
| Female: | 85% |
| Diversity Index: | 60% |
| Median Age: | 35 |

| Background | |
|---|---|
| Rural Childhood: | 40% |
| HS Degree in VA: | 74% |
| % Work Non-Metro: | 14% |

| Education | |
|---|---|
| High School/GED: | 56% |
| Associate Degree: | 21% |

| Finances | |
|---|---|
| Median Income: | $30k-$35k |
| Health Insurance: | 63% |
| Under 40 w/ Ed. Debt: | 49% |

| Current Employment | |
|---|---|
| Employed in Prof.: | 81% |
| Hold 1 Full-Time Job: | 68% |
| Satisfied?: | 90% |

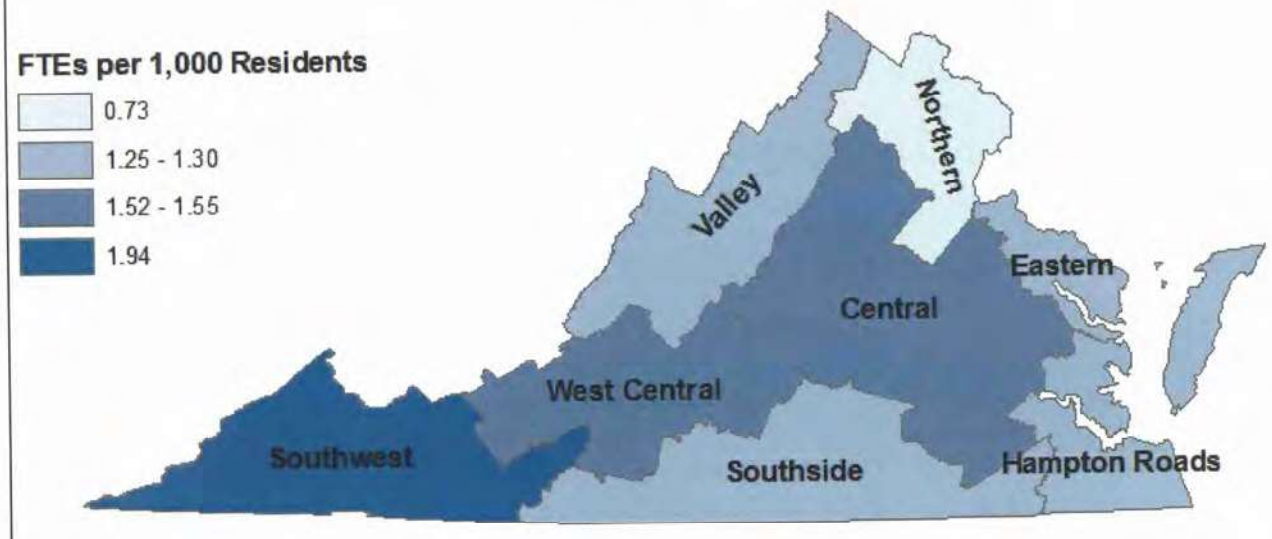
| Job Turnover | |
|---|---|
| Switched Jobs: | 4% |
| Employed Over 2 Yrs.: | 56% |

| Primary Roles | |
|---|---|
| Medication Disp.: | 57% |
| Administration: | 5% |
| Supervision: | 2% |

Source: Va. Healthcare Workforce Data Center

## Full-Time Equivalency Units Provided by Pharmacy Technicians per 1,000 Residents by Virginia Performs Region

Source: Va Healthcare Workforce Data Center




*Annual Estimates of the Resident Population: July 1, 2019*
*Source: U.S. Census Bureau, Population Division*

0 25 50 100 150 200 Miles

## Results in Brief

This report contains the results of the 2020 Pharmacy Technician Workforce survey. Nearly 11,000 pharmacy technicians voluntarily participated in this 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 pharmacy technicians. These survey respondents represent 77% of the 14,158 pharmacy technicians who are licensed in the state and 98% of renewing practitioners.

The HWDC estimates that 13,021 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 10,203 "full-time equivalency units", which the HWDC defines simply as working 2,000 hours per year.

More than four out of every five pharmacy technicians are female, and the median age of this workforce is 35. In a random encounter between two pharmacy technicians, there is a 60% chance that they would be of different races or ethnicities, a measure known as the diversity index. For pharmacy technicians who are under the age of 40, the diversity index increases to 64%. Both of these values are above the comparable diversity index of 57% for Virginia's population as a whole. Two out of every five pharmacy technicians grew up in a rural area, and 27% of these professionals currently work in non-metro areas of Virginia. Overall, 14% of pharmacy technicians work in non-metro areas of the state.

More than 80% of all pharmacy technicians are currently employed in the profession, 68% hold one full-time job, and 46% work between 40 and 49 hours per week. Nine out of every ten pharmacy technicians work in the private sector, including 74% who work in for-profit establishments. The median annual income of pharmacy technicians is between $30,000 and $35,000. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 63% who have access to health insurance. Nine out of every ten pharmacy technicians indicated that they are satisfied with their current work situation, including nearly half who indicated that they are "very satisfied".

## Summary of Trends

In this section, all statistics for the current year are compared to the 2015 pharmacy technician workforce. The number of licensed pharmacy technicians has fallen by 4% (14,158 vs. 14,710). In addition, the size of Virginia's pharmacy technician workforce has declined by 6% (13,021 vs. 13,834), and the number of FTEs provided by this workforce has fallen by 1% (10,203 vs. 10,327). However, renewing pharmacy technicians were more likely to respond to the survey (98% vs. 96%).

Virginia's pharmacy technicians are more likely to be female (85% vs. 84%), and the median age of this workforce has increased (35 vs. 34). At the same time, the diversity index of this workforce has increased (60% vs. 58%). This is also the case for those pharmacy technicians who are under the age of 40 (64% vs. 62%). There has been no change in the percentage of pharmacy technicians who grew up in a rural area (40%). Likewise, there has also been no change in the percentage of all pharmacy technicians who currently work in non-metro areas of the state (14%).

Pharmacy technicians are more likely to work in the profession (81% vs. 78%), hold one full-time job (68% vs. 62%), and work between 40 and 49 hours per week (46% vs. 41%). Pharmacy technicians are slightly more likely to work in the private sector (90% vs. 89%) and less likely to work for state or local governments (6% vs. 8%). As for establishment types, pharmacy technicians are relatively more likely to work in the inpatient department of hospitals (16% vs. 14%) instead of large chain community pharmacies (33% vs. 35%).

The median annual income of Virginia's pharmacy technician workforce has increased ($30k-$35k vs. $20k-$25k). In addition, pharmacy technicians are more likely to receive at least one employer-sponsored benefit (81% vs. 77%), including those who have access to health insurance (63% vs. 59%). Pharmacy technicians indicated that they are more likely to be satisfied with their current work situation (90% vs. 89%), and this also includes those pharmacy technicians who indicated that they are "very satisfied" (49% vs. 48%).

## A Closer Look:

| Licensee Counts | | |
|---|---|---|
| License Status | # | % |
| Renewing Practitioners | 10,606 | 75% |
| New Licensees | 1,469 | 10% |
| Non-Renewals | 2,083 | 15% |
| All Licensees | 14,158 | 100% |

Source: Va. Healthcare Workforce Data Center

*HWDC surveys tend to achieve very high response rates. Nearly all renewing pharmacy technicians submitted a survey. These represent 77% of all pharmacy technicians who held a license at some point in 2020.*

### Definitions

1. **The Survey Period:** The survey was conducted in December 2020.
2. **Target Population:** All professionals who held a Virginia license at some point in 2020.
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 professionals newly licensed in 2020.

| Response Rates | | | |
|---|---|---|---|
| Statistic | Non Respondents | Respondents | Response Rate |
| **By Age** | | | |
| Under 30 | 1,433 | 2,877 | 67% |
| 30 to 34 | 541 | 1,823 | 77% |
| 35 to 39 | 356 | 1,522 | 81% |
| 40 to 44 | 256 | 1,131 | 82% |
| 45 to 49 | 151 | 997 | 87% |
| 50 to 54 | 152 | 943 | 86% |
| 55 to 59 | 138 | 734 | 84% |
| 60 and Over | 235 | 869 | 79% |
| **Total** | **3,262** | **10,896** | **77%** |
| **New Licenses** | | | |
| Issued in 2020 | 1,065 | 404 | 28% |
| **Metro Status** | | | |
| Non-Metro | 374 | 1,634 | 81% |
| Metro | 2,329 | 8,603 | 79% |
| Not in Virginia | 559 | 659 | 54% |

Source: Va. Healthcare Workforce Data Center

| Response Rates | |
|---|---|
| Completed Surveys | 10,896 |
| Response Rate, All Licensees | 77% |
| Response Rate, Renewals | 98% |

Source: Va. Healthcare Workforce Data Center

### At a Glance:

**Licensed Pharmacy Tech.**

| | |
|---|---|
| Number: | 14,158 |
| New: | 10% |
| Not Renewed: | 15% |

**Survey Response Rates**

| | |
|---|---|
| All Licensees: | 77% |
| Renewing Practitioners: | 98% |

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Workforce**

| | |
|---|---|
| Pharmacy Tech. Workforce: | 13,021 |
| FTEs: | 10,203 |

**Utilization Ratios**

| | |
|---|---|
| Licensees in VA Workforce: | 92% |
| Licensees per FTE: | 1.39 |
| Workers per FTE: | 1.28 |

Source: Va. Healthcare Workforce Data Center

## Definitions

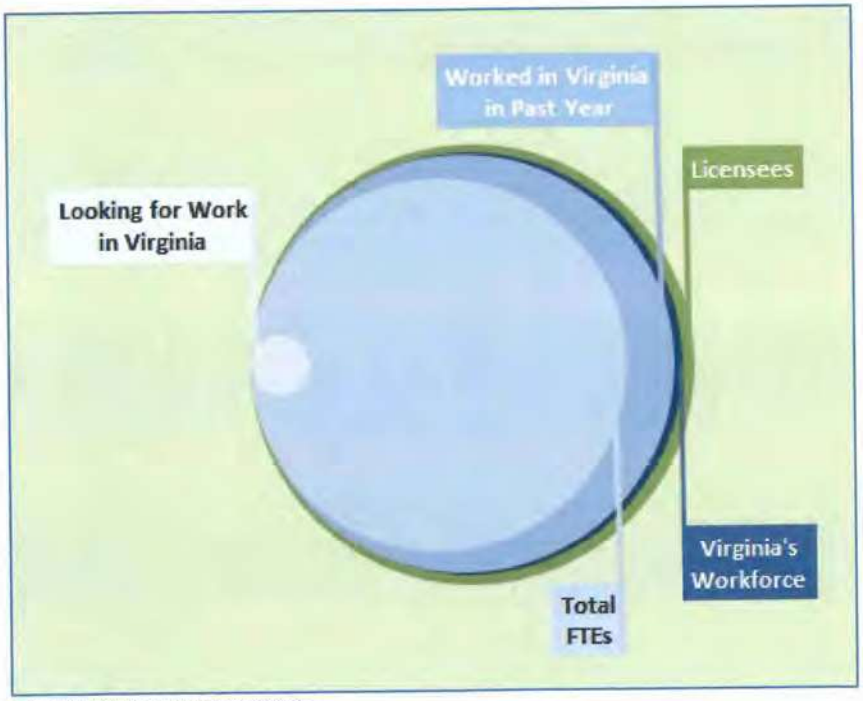
1. **Virginia's Workforce:** A licensee with a primary or secondary work site in Virginia at any time in the past year or who indicated intent to return to Virginia's workforce at any point in the future.
2. **Full-Time Equivalency Unit (FTE):** The HWDC uses 2,000 (40 hours for 50 weeks) as its baseline 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.

**Pharmacy Tech. Workforce**

| Status | # | % |
|---|---|---|
| Worked in Virginia in Past Year | 12,766 | 98% |
| Looking for Work in Virginia | 256 | 2% |
| Virginia's Workforce | 13,021 | 100% |
| Total FTEs | 10,203 | |
| Licensees | 14,158 | |

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 | 603 | 17% | 2,943 | 83% | 3,546 | 32% |
| 30 to 34 | 288 | 16% | 1,535 | 84% | 1,824 | 17% |
| 35 to 39 | 196 | 14% | 1,226 | 86% | 1,422 | 13% |
| 40 to 44 | 153 | 14% | 917 | 86% | 1,071 | 10% |
| 45 to 49 | 111 | 13% | 754 | 87% | 864 | 8% |
| 50 to 54 | 109 | 13% | 713 | 87% | 822 | 7% |
| 55 to 59 | 87 | 14% | 561 | 87% | 648 | 6% |
| 60 and Over | 103 | 13% | 700 | 87% | 803 | 7% |
| **Total** | **1,650** | **15%** | **9,350** | **85%** | **10,999** | **100%** |

*Source: Va. Healthcare Workforce Data Center*

## At a Glance:

**Gender**

| | |
|---|---|
| % Female: | 85% |
| % Under 40 Female: | 84% |

**Age**

| | |
|---|---|
| Median Age: | 35 |
| % Under 40: | 62% |
| % 55 and Over: | 13% |

**Diversity**

| | |
|---|---|
| Diversity Index: | 60% |
| Under 40 Div. Index: | 64% |

*Source: Va. Healthcare Workforce Data Center*

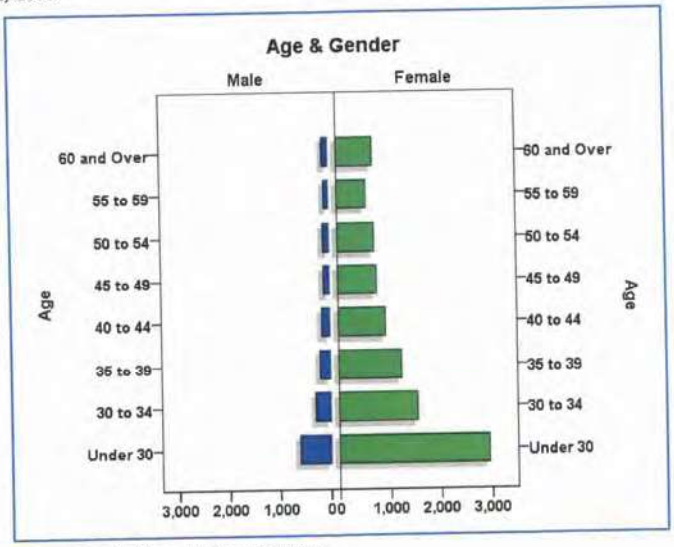
| Race & Ethnicity | | | | | |
|---|---|---|---|---|---|
| Race/ Ethnicity | Virginia* | Pharmacy Tech. | | Pharmacy Tech. Under 40 | |
| | % | # | % | # | % |
| White | 61% | 6,418 | 58% | 3,688 | 54% |
| Black | 19% | 2,455 | 22% | 1,635 | 24% |
| Hispanic | 10% | 645 | 6% | 499 | 7% |
| Asian | 7% | 959 | 9% | 587 | 9% |
| Two or More Races | 3% | 430 | 4% | 339 | 5% |
| Other Race | 0% | 167 | 2% | 105 | 2% |
| **Total** | **100%** | **11,074** | **100%** | **6,853** | **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, 2019.

*Source: Va. Healthcare Workforce Data Center*

*In a chance encounter between two professionals, there is a 60% chance that they would be of different races or ethnicities (a measure known as the diversity index). For Virginia's population as a whole, the diversity index is 57%.*

*Among the 62% of pharmacy technicians who are under the age of 40, 84% are female. In addition, the diversity index among these professionals is 64%.*




*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: | 72% |

**Location Choice**

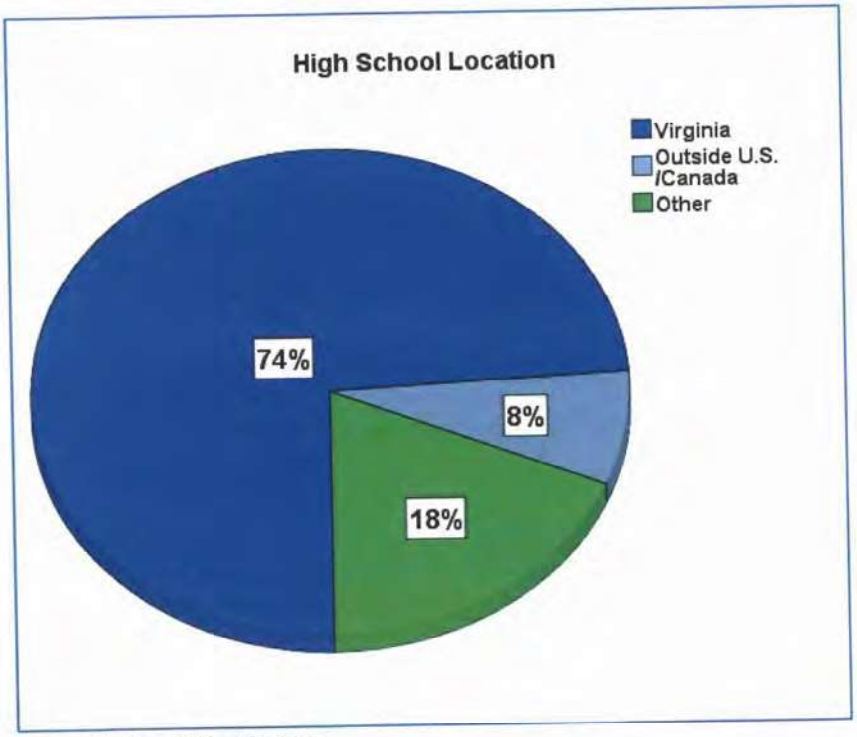
| | |
|---|---|
| % Work Non-Metro: | 14% |
| % Rural to Non-Metro: | 27% |
| % Urban/Suburban to Non-Metro: | 4% |

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% | 31% | 11% |
| 3 | Metro, 250,000 or Less | 63% | 27% | 10% |
| | **Non-Metro Counties** | | | |
| 4 | Urban, Pop. 20,000+, Metro Adjacent | 67% | 23% | 10% |
| 6 | Urban, Pop. 2,500-19,999, Metro Adjacent | 82% | 10% | 8% |
| 7 | Urban, Pop. 2,500-19,999, Non-Adjacent | 93% | 3% | 4% |
| 8 | Rural, Metro Adjacent | 86% | 8% | 6% |
| 9 | Rural, Non-Adjacent | 68% | 25% | 7% |
| | **Overall** | **40%** | **41%** | **19%** |

Source: Va. Healthcare Workforce Data Center




Source: Va. Healthcare Workforce Data Center

*Among all pharmacy technicians, 40% grew up in self-described rural areas, and 27% of these professionals currently work in non-metro counties. Overall, 14% of pharmacy technicians are employed in non-metro areas of the state.*

## Top Ten States for Pharmacy Technician Recruitment

| Rank | High School Location | | | |
|---|---|---|---|---|
| | All Pharmacy Technicians | # | Licensed in the Past Five Years | # |
| 1 | Virginia | 8,057 | Virginia | 2,995 |
| 2 | Outside U.S./Canada | 836 | Outside U.S./Canada | 303 |
| 3 | New York | 180 | North Carolina | 85 |
| 4 | North Carolina | 170 | Maryland | 79 |
| 5 | Maryland | 162 | New York | 66 |
| 6 | West Virginia | 138 | Florida | 62 |
| 7 | Pennsylvania | 138 | Pennsylvania | 58 |
| 8 | Florida | 134 | West Virginia | 56 |
| 9 | California | 113 | Texas | 47 |
| 10 | New Jersey | 109 | New Jersey | 43 |

Source: Va. Healthcare Workforce Data Center

*Nearly three-fourths of all pharmacy technicians received their high school diploma in Virginia. Among those pharmacy technicians who obtained their initial license in the past five years, 72% also received their high school degree in the state.*

*Among all of Virginia's licensed pharmacy technicians, 8% did not participate in the state's workforce in 2020. However, 79% of these professionals worked at some point in the past year, including 60% who currently work as pharmacy technicians.*

### At a Glance:

**Not in VA Workforce**

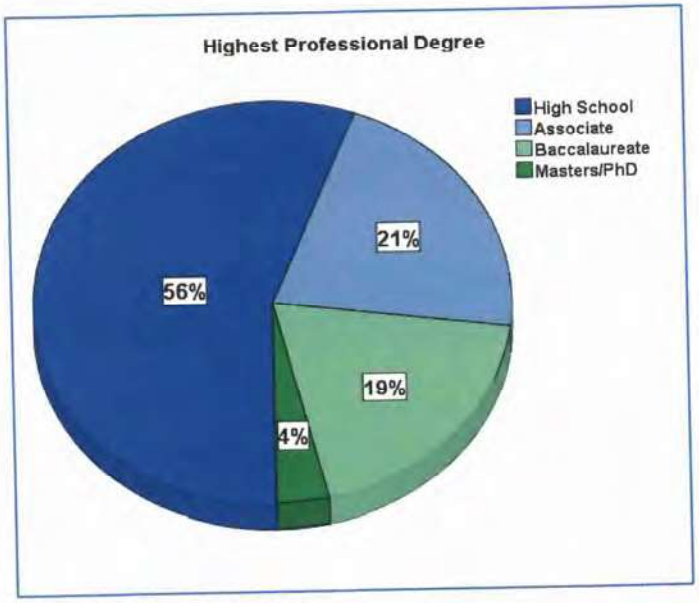
| | |
|---|---|
| Total: | 1,130 |
| % of Licensees: | 8% |
| Federal/Military: | 4% |
| Va. Border State/D.C.: | 34% |

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

| Highest Professional Degree | | |
|---|---|---|
| Degree | # | % |
| High School/GED | 6,026 | 56% |
| Associate | 2,301 | 21% |
| Baccalaureate | 2,079 | 19% |
| Masters | 350 | 3% |
| PhD | 34 | 0% |
| Total | 10,791 | 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 49% of those under the age of 40. For those with education debt, the median amount is between $18,000 and $20,000.*

### At a Glance:

**Education**

High School/GED: 56%
Associate Degree: 21%

**Education Debt**

Carry Debt: 38%
Under Age 40 w/ Debt: 49%
Median Debt: $18k-$20k

Source: Va. Healthcare Workforce Data Center

*More than half of all pharmacy technicians 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 | 5,375 | 62% | 2,751 | 51% |
| Less than $10,000 | 1,023 | 12% | 803 | 15% |
| $10,000-$19,999 | 704 | 8% | 560 | 10% |
| $20,000-$29,999 | 537 | 6% | 438 | 8% |
| $30,000 or More | 1,052 | 12% | 796 | 15% |
| Total | 8,691 | 100% | 5,348 | 100% |

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Top Certifications**

| | |
|---|---|
| PTCB: | 64% |
| ExCPT: | 10% |
| Total w/ Cert.: | 75% |

**National Certifications**

| | |
|---|---|
| Required: | 56% |
| Pay Raise w/ Cert.: | 43% |

Source: Va. Healthcare Workforce Data Center

| Professional Certifications | | |
|---|---|---|
| Certification | # | % of Workforce |
| Pharmacy Technician Certification Board (PTCB) | 8,396 | 64% |
| Exam for Certification of Pharmacy Technicians (ExCPT) | 1,351 | 10% |
| **Total with Certification** | **9,747** | **75%** |

Source: Va. Healthcare Workforce Data Center

*Three out of every four of Virginia's pharmacy technicians hold a professional certification, including 64% who have a Pharmacy Technician Certification Board (PTCB) credential.*

*More than half of all pharmacy technicians work for an employer that requires a national certification as a condition of employment. Meanwhile, 43% of pharmacy technicians work for an employer that offers a pay raise for those who have obtained a national certification.*

| National Certifications | | |
|---|---|---|
| Required for Employment? | # | % |
| Yes | 5,930 | 56% |
| No | 4,690 | 44% |
| Pay Raise with Certification? | # | % |
| Yes | 4,136 | 43% |
| No | 4,684 | 49% |
| No Certification Held | 723 | 8% |

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Employment**

Employed in Profession: 81%
Involuntarily Unemployed: 1%

**Positions Held**

1 Full-Time: 68%
2 or More Positions: 8%

**Weekly Hours:**

40 to 49: 46%
60 or More: 3%
Less than 30: 16%

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

| Current Work Status | | |
|---|---|---|
| **Status** | **#** | **%** |
| **Employed, Capacity Unknown** | 25 | 0% |
| **Employed in a Pharmacy Technician-Related Capacity** | 8,667 | 81% |
| **Employed, NOT in a Pharmacy Technician-Related Capacity** | 1,604 | 15% |
| **Not Working, Reason Unknown** | 0 | 0% |
| **Involuntarily Unemployed** | 115 | 1% |
| **Voluntarily Unemployed** | 280 | 3% |
| **Retired** | 62 | 1% |
| **Total** | **10,753** | **100%** |

Source: Va. Healthcare Workforce Data Center

*More than 80% of all pharmacy technicians are currently employed in the profession, 68% hold one full-time job, and 46% work between 40 and 49 hours per week.*

| Current Positions | | |
|---|---|---|
| **Positions** | **#** | **%** |
| **No Positions** | 457 | 4% |
| **One Part-Time Position** | 2,012 | 19% |
| **Two Part-Time Positions** | 140 | 1% |
| **One Full-Time Position** | 7,199 | 68% |
| **One Full-Time Position & One Part-Time Position** | 682 | 6% |
| **Two Full-Time Positions** | 30 | 0% |
| **More than Two Positions** | 34 | 0% |
| **Total** | **10,554** | **100%** |

Source: Va. Healthcare Workforce Data Center

| Current Weekly Hours | | |
|---|---|---|
| **Hours** | **#** | **%** |
| **0 Hours** | 457 | 4% |
| **1 to 9 Hours** | 346 | 3% |
| **10 to 19 Hours** | 494 | 5% |
| **20 to 29 Hours** | 856 | 8% |
| **30 to 39 Hours** | 2,770 | 27% |
| **40 to 49 Hours** | 4,704 | 46% |
| **50 to 59 Hours** | 373 | 4% |
| **60 to 69 Hours** | 100 | 1% |
| **70 to 79 Hours** | 81 | 1% |
| **80 or More Hours** | 117 | 1% |
| **Total** | **10,298** | **100%** |

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

| Income | | |
|---|---|---|
| **Annual Income** | **#** | **%** |
| **Volunteer Work Only** | 93 | 2% |
| **Less than $10,000** | 470 | 10% |
| **$10,000-$14,999** | 277 | 6% |
| **$15,000-$19,999** | 335 | 7% |
| **$20,000-$24,999** | 559 | 11% |
| **$25,000-$29,999** | 646 | 13% |
| **$30,000-$34,999** | 854 | 18% |
| **$35,000-$39,999** | 556 | 11% |
| **$40,000-$44,999** | 495 | 10% |
| **$45,000-$49,999** | 244 | 5% |
| **$50,000 or More** | 353 | 7% |
| **Total** | **4,882** | **100%** |

*Source: Va. Healthcare Workforce Data Center*

### At a Glance:

**Annual Income**
Median Income: $30k-$35k

**Benefits**
Health Insurance: 63%
Retirement: 58%

**Satisfaction**
Satisfied: 90%
Very Satisfied: 49%

*Source: Va. Healthcare Workforce Data Center*

| Job Satisfaction | | |
|---|---|---|
| **Level** | **#** | **%** |
| **Very Satisfied** | 5,147 | 49% |
| **Somewhat Satisfied** | 4,325 | 41% |
| **Somewhat Dissatisfied** | 717 | 7% |
| **Very Dissatisfied** | 339 | 3% |
| **Total** | **10,527** | **100%** |

*Source: Va. Healthcare Workforce Data Center*

*The typical pharmacy technician earns between $30,000 and $35,000 per year. In addition, 81% of all pharmacy technicians receive at least one employer-sponsored benefit, including 63% who have access to health insurance.*

| Employer-Sponsored Benefits | | | |
|---|---|---|---|
| **Benefit** | **#** | **%** | **% of Wage/Salary Employees** |
| **Paid Leave** | 5,739 | 66% | 60% |
| **Health Insurance** | 5,464 | 63% | 57% |
| **Dental Insurance** | 5,231 | 60% | 55% |
| **Retirement** | 5,023 | 58% | 53% |
| **Group Life Insurance** | 3,096 | 36% | 33% |
| **Signing/Retention Bonus** | 355 | 4% | 4% |
| **At Least One Benefit** | **7,037** | **81%** | **74%** |

*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 . . .? | # | % |
| Work Two or More Positions at the Same Time? | 1,209 | 9% |
| Switch Employers or Practices? | 472 | 4% |
| Experience Voluntary Unemployment? | 442 | 3% |
| Work Part-Time or Temporary Positions, but Would Have Preferred a Full-Time/Permanent Position? | 429 | 3% |
| Experience Involuntary Unemployment? | 223 | 2% |
| **Experienced At Least One** | **2,300** | **18%** |

Source: Va. Healthcare Workforce Data Center

*Only 2% of pharmacy technicians were involuntarily unemployed at some point in the past year. For comparison, Virginia's average monthly unemployment rate was 6.0%.[1]*

## At a Glance:

**Unemployment Experience**

Involuntarily Unemployed: 2%
Underemployed: 3%

**Turnover & Tenure**

Switched Jobs: 4%
New Location: 20%
Over 2 Years: 56%
Over 2 Yrs., 2nd Location: 45%

**Employment Type**

Hourly Wage: 91%

Source: Va. Healthcare Workforce Data Center

| Location Tenure | | | | |
|---|---|---|---|---|
| Tenure | Primary | | Secondary | |
| | # | % | # | % |
| Not Currently Working at This Location | 275 | 3% | 178 | 11% |
| Less than 6 Months | 751 | 8% | 218 | 13% |
| 6 Months to 1 Year | 863 | 9% | 168 | 10% |
| 1 to 2 Years | 2,448 | 25% | 354 | 21% |
| 3 to 5 Years | 2,593 | 26% | 336 | 20% |
| 6 to 10 Years | 1,257 | 13% | 179 | 11% |
| More than 10 Years | 1,746 | 18% | 239 | 14% |
| **Subtotal** | **9,932** | **100%** | **1,672** | **100%** |
| Did Not Have Location | 580 | | 11,104 | |
| Item Missing | 2,509 | | 245 | |
| **Total** | **13,021** | | **13,021** | |

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.*

*More than 90% of pharmacy technicians receive an hourly wage at their primary work location.*

| Employment Type | | |
|---|---|---|
| Primary Work Site | # | % |
| Hourly Wage | 8,464 | 91% |
| Salary/Commission | 738 | 8% |
| By Contract/Per Diem | 44 | 0% |
| Unpaid | 25 | 0% |
| Business/Practice Income | 13 | 0% |
| **Subtotal** | **9,283** | **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 2.8% and a high of 10.8%. The unemployment rate from December 2020 was still preliminary at the time of publication.

## At a Glance:

**Concentration**

| | |
|---|---|
| Top Region: | 25% |
| Top 3 Regions: | 68% |
| Lowest Region: | 2% |

**Locations**

| | |
|---|---|
| 2 or More (Past Year): | 19% |
| 2 or More (Now*): | 15% |

Source: Va. Healthcare Workforce Data Center

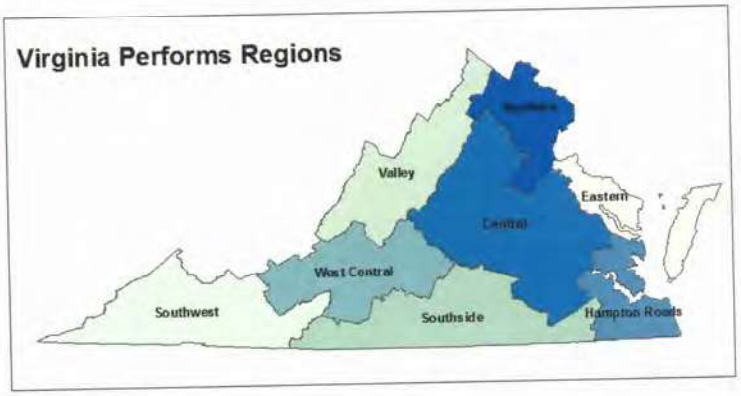
*More than two-thirds of all pharmacy technicians work in Central Virginia, Northern Virginia, and Hampton Roads.*

## A Closer Look:

**Regional Distribution of Work Locations**

| Virginia Performs Region | Primary Location | | Secondary Location | |
|---|---|---|---|---|
| | # | % | # | % |
| Central | 2,420 | 25% | 436 | 24% |
| Northern | 2,137 | 22% | 411 | 23% |
| Hampton Roads | 2,096 | 21% | 372 | 21% |
| West Central | 1,137 | 12% | 193 | 11% |
| Southwest | 711 | 7% | 102 | 6% |
| Valley | 647 | 7% | 83 | 5% |
| Southside | 423 | 4% | 86 | 5% |
| Eastern | 183 | 2% | 34 | 2% |
| Virginia Border State/D.C. | 29 | 0% | 31 | 2% |
| Other U.S. State | 19 | 0% | 51 | 3% |
| Outside of the U.S. | 3 | 0% | 7 | 0% |
| **Total** | **9,805** | **100%** | **1,806** | **100%** |
| Item Missing | 2,636 | | 112 | |

Source: Va. Healthcare Workforce Data Center




*Among all pharmacy technicians, 15% currently have multiple work locations, while 19% have had multiple work locations at some point in the past year.*

**Number of Work Locations**

| Locations | Work Locations in Past Year | | Work Locations Now* | |
|---|---|---|---|---|
| | # | % | # | % |
| 0 | 253 | 3% | 453 | 5% |
| 1 | 7,992 | 79% | 8,132 | 80% |
| 2 | 1,184 | 12% | 1,009 | 10% |
| 3 | 590 | 6% | 492 | 5% |
| 4 | 40 | 0% | 14 | 0% |
| 5 | 21 | 0% | 12 | 0% |
| 6 or More | 48 | 1% | 17 | 0% |
| **Total** | **10,129** | **100%** | **10,129** | **100%** |

*At the time of survey completion, December 2020.

Source: Va. Healthcare Workforce Data Center

## A Closer Look:

| Location Sector | | | | |
|---|---|---|---|---|
| Sector | Primary Location | | Secondary Location | |
| | # | % | # | % |
| **For-Profit** | 6,866 | 74% | 1,134 | 73% |
| **Non-Profit** | 1,512 | 16% | 232 | 15% |
| **State/Local Government** | 577 | 6% | 102 | 7% |
| **Veterans Administration** | 49 | 1% | 5 | 0% |
| **U.S. Military** | 180 | 2% | 43 | 3% |
| **Other Federal Gov't** | 124 | 1% | 27 | 2% |
| **Total** | **9,308** | **100%** | **1,543** | **100%** |
| **Did Not Have Location** | 580 | | 11,104 | |
| **Item Missing** | 3,133 | | 375 | |

*Source: Va. Healthcare Workforce Data Center*

### At a Glance:
**(Primary Locations)**

**Sector**

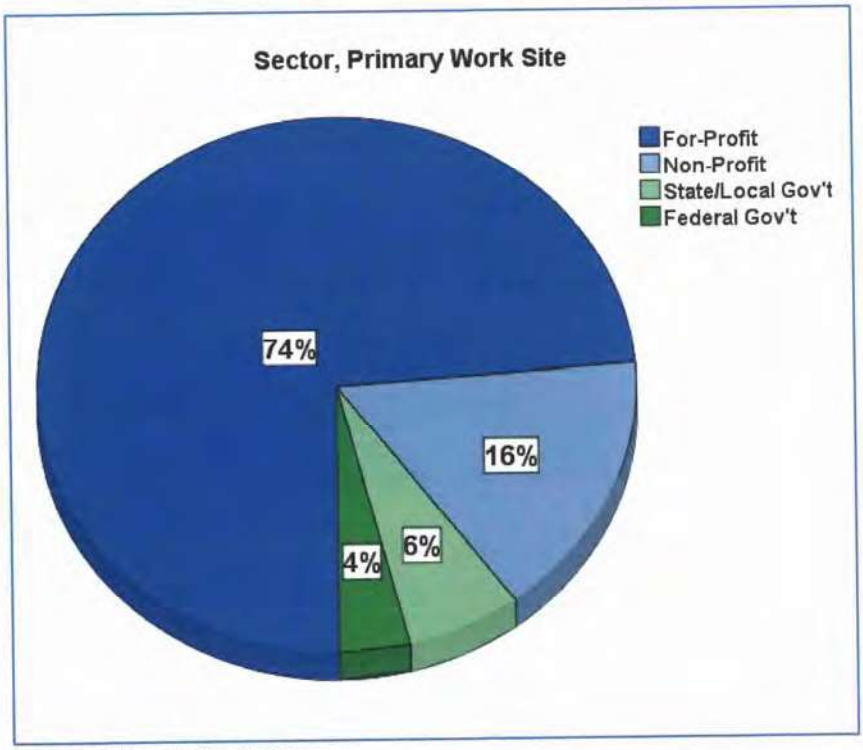
For-Profit: 74%
Federal: 4%

**Top Establishments**

Large Chain Pharmacy (11+ Stores): 33%
Hospital/Health System (Inpatient): 16%
Independent Pharmacy (1-4 Stores): 10%

*Source: Va. Healthcare Workforce Data Center*

*Nine out of every ten pharmacy technicians work in the private sector, including 74% who work in a for-profit establishment. Another 6% of pharmacy technicians work for a state or local government.*



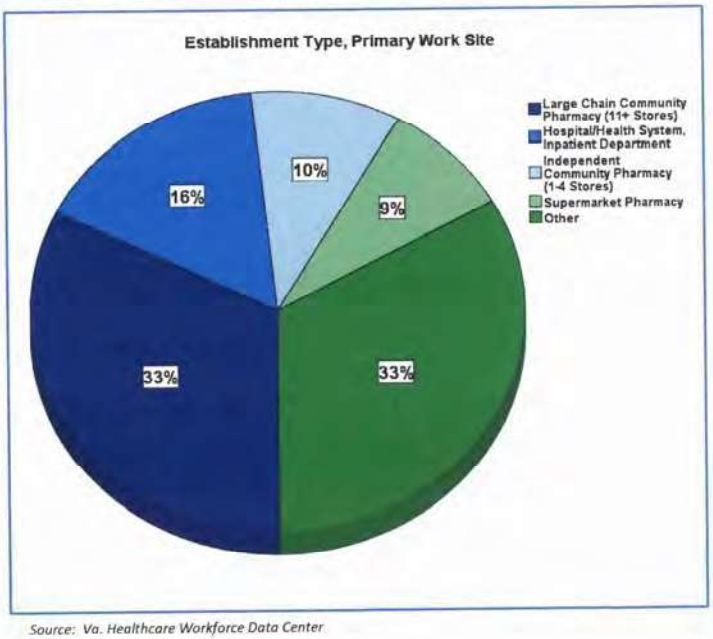

*Source: Va. Healthcare Workforce Data Center*

| Location Type | | | | |
|---|---|---|---|---|
| Establishment Type | Primary Location | | Secondary Location | |
| | # | % | # | % |
| Large Chain Community Pharmacy (11+ Stores) | 2,972 | 33% | 534 | 36% |
| Hospital/Health System, Inpatient Department | 1,452 | 16% | 174 | 12% |
| Independent Community Pharmacy (1-4 Stores) | 900 | 10% | 112 | 7% |
| Supermarket Pharmacy | 783 | 9% | 110 | 7% |
| Hospital/Health System, Outpatient Department | 632 | 7% | 65 | 4% |
| Nursing Home/Long-Term Care | 399 | 4% | 49 | 3% |
| Mass Merchandiser (i.e. Big Box Store) | 356 | 4% | 48 | 3% |
| Clinic-Based Pharmacy | 263 | 3% | 41 | 3% |
| Pharmacy Benefit Administration (e.g. PBM, Managed Care) | 212 | 2% | 18 | 1% |
| Home Health/Infusion | 130 | 1% | 12 | 1% |
| Mail Service Pharmacy | 110 | 1% | 16 | 1% |
| Small Chain Community Pharmacy (5-10 Stores) | 104 | 1% | 38 | 3% |
| Academic Institution | 49 | 1% | 32 | 2% |
| Wholesale Distributor | 43 | 0% | 12 | 1% |
| Manufacturer | 28 | 0% | 16 | 1% |
| Other | 703 | 8% | 219 | 15% |
| **Total** | **9,136** | **100%** | **1,496** | **100%** |
| Did Not Have Location | 580 | | 11,104 | |

*Source: Va. Healthcare Workforce Data Center*

*One-third of all pharmacy technicians in Virginia work in large chain community pharmacies, while another 16% work in the inpatient department of hospitals.*

*For pharmacy technicians who also have a secondary work location, 36% are employed by large chain community pharmacies, while 12% are employed at the inpatient department of hospitals.*




*Source: Va. Healthcare Workforce Data Center*

## At a Glance:
### (Primary Locations)

**Typical Time Allocation**

| | |
|---|---|
| Medication Disp.: | 70%-79% |
| Administration: | 10%-19% |
| Teaching: | 1%-9% |

**Roles**

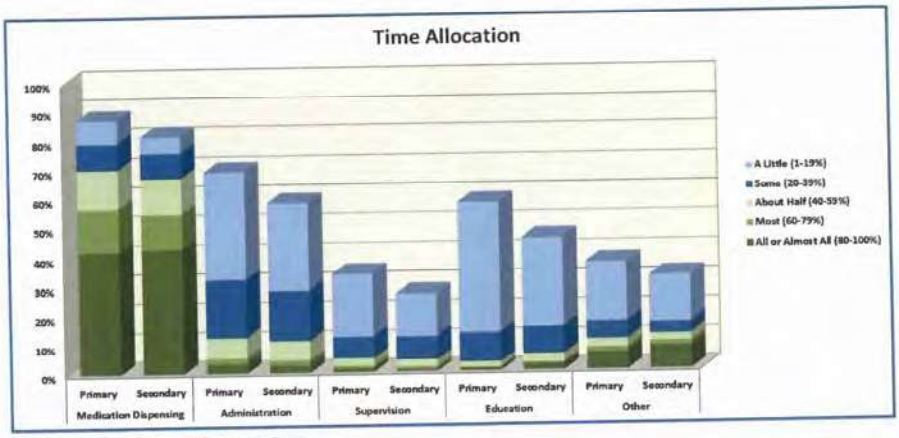
| | |
|---|---|
| Medication Disp.: | 57% |
| Administration: | 5% |
| Supervision: | 2% |
| Education: | 1% |

**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*

*Nearly 60% of all pharmacy technicians fill a medication dispensing & 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%) | 42% | 43% | 3% | 3% | 1% | 1% | 1% | 2% | 6% | 8% |
| Most (60-79%) | 15% | 12% | 2% | 2% | 1% | 1% | 0% | 1% | 1% | 2% |
| About Half (40-59%) | 14% | 12% | 7% | 7% | 3% | 3% | 2% | 3% | 3% | 3% |
| Some (20-39%) | 9% | 9% | 20% | 17% | 8% | 8% | 10% | 9% | 6% | 4% |
| A Little (1-19%) | 8% | 5% | 37% | 30% | 21% | 14% | 44% | 30% | 20% | 16% |
| None (0%) | 13% | 19% | 31% | 42% | 66% | 73% | 42% | 55% | 63% | 68% |

*Source: Va. Healthcare Workforce Data Center*

## A Closer Look:

| Retirement Expectations | | | | |
|---|---|---|---|---|
| Expected Retirement Age | All | | 50 and Over | |
| | # | % | # | % |
| Under Age 50 | 2,050 | 24% | - | - |
| 50 to 54 | 457 | 5% | 39 | 2% |
| 55 to 59 | 531 | 6% | 96 | 5% |
| 60 to 64 | 1,409 | 17% | 413 | 24% |
| 65 to 69 | 2,093 | 25% | 750 | 43% |
| 70 to 74 | 520 | 6% | 220 | 13% |
| 75 to 79 | 130 | 2% | 36 | 2% |
| 80 and Over | 116 | 1% | 24 | 1% |
| I Do Not Intend to Retire | 1,131 | 13% | 175 | 10% |
| Total | 8,437 | 100% | 1,753 | 100% |

Source: Va. Healthcare Workforce Data Center

## At a Glance:

**Retirement Expectations**

**All Pharmacy Technicians**

Under 65: 53%
Under 60: 36%

**Pharm. Tech. 50 and Over**

Under 65: 31%
Under 60: 8%

**Time Until Retirement**

Within 2 Years: 5%
Within 10 Years: 14%
Half the Workforce: By 2045

Source: Va. Healthcare Workforce Data Center

*More than 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, 20% of all pharmacy technicians expect to pursue additional educational opportunities, and 7% expect to increase their patient care hours.*

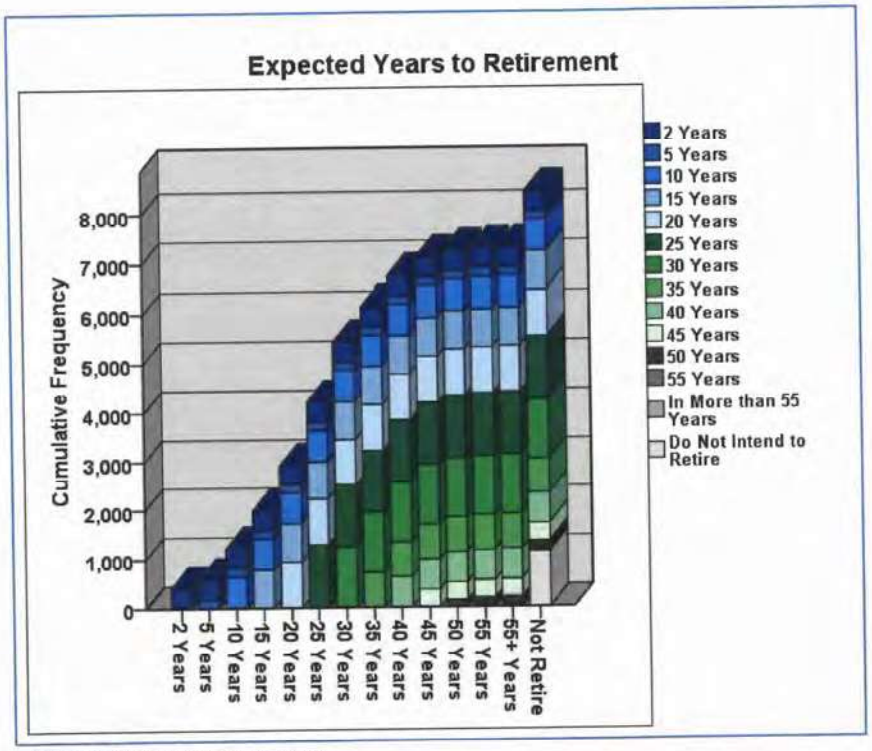
| Future Plans | | |
|---|---|---|
| Two-Year Plans: | # | % |
| **Decrease Participation** | | |
| Leave Profession | 1,130 | 9% |
| Leave Virginia | 522 | 4% |
| Decrease Patient Care Hours | 204 | 2% |
| Decrease Teaching Hours | 88 | 1% |
| **Increase Participation** | | |
| Pursue Additional Education | 2,610 | 20% |
| Increase Patient Care Hours | 949 | 7% |
| Increase Teaching Hours | 704 | 5% |
| Return to the Workforce | 137 | 1% |

Source: Va. Healthcare Workforce Data Center

*By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacy technicians. Only 5% of pharmacy technicians expect to retire in the next two years, while 14% expect to retire within the next ten years. Half of the current workforce expect to retire by 2045.*

| Time to Retirement | | | |
|---|---|---|---|
| Expect to Retire Within. . . | # | % | Cumulative % |
| 2 Years | 409 | 5% | 5% |
| 5 Years | 163 | 2% | 7% |
| 10 Years | 639 | 8% | 14% |
| 15 Years | 771 | 9% | 23% |
| 20 Years | 937 | 11% | 35% |
| 25 Years | 1,278 | 15% | 50% |
| 30 Years | 1,223 | 14% | 64% |
| 35 Years | 707 | 8% | 73% |
| 40 Years | 616 | 7% | 80% |
| 45 Years | 356 | 4% | 84% |
| 50 Years | 140 | 2% | 86% |
| 55 Years | 41 | 0% | 86% |
| In More than 55 Years | 25 | 0% | 87% |
| Do Not Intend to Retire | 1,131 | 13% | 100% |
| Total | 8,437 | 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 2040. Retirement will peak at 15% of the current workforce around 2045 before declining to below 10% of the current workforce again around 2055.*

## At a Glance:

**FTEs**

| | |
|---|---|
| Total: | 10,203 |
| FTEs/1,000 Residents[2]: | 1.195 |
| Average: | 0.82 |

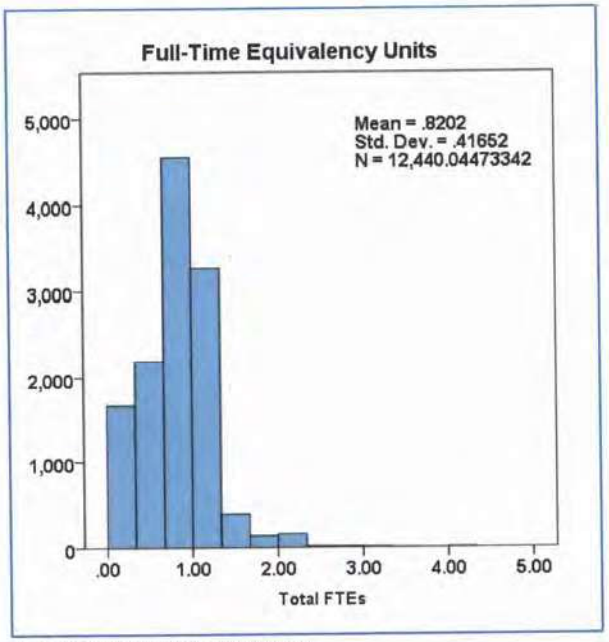
**Age & Gender Effect**

| | |
|---|---|
| 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:

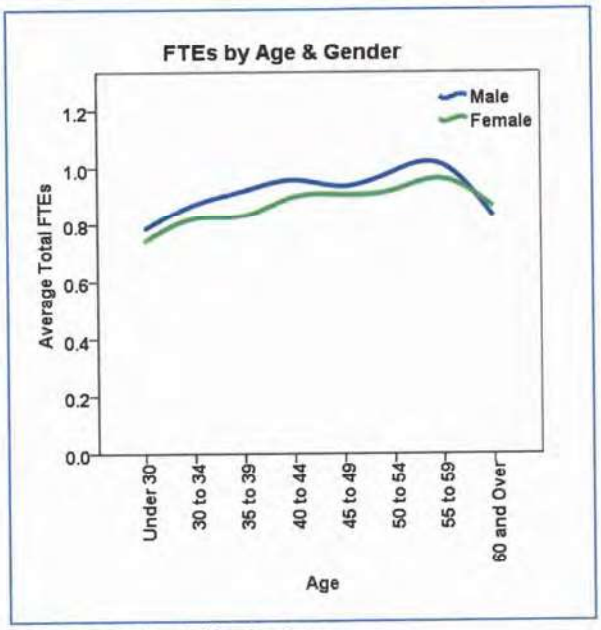



Source: Va. Healthcare Workforce Data Center

*The typical pharmacy technician provided 0.89 FTEs in 2020, or approximately 36 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 | 0.76 | 0.89 |
| 30 to 34 | 0.80 | 0.82 |
| 35 to 39 | 0.82 | 0.80 |
| 40 to 44 | 0.86 | 0.91 |
| 45 to 49 | 0.85 | 0.89 |
| 50 to 54 | 0.90 | 0.92 |
| 55 to 59 | 0.97 | 0.97 |
| 60 and Over | 0.83 | 0.80 |
| **Gender** | | |
| Male | 0.87 | 0.96 |
| Female | 0.83 | 0.91 |

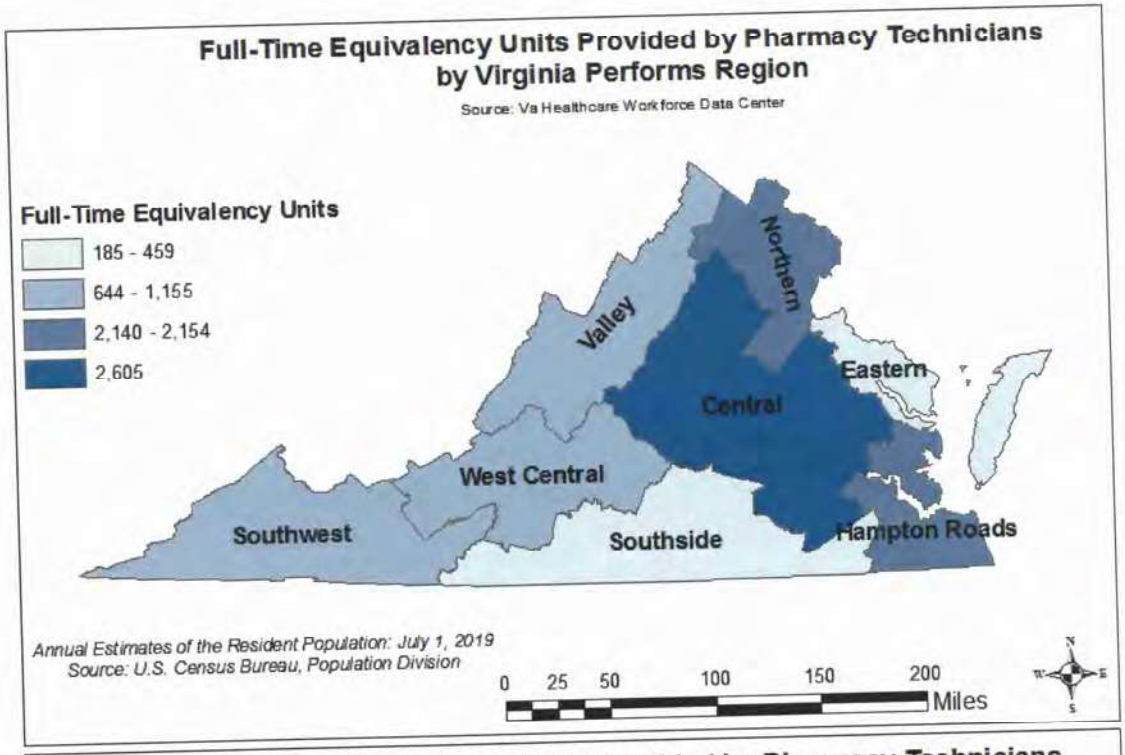
Source: Va. Healthcare Workforce Data Center

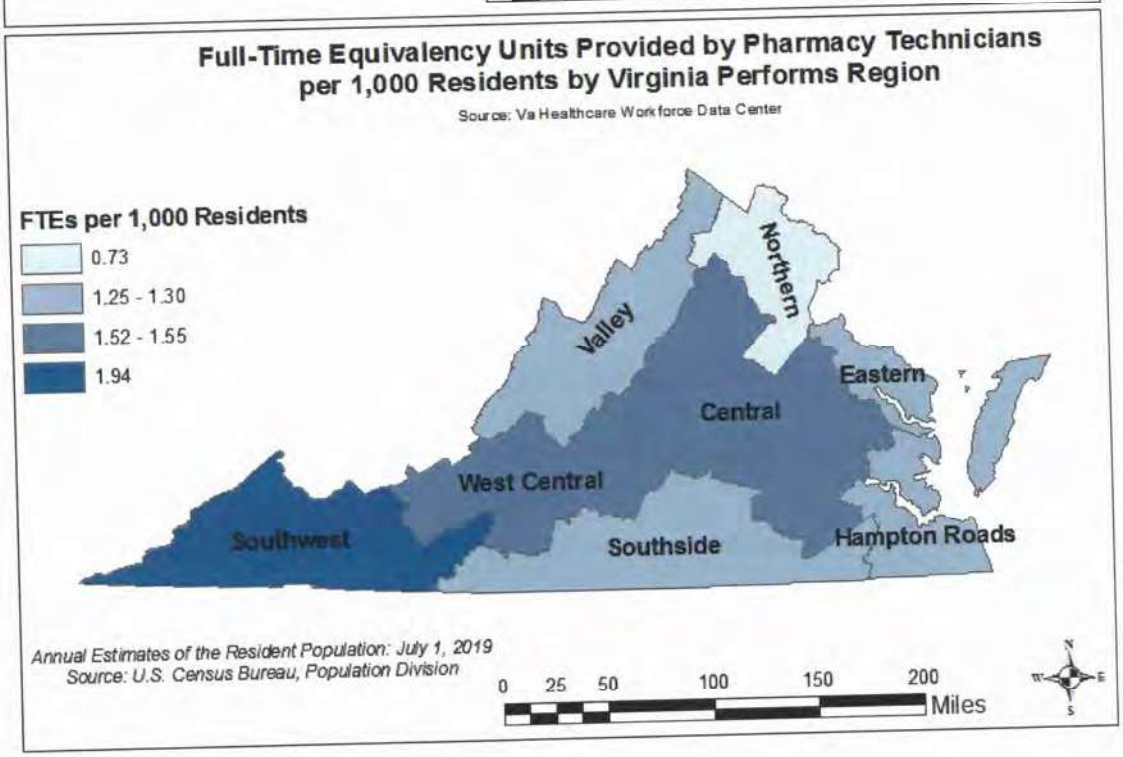


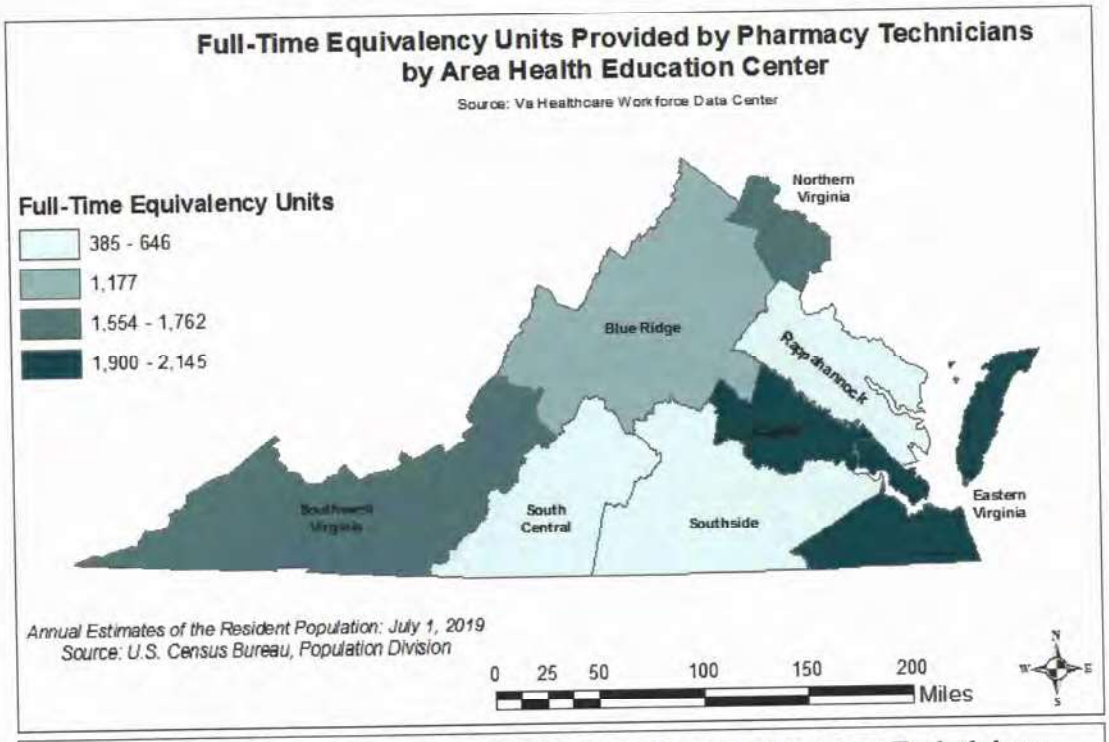

Source: Va. Healthcare Workforce Data Center

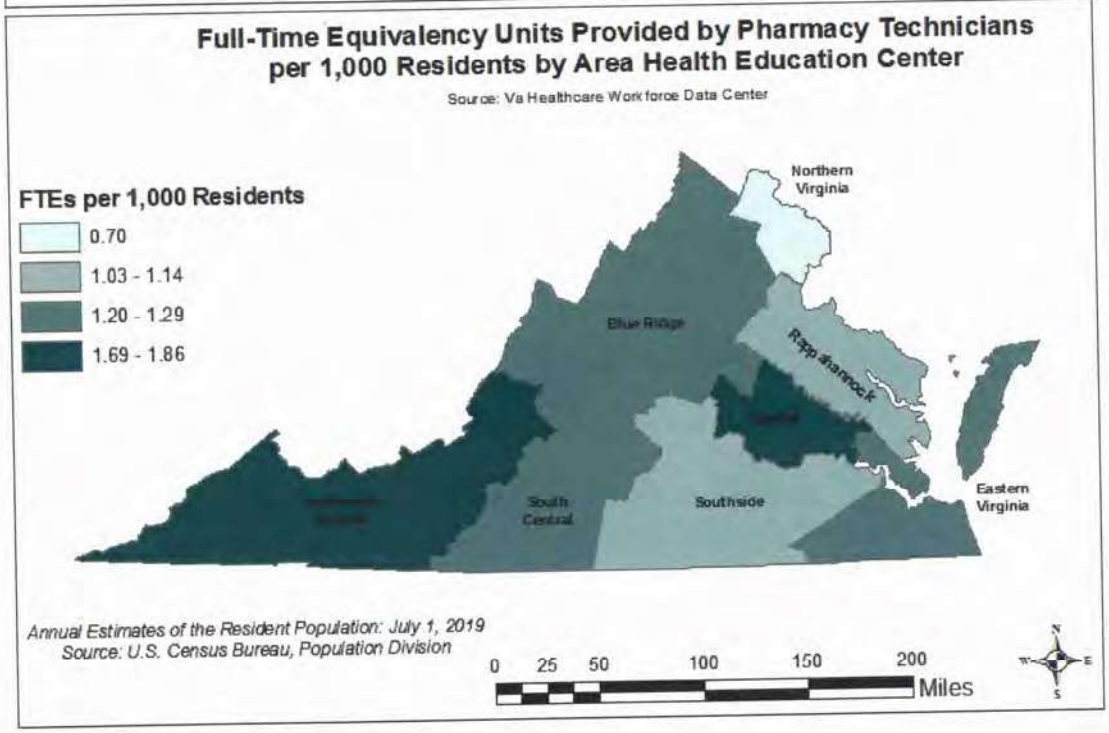
[2] Number of residents in 2019 was used as the denominator.
[3] Due to assumption violations in Mixed between-within ANOVA (Levene's Test was significant).

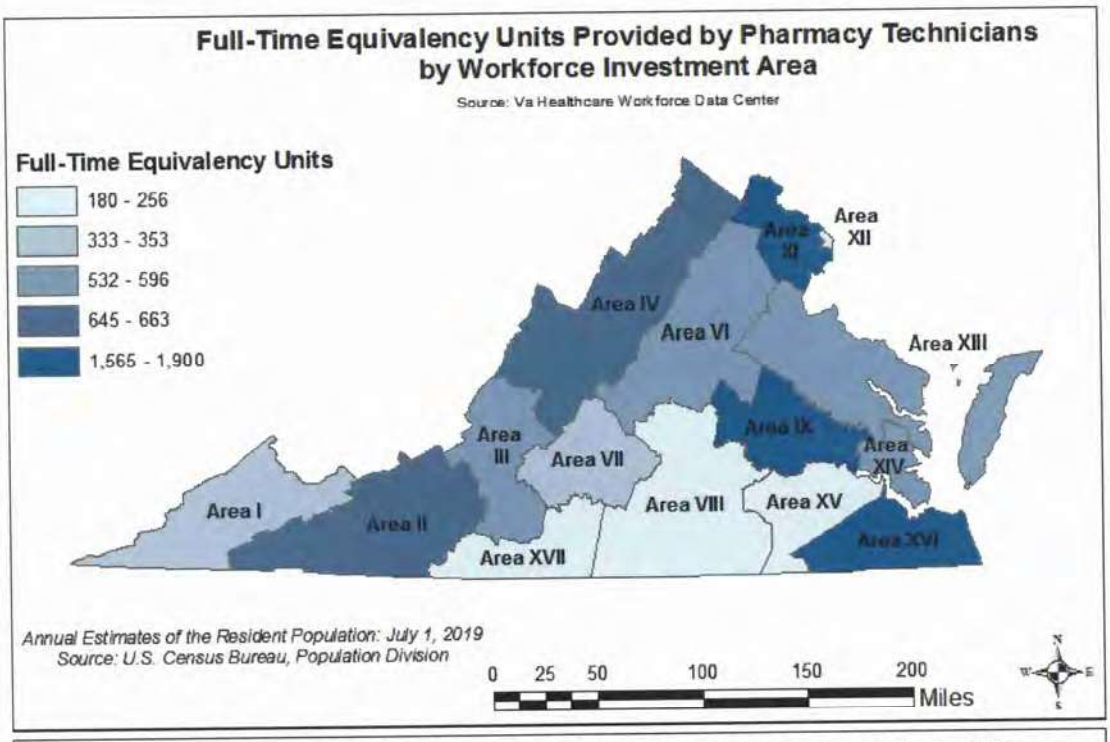
## Virginia Performs Regions

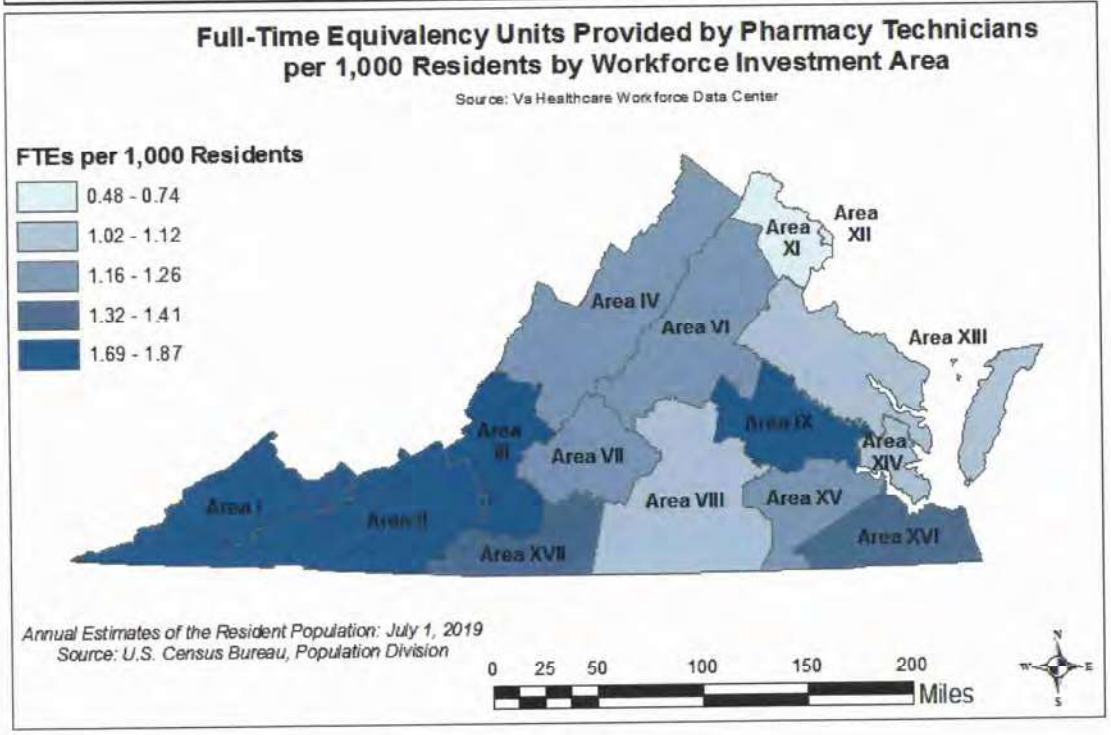


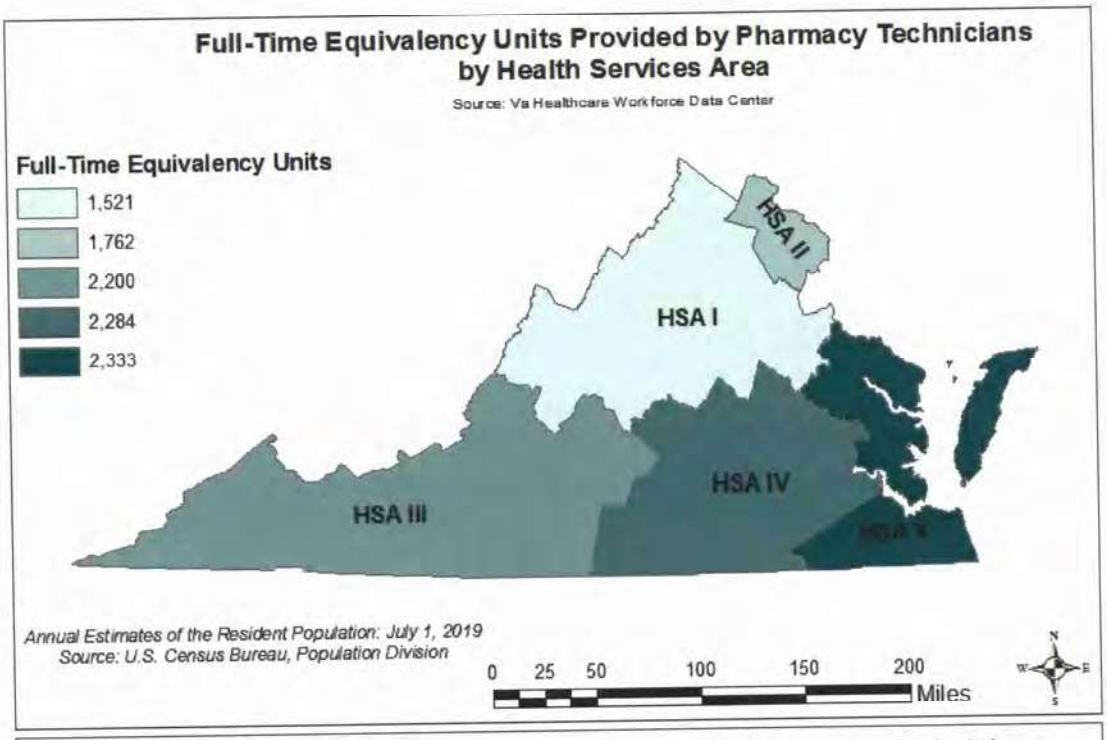



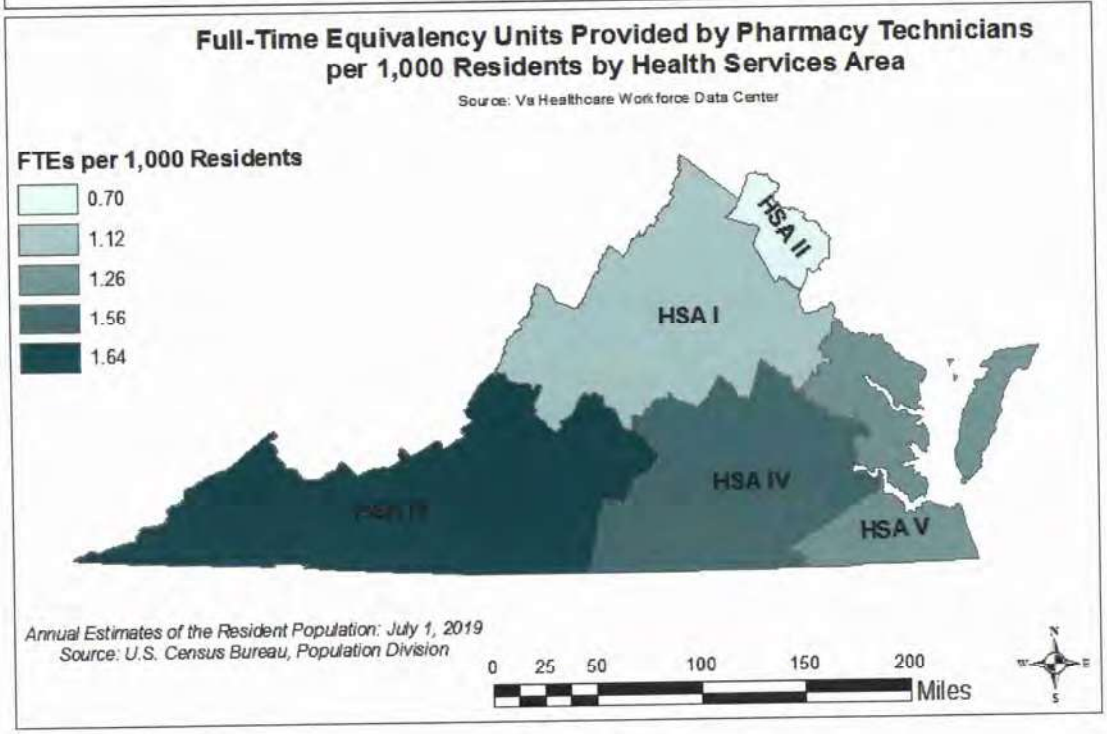

Full-Time Equivalency Units Provided by Pharmacy Technicians
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
385 - 646
1,177
1,554 - 1,762
1,900 - 2,145
Northern Virginia
Blue Ridge
Rappahannock
Eastern Virginia
South Central
Southside
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

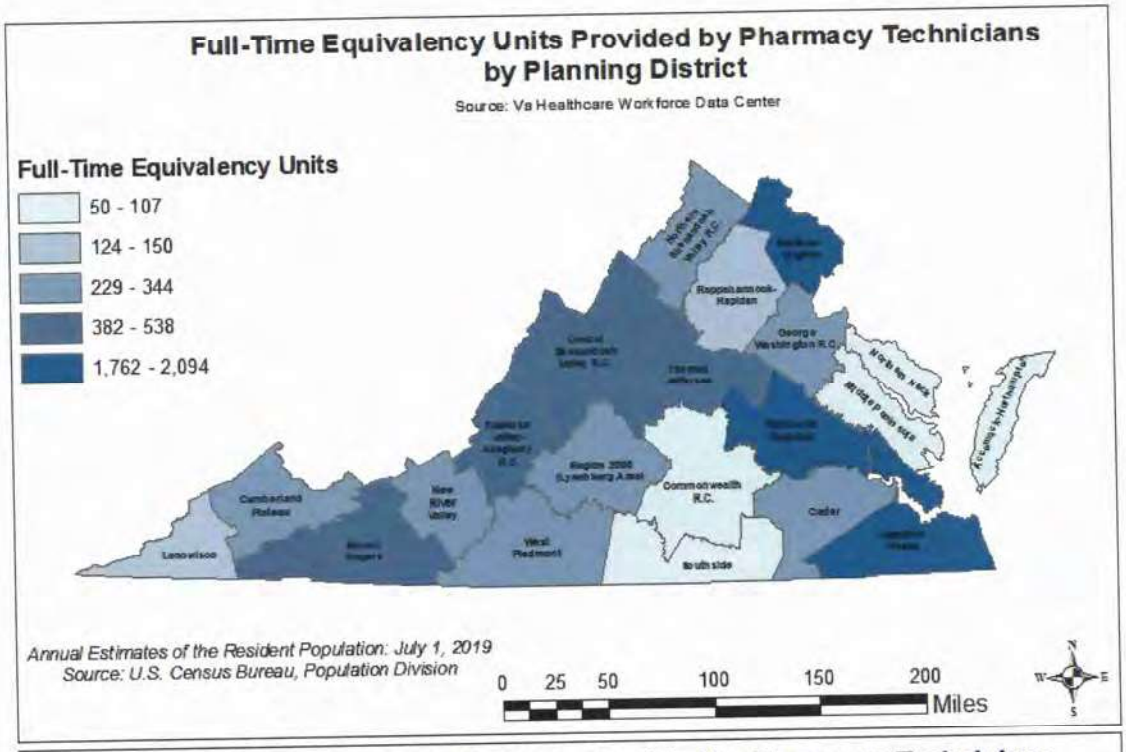

Full-Time Equivalency Units Provided by Pharmacy Technicians
per 1,000 Residents by Area Health Education Center
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.70
1.03 - 1.14
1.20 - 1.29
1.69 - 1.86
Northern Virginia
Blue Ridge
Rappahannock
Eastern Virginia
South Central
Southside
Annual Estimates of the Resident Population: July 1, 2019
Source: U.S. Census Bureau, Population Division
0 25 50 100 150 200
Miles

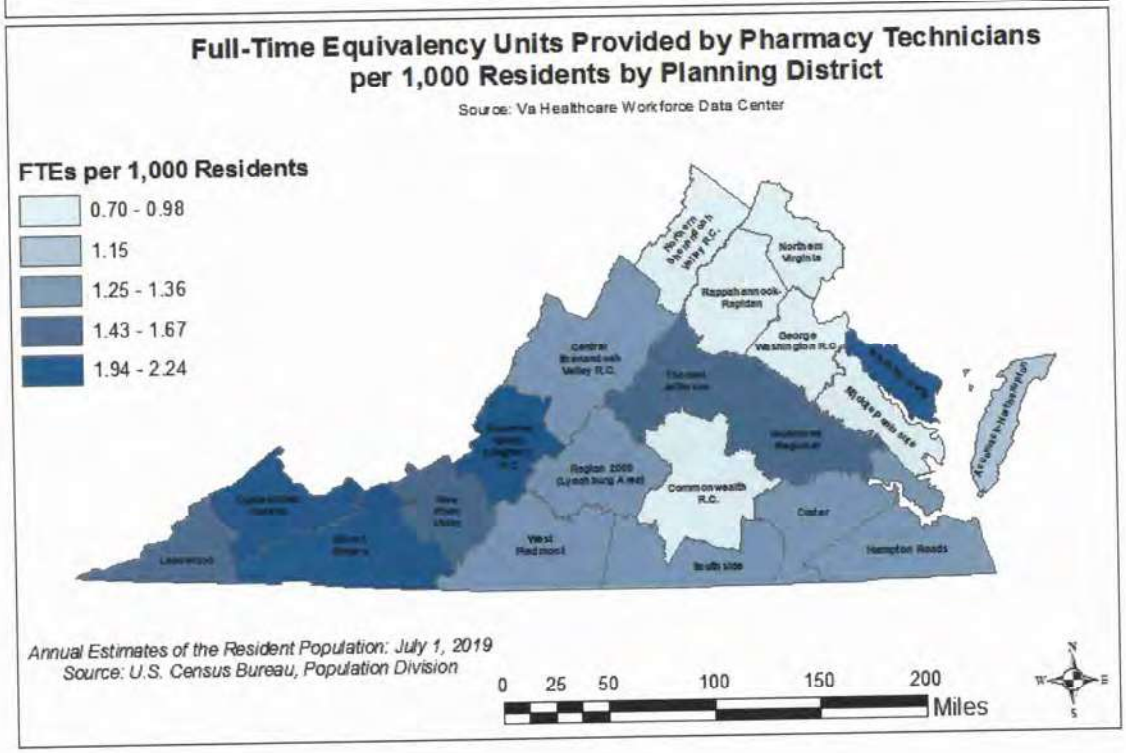

Full-Time Equivalency Units Provided by Pharmacy Technicians
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
180 - 256
333 - 353
532 - 596
645 - 663
1,565 - 1,900
Area I
Area II
Area III
Area IV
Area VI
Area VII
Area VIII
Area IX
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
Annual Estimates of the Resident Population: July 1, 2019
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
0.48 - 0.74
1.02 - 1.12
1.16 - 1.26
1.32 - 1.41
1.69 - 1.87
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, 2019
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
1,521
1,762
2,200
2,284
2,333
HSA II
HSA I
HSA III
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2019
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 Health Services Area
Source: Va Healthcare Workforce Data Center
FTEs per 1,000 Residents
0.70
1.12
1.26
1.56
1.64
HSA II
HSA I
HSA IV
HSA V
Annual Estimates of the Resident Population: July 1, 2019
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 by Planning District
Source: Va Healthcare Workforce Data Center
Full-Time Equivalency Units
50 - 107
124 - 150
229 - 344
382 - 538
1,762 - 2,094
Rappahannock-Rapidan
George Washington R.C.
Commonwealth R.C.
Cumberland Plateau
New River Valley
West Piedmont
Southside
Crater
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2019
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
0.70 - 0.98
1.15
1.25 - 1.36
1.43 - 1.67
1.94 - 2.24
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Commonwealth R.C.
West Piedmont
Southside
Crater
Hampton Roads
Annual Estimates of the Resident Population: July 1, 2019
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+ | 8,382 | 78.37% | 1.276 | 1.131 | 1.471 |
| Metro, 250,000 to 1 Million | 1,286 | 79.63% | 1.256 | 1.113 | 1.448 |
| Metro, 250,000 or Less | 1,264 | 79.91% | 1.251 | 1.109 | 1.443 |
| Urban, Pop. 20,000+, Metro Adj. | 295 | 87.12% | 1.148 | 1.017 | 1.323 |
| Urban, Pop. 20,000+, Non-Adj. | 0 | NA | NA | NA | NA |
| Urban, Pop. 2,500-19,999, Metro Adj. | 708 | 79.66% | 1.255 | 1.112 | 1.447 |
| Urban, Pop. 2,500-19,999, Non-Adj. | 513 | 80.51% | 1.242 | 1.101 | 1.432 |
| Rural, Metro Adj. | 282 | 79.43% | 1.259 | 1.116 | 1.451 |
| Rural, Non-Adj. | 210 | 83.81% | 1.193 | 1.057 | 1.376 |
| Virginia Border State/D.C. | 767 | 60.63% | 1.649 | 1.462 | 1.902 |
| Other U.S. State | 451 | 43.02% | 2.325 | 2.060 | 2.680 |

*Source: Va. Healthcare Workforce Data Center*

| Age | Age Weight | | | Total Weight | |
|---|---|---|---|---|---|
| | # | Rate | Weight | Min. | Max. |
| Under 30 | 4,310 | 66.75% | 1.498 | 1.323 | 2.680 |
| 30 to 34 | 2,364 | 77.12% | 1.297 | 1.146 | 2.320 |
| 35 to 39 | 1,878 | 81.04% | 1.234 | 1.090 | 2.208 |
| 40 to 44 | 1,387 | 81.54% | 1.226 | 1.083 | 2.194 |
| 45 to 49 | 1,148 | 86.85% | 1.151 | 1.017 | 2.060 |
| 50 to 54 | 1,095 | 86.12% | 1.161 | 1.026 | 2.078 |
| 55 to 59 | 872 | 84.17% | 1.188 | 1.049 | 2.125 |
| 60 and Over | 1,104 | 78.71% | 1.270 | 1.122 | 2.273 |

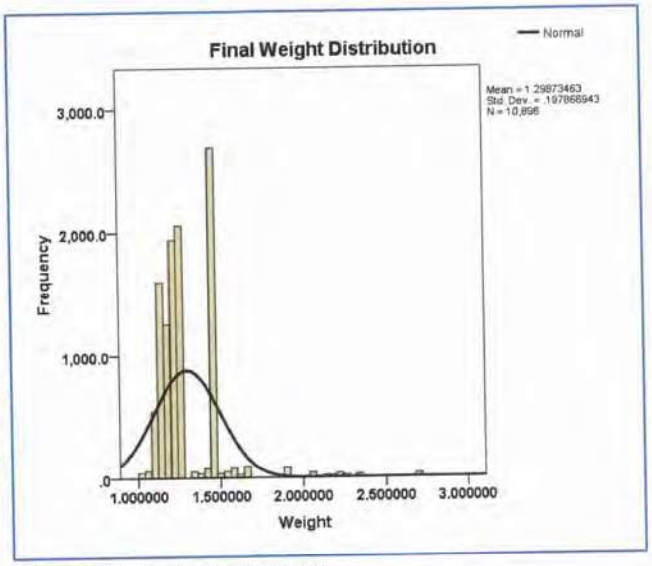
*Source: Va. Healthcare Workforce Data Center*

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: 0.769600**




*Source: Va. Healthcare Workforce Data Center*

**Agenda Item: Regulatory Actions - Chart of Regulatory Actions**
**As of September 13, 2021**

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Reporting of immunizations to VIIS [Action 5598]<br>Emergency - *Register Date: 10/12/20* [Stage 9064] |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Use of medication carousels and RFID technology [Action 5480]<br>Proposed - *Register Date: 8/16/21 Comment closes 10/15/21* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Implementation of legislation for pharmacists initiating treatment [Action 5604]<br>Proposed - *At Secretary's Office for 88 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>Final - *At Governor's Office for 1209 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | (E) Scheduling of chemicals in Schedule I [Action 5750]<br>Final - *Register Date: 8/16/21 Effective: 9/15/21* |
| [18 VAC 110 - 21] | Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians | Implementation of legislation for registration of pharmacy technicians [Action 5603]<br>Proposed - *At Secretary's Office for 88 days* |
| [18 VAC 110 - 30] | Regulations for Practitioners of the Healing Arts to Sell Controlled Substances | Limited license for prescribing Schedule VI drugs in non-profit clinics [Action 5605]<br>Proposed - *Register Date: 8/16/21 Comment closes: 10/15/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Amendments resulting from SB976 of the 2020 General Assembly [Action 5629]<br>Emergency/NOIRA - *Register Date: 3/1/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Response to petition for rulemaking [Action 5611]<br>NOIRA - *Register Date: 3/1/21* [Stage 9081] |

| | | |
|---|---|---|
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Registered agents and wholesale distribution [Action 5398]<br>Proposed - *Register Date: 3/1/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452]<br>Proposed - *Register Date: 5/24/21* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | (E) Changes relating to 2021 legislation and previous amendments [Action 5765]<br>Final - *Register Date: 8/2/21*<br>*Effective: 9/1/21* |

# Department of Health Professions
# Regulatory/Policy Actions – 2021 General Assembly

**EMERGENCY REGULATIONS:**

| Legislative source | Mandate | Promulgating agency | Board adoption date | Effective date Within 280 days of enactment |
|---|---|---|---|---|
| HB2079 | Authorization for a pharmacist to initiate treatment certain drugs, devices, controlled paraphernalia, and supplies and equipment described in § **54.1-3303.1** | Pharmacy | 9/24/21 | |

**EXEMPT REGULATORY ACTIONS**

| Legislative source | Mandate | Promulgating agency | Adoption date | Effective date |
|---|---|---|---|---|
| HB1988 | Changes to pharmaceutical processors | Pharmacy | 7/6/21 | By Sept. 1st |
| HB2218/SB1333 | Sale of cannabis botanical products | Pharmacy | 7/6/21 | By Sept. 1st |
| HB2218/SB1333 | Revision of fee schedule for pharmaceutical processors and dispensaries to cover cost of new data system | Pharmacy | No planned adoption date | |
| SB1464 | Deletion of sections of 322 with chemicals now scheduled in Code | Pharmacy | 9/24/21 | |

**NON-REGULATORY ACTIONS**

| Legislative source | Affected agency | Action needed | Due date |
|---|---|---|---|
| HB1304/SB830 (2020) | Pharmacy | To convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform. | November 1, 2021 |
| HB1987 | Boards with prescriptive authority | Revise guidance documents with references to 54.1-3303 | As boards meeting after July 1 |
| HB2079 | Pharmacy (with Medicine & VDH) | To establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § **54.1-3303.1**. Such | Concurrent with emergency regulations |

| | | | |
|---|---|---|---|
| | | protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment. | |
| HB2079 | Pharmacy (with Medicine) | To convene a work group to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of 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, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety. | November 1, 2021 |
| HB2218/SB1333 | Pharmacy | To work on acquisition of a new data system/analysis of costs | |

## Future Policy Actions:

**HB2559 (2019)** - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by **November 1, 2022**.

**Agenda Item: Adoption of Emergency Regulations – Pharmacists initiating treatment**

**Included in your agenda package are:**

Copy of the legislation passed in the 2021 General Assembly (HB2079) – note 3rd enactment clause requiring adoption of regulations within 280 days.

Copy of the draft emergency regulations as recommended by the Workgroup (see minutes from the Workgroup meeting on August 9, 2021 and August 17, 2020 in agenda package)

**Board action:**

Adoption of emergency regulations as required by the 3rd enactment clause in the legislation. Amendments that are underlined in black are the current emergency regulations from the 2020 legislation and workgroup. Amendments in RED are the recommended amendments from the 2021 legislation and workgroup.

## CHAPTER 214

*An Act to amend and reenact §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia, relating to pharmacists; initiation of treatment; certain drugs and devices.*

[H 2079]

Approved March 18, 2021

**Be it enacted by the General Assembly of Virginia:**

**1. That §§ 54.1-3300 and 54.1-3303.1 of the Code of Virginia are amended and reenacted as follows:**

**§ 54.1-3300. Definitions.**

As used in this chapter, unless the context requires a different meaning:

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include (i) the proper and safe storage and distribution of drugs; (ii) the maintenance of proper records; (iii) the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; (iv) the management of patient care under the terms of a collaborative agreement as defined in this section; and (v) the initiating of treatment with or dispensing or administering of certain drugs, *devices, or controlled paraphernalia* in accordance with the provisions of § 54.1-3303.1.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34

(§ 54.1-3400 et seq.) unless the context requires a different meaning.

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

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

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

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

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

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

*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.*

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

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

**2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2021. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to recommend protocols to the Board of Pharmacy for review and implementation. No pharmacist shall initiate treatment with or dispense or administer such drug, device, controlled paraphernalia, or supply or equipment until such protocols have been adopted. Such protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment pursuant to § 54.1-3303.1 of the Code of Virginia, as amended by this act.**

**3. That the Board of Pharmacy, in collaboration with the Board of Medicine, shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment. Such regulation shall include authorization for a pharmacist to initiate treatment with or dispense or administer drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1 of the Code of Virginia, as amended by this act, in accordance with protocols adopted by the Board of Pharmacy. The Board of Pharmacy shall convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine to develop recommendations and propose language for inclusion in such regulations.**

**4. That the Board of Pharmacy shall convene a work group composed of an equal number of**

representatives of the Boards of Pharmacy and Medicine as well as representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board of Pharmacy may deem appropriate to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of 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, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety and report its recommendations to the Governor and the Chairmen of the Joint Commission on Health Care, the House Committee on Health, Welfare and Institutions, and the Senate Committee on Education and Health by November 1, 2021.

**Board of Pharmacy**

**Implementation of legislation for pharmacists initiating treatment**

Chapter 20

Regulations Governing the Practice of Pharmacy

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

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

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

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

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

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

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

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

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

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

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

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs, ~~and~~ devices, controlled paraphernalia, and other supplies and equipment 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; ~~and~~

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

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

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.

B. Pharmacists who initiate treatment with, dispense, or administer a drug, ~~or~~ device, controlled paraphernalia, or other supplies or equipment pursuant to subsection A shall:

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

2. Notify the patient's primary health care provider that treatment has been initiated with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. 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.

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 U.S.C. § 1320d et seq.

**Agenda Item: Adoption of Protocols – Pharmacists initiating treatment**

**Included in your agenda package are:**

Copy of the summary of legislation passed in the 2021 General Assembly

Copy of the Statewide Protocols as recommended by the Workgroup (see minutes from the Workgroup meeting on August 9, 2021 in agenda package)

**Board action:**

Adoption of Protocols (Board should review all protocols and adopt in a block unless there are amendments to one or more of the protocols).

# HB 2079 Pharmacists; initiation of treatment with and dispensing and administering of drugs and devices.

Introduced by: **Sam Rasoul | all patrons** ... **notes | add to my profiles | history**

## SUMMARY AS PASSED HOUSE:

**Pharmacists; initiation of treatment; certain drugs and devices.** Expands provisions governing the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists to allow the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia to persons 18 years of age or older, in accordance with protocols developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health, and of (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) tuberculin purified protein derivative for tuberculosis testing; (iii) 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 (iv) drugs, devices, controlled paraphernalia, 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. The bill requires any pharmacist who administers a vaccination pursuant to clause (i) to report such administration to the Virginia Immunization Information System. The bill also (a) requires the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, to establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, and controlled paraphernalia by pharmacists in accordance with the provisions of the bill by November 1, 2021; (b) requires the Board of Pharmacy, in collaboration with the Board of Medicine, to adopt regulations within 280 days of the bill's enactment to implement the provisions of the bill; and (c) requires the Board of Pharmacy to convene a work group composed of an equal number of representatives of the Boards of Pharmacy and Medicine and other stakeholders to provide recommendations regarding the developing of protocols for the initiation of treatment with and dispensing and administering of certain drugs and devices by pharmacists to persons 18 years of age or older.

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Vaccine Statewide Protocol

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

### PHARMACIST EDUCATION AND TRAINING

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

### PATIENT INCLUSION CRITERIA

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

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

### PATIENT EXCLUSION CRITERIA

Patients NOT eligible for vaccine under this protocol:

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

### COUNSELING

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

### RECORDKEEPING

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

**NOTIFICATION OF PRIMARY CARE PROVIDER**

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

# VIRGINIA BOARD OF PHARMACY

## Pharmacist Statewide Protocol to Lower Out-of-Pocket Expenses

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

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

### PHARMACIST EDUCATION AND TRAINING

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

### PATIENT INCLUSION CRITERIA

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

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

### EXAMPLES OF INCLUDED DEVICES AND CONTROLLED PARAPHERNALIA

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

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

- Ostomy products and supplies

## RECORDKEEPING

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

## NOTIFICATION OF PRIMARY CARE PROVIDER

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

[1]"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book.", § 54.1-3401.

# VIRGINIA BOARD OF PHARMACY

## Preventive Care

## HIV Pre-Exposure Prophylaxis (PrEP) Statewide Protocol

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

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

### STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PrEP Patient Intake Form (pg. 2-3)
- Utilize the standardized PrEP Assessment and Treatment Care Pathway (pg.4-8)
- Utilize the standardized PrEP Provider Fax (pg.10)

### PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

# Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form - DRAFT

## (CONFIDENTIAL-Protected Health Information)

Date ____/____/_____ Date of Birth ____/____/_____ Age____

Legal Name_____ Preferred Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____

Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

Any allergies to medications? Yes / No If yes, please list _____

**Background Information:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you and what Human Immunodeficiency Virus (HIV) and Sexually Transmitted Infection (STI) testing is recommended.

**Do you answer yes to any of the following?** **□ yes □ no**

| |
|---|
| 1. Do you sexually partner with men, women, transgender, or non-binary people? |
| 2. Please estimate how often you use condoms for sex. Please estimate the date of the last time you had sex without a condom.<br>_____% of the time<br>__/__/__ last sex without a condom |
| 3. Do you have oral sex?<br>• Giving- you perform oral sex on someone else<br>• Receiving- someone performs oral sex on you |
| 4. Do you have vaginal sex?<br>• Receptive- you have a vagina and you use it for vaginal sex<br>• Insertive- you have a penis and you use it for vaginal sex |
| 5. Do you have anal sex?<br>• Receptive- someone uses their penis to perform anal sex on you<br>• Insertive- you use your penis to perform anal sex on someone else |
| 6. Do you inject drugs? |
| 7. Are you in a relationship with an HIV-positive partner? |
| 8. Do you exchange sex for money or goods? (includes paying for sex) |
| 9. Do you use poppers (inhaled nitrates) and/or methamphetamine for sex? |

**Medical History:** These questions are highly confidential and help the pharmacist to determine if PrEP is right for you.

| | |
|---|---|
| 1. Have you ever tested positive for Human Immunodeficiency Virus (HIV)? | □ yes □ no |
| 2. Do you see a (healthcare provider) for management of Hepatitis B? | □ yes □ no |
| 3. Have you ever received an immunization for Hepatitis B? If yes, when:<br>• If no, would you like a Hepatitis B immunization today? □ yes □ no | □ yes □ no<br>Date of vaccine __/__/__ |
| 4. Do you see a healthcare provider for problems with your kidneys? | □ yes □ no |
| 5. Do you take non-steroid anti-inflammatory drugs (NSAIDS)?<br>• Includes: Advil/Motrin (ibuprofen), aspirin, Aleve (naproxen) | □ yes □ no |
| 6. Are you currently or planning to become pregnant or breastfeeding? | □ yes □ no |
| 7. Do you have any other medical problems the pharmacist should know? If yes, list them here: _____ | □ yes □ no |

## Pre-Exposure Prophylaxis (PrEP) Self-Screening Patient Intake Form - DRAFT

(CONFIDENTIAL-Protected Health Information)

**Testing and Treatment:**

| | |
|---|---|
| 1. I understand that I must get an HIV test every 90 days to get my PrEP prescription filled. The pharmacist must document a negative HIV test to fill my PrEP prescription.<br>• I may be able to have tests performed at the pharmacy.<br>• I can bring in my HIV test results, showing negative HIV and/or STI testing, within the last 2 weeks.<br>o I brought my labs in today □ Yes □ No<br>• I understand that if I have condomless sex within 2 weeks before and between the time I get my HIV test and when I get my PrEP that the test results may not be accurate. This could lead to PrEP drug resistance if I become HIV positive and I will need a repeat HIV test within one month. | □ Yes □ No |
| 2. I understand that I must complete STI screening at least every 6 months while on PrEP. Undiagnosed STIs will increase the risk of getting HIV.<br>• I understand if I have condomless sex between the time I get my STI testing and when I get my PrEP that the results may not be accurate. | □ Yes □ No |
| 3. I understand that the effectiveness of PrEP is dependent on my taking all my doses. Missing doses increases the risk of getting HIV. | □ Yes □ No |

**Please write down the names of any prescription or over the counter medications or supplements you take. Please include herbal and nutritional products as well. This helps the pharmacist make sure there are no harmful interactions with your PrEP.**

**Please list any questions you have for the pharmacy staff:**

**Patient Signature:** _____ **Date:** _____

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway - DRAFT

## (CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

### Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

| Risk Factor: | Notes and considerations |
|---|---|
| 1. Sexual partners | • MSM activity is highest risk for HIV.<br>• Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present. |
| 2. Estimated condom use _____% of the time __/__/__ last sex without a condom | • Condomless sex greatly increases risk of HIV and STIs.<br>• For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).<br>• Condomless sex within last 14 days, repeat HIV test in one month. |
| 3. Oral sex | • Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals.<br>• STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex. |
| 4. Vaginal sex | • Receptive vaginal sex can be high risk for HIV.<br>• Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present. |
| 5. Anal sex | • Receptive anal sex has the most risk of HIV of any sex act.<br>• Insertive anal sex has high risk for HIV.<br>• STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex. |
| 6. Injection drug use | • Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes. |
| 7. HIV-positive partner | • People living with HIV who have undetectable viral loads will not transmit HIV.<br>• For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP. |
| 8. Exchanging sex for money or goods | • People who buy or sell sex are at high risk for HIV. |
| 9. Popper and/or methamphetamine use | • Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.<br>• Recommend adequate lubrication in persons who use poppers for sex. |

**1. Is one or More Risk Factor Present:** □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway - DRAFT

## (CONFIDENTIAL- Protected Health Information)

Name_____ Date of Birth_____ Age_____ Today's Date_____

### Background Information/ HIV and STI risk factors:

Document that a risk factor is present (circle below) and refer to the notes and considerations below to evaluate the risk factor(s). If a person has one or more risk factor, PrEP is recommended. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

| Risk Factor: | Notes and considerations |
|---|---|
| 1. Sexual partners | • MSM activity is highest risk for HIV.<br>• Men who have insertive vaginal sex may not be at high risk of HIV unless other risk factors are present. |
| 2. Estimated condom use _____% of the time<br>__/__/__ last sex without a condom | • Condomless sex greatly increases risk of HIV and STIs.<br>• For patients with condomless sex within the last 72 hours, consider Post-Exposure Prophylaxis (PEP).<br>• Condomless sex within last 14 days, repeat HIV test in one month. |
| 3. Oral sex | • Oral sex is not considered high risk for HIV unless there is blood or ulcerations in the mouth or genitals.<br>• STIs such as gonorrhea and chlamydia can inhabit the mouth and should be screened for in persons who have oral sex. |
| 4. Vaginal sex | • Receptive vaginal sex can be high risk for HIV.<br>• Insertive vaginal sex is not considered high risk for HIV unless other risk factors are present. |
| 5. Anal sex | • Receptive anal sex has the most risk of HIV of any sex act.<br>• Insertive anal sex has high risk for HIV.<br>• STIs such as gonorrhea and chlamydia can inhabit the rectum and should be screened in persons who have anal sex. |
| 6. Injection drug use | • Injection drug use is high risk for HIV. Consider referral for syringe exchange or sale of clean syringes. |
| 7. HIV-positive partner | • People living with HIV who have undetectable viral loads will not transmit HIV.<br>• For partners of people living with HIV, consider partner's HIV viral load when recommending PrEP. |
| 8. Exchanging sex for money or goods | • People who buy or sell sex are at high risk for HIV. |
| 9. Popper and/or methamphetamine use | • Popper (inhaled nitrates) and/or methamphetamine use is associated with an increased risk of HIV.<br>• Recommend adequate lubrication in persons who use poppers for sex. |

**1. Is one or More Risk Factor Present:** □ **yes** □ ***no***

- If yes, HIV PrEP is recommended. Proceed to next section: Testing.
- *If no, HIV PrEP is not recommended. Refer to a healthcare provider.*

## Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway - DRAFT

(CONFIDENTIAL- Protected Health Information)

**Testing:**

The pharmacist must verify appropriate labs are complete. *Italics* below indicate need for referral.

| Test Name | Date of Test | Result | Needs referral |
|---|---|---|---|
| • HIV ag/ab (4th gen) test: | ____/____/____ | □ *reactive* □ *indeterminate* □ negative | □ *Yes* |
| *Reactive and indeterminate tests are an automatic referral to county health or the patient's healthcare provider for confirmatory testing.* NOTE: HIV test must be performed within the 14 days prior to prescribing and dispensing. | | | |
| • Syphilis/Treponemal antibody: | ____/____/____ | □ *reactive* □ *indeterminate* □ negative | □ *Yes* |
| *Reactive treponemal antibody testing will result in an automatic referral to county health or the patient's primary care provider for follow-up and confirmatory testing.* | | | |
| • Hepatitis B surface antigen: | ____/____/____ | □ *positive* □ negative | □ *Yes* |
| *Positive surface antigen indicates either acute or chronic Hepatitis B and PrEP should be referred to county health or a specialist physician.* | | | |
| • Hepatitis C surface antigen: | ____/____/____ | □ *positive* □ negative | □ *Yes* |
| *Positive surface antigen indicates either acute or chronic Hepatitis C and PrEP should be referred to county health or a specialist physician.* | | | |
| • Pregnancy: | ____/____/____ | □ *positive* □ negative | □ *Yes* |
| *Positive result indicates pregnancy and PrEP should be referred to county health or a specialist physician.* | | | |
| • Gonorrhea/Chlamydia: | ____/____/____ | | □ *Yes* |
| Urinalysis result: □ *reactive* □ *indeterminate* □ negative | Pharyngeal test result: □ *reactive* □ *indeterminate* □ negative | Rectal test result: □ *reactive* □ *indeterminate* □ negative | |
| *All reactive or indeterminate chlamydia and/or gonorrhea results will result in an automatic referral to county health or the patient's healthcare provider for evaluation and treatment.* | | | |
| • Renal function (CrCl): SCr _____mg/dL | ____/____/____ | _____ mL/min □ CrCl > 60 mL/min □ CrCl 30-60 mL/min □ *CrCl < 30 mL/min* | □ *Yes* |
| CrCl > 60mL/min: Kidney function adequate for PrEP; CrCl 30-60mL/min: Only Descovy (emtricitabine & tenofovir alafenamide) indicated; *CrCl <30 mL/min: referral for evaluation/follow-up. NOTE: Concurrent NSAID use would favor Descovy* (emtricitabine & tenofovir alafenamide). | | | |
| • ALT/AST: Baseline + at 4-6 weeks recommended. | ____/____/____ | ALT_____u/L AST_____u/L | |
| • Signs/symptoms of STI not otherwise specified: | ____/____/____ | □ *Present* | □ *Yes* |
| • Condomless sex in past two weeks | ____/____/____ | □ *Yes* | □ *Yes* |

**2. Is HIV ab/ag 4th gen test complete?** □ **yes/non-reactive** □ ***yes/reactive or indeterminate*** □ ***no***

- If yes and non-reactive: Proceed to question #3
- *If yes and reactive or indeterminate: RPH many NOT prescribe PrEP. Patient should be referred to healthcare provider. NOTE: Sample language below.*
- *If no, obtain HIV ab/ag 4th gen test. Repeat question #2 once results are available.*

**3. Are all required labs complete?** □ **yes** □ ***no***

- If yes, pharmacist may prescribe PrEP and next labs due in 90 days. Proceed to next section: Medical History.
- If no, pharmacist may prescribe PrEP, but patient needs to complete all required labs and bring them in within 30 days. Proceed to next section: Medical History.

*Sample language for reactive or indeterminate tests:*

*Your HIV test has tested reactive (or indeterminate). This is not a diagnosis of HIV or AIDS. We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity. We will delay starting (or refilling) your PrEP until we have confirmation, you're HIV negative.*

*Sample language for reactive (indeterminate) STI tests:*

Your STI test has tested reactive (or indeterminate). This is not a diagnosis of (chlamydia, gonorrhea, or syphilis). We will need to confirm that this is the true result or to confirm a result with a more specific test before a diagnosis can be made. We are going to refer you to your health care provider (or your county health department) so that they may perform the confirmatory test and clarify the result. Until you have had your confirmatory test, we are going to recommend you abstain from any condomless sexual activity including giving or receiving oral sex.

**Medical History:** The following are referral conditions and considerations for pharmacist prescribing of PrEP. If a patient has one or more contraindications, the pharmacist must refer the patient to a specialist for consultation or management of PrEP.

| Medical history factor | Notes and considerations |
|---|---|
| | **REFERRAL CONDITIONS** |
| 1. Positive HIV test<br>*Needs Referral:*<br>□ *yes* □ no | • A positive or indeterminate HIV test either indicates HIV infection, a false positive, or a result requiring specialist interpretation.<br>• Confirmatory testing is beyond the testing capacity of the community pharmacist and the patient should be referred for PrEP management. |
| 2. Presence of Hepatitis B infection<br>*Needs Referral:*<br>□ *yes* □ no | • Truvada and Descovy are treatments for Hepatitis B. In patients with Hepatitis B who stop PrEP, this may cause a HepB disease flare.<br>• People with HepB infection must have their PrEP managed by a gastroenterologist or infectious disease specialist. |
| 3. Impaired kidney function (<30mL/min)<br>*Needs Referral:*<br>□ *yes* □ no | • Truvada is approved for patients with a CrCl >60mL/min.<br>• Consider Descovy in cis-gender men and male to female transgender women who have risk factors for kidney disease with a CrCl >30mL/min, but less than 60mL/min.<br>• Pharmacist prescribing of PrEP is contraindicated for patients who are under the care of a specialist for chronic kidney disease. |
| 4. Other medications<br>*Needs Referral:*<br>□ *yes* □ no | • Evaluate for comorbid medications that can be nephrotoxic or decrease bone mineral density.<br>• For cis-gender men and male to female transgender women who are on medications that could be nephrotoxic or could lower bone mineral density, consider Descovy over Truvada. |
| | **CONSIDERATIONS** |
| 5. NSAID use<br>Precaution- Counseled on limiting use:<br>□ yes □ no | • Tenofovir use in conjunction with NSAIDs may increase the risk of kidney damage.<br>• Concurrent use is not contraindicated, but patient should be counseled on limiting NSAID use. |
| 6. Hepatitis B vaccinated<br>If not, would the patient like to be vaccinated?<br>□ yes □ no | • Vaccination for Hepatitis B is preferred, but lack of vaccination is not a contraindication for PrEP.<br>• Counsel on risk factors for Hepatitis B and recommend vaccination.<br>• If patient would like to be vaccinated, proceed according to OAR 855-019-0280. |
| 7. Pregnant or breastfeeding | • Pregnancy and breastfeeding are not contraindications for PrEP.<br>• Women at risk of HIV who are also pregnant are at higher risk of intimate partner violence.<br>• Truvada is preferred due to better data in these populations. |

**4. Are one or More Referral Condition(s) Present? □ *yes* □ no**

- *If yes, HIV PrEP is recommended but pharmacists are not authorized to initiate treatment in accordance with this protocol. Refer the patient for further evaluation and management of PrEP by the patient's healthcare provider or appropriate specialist.*
- If no, HIV PrEP is recommended and pharmacists are authorized to initiate treatment and dispense PrEP in accordance with this protocol. Proceed to next sections: Regimen Selection and Prescription.

# Pre-Exposure Prophylaxis (PrEP) Assessment and Treatment Care Pathway - DRAFT

## (CONFIDENTIAL- Protected Health Information)

**Regimen Selection:**

| Considerations* | Preferred regimen |
|---|---|
| Cis-gender male or male to female transgender woman.<br>• Both Truvada and Descovy are FDA approved in these populations. May prescribe based on patient preference. | May choose Truvada or Descovy |
| Cis-gender female or female to male transgender man.<br>• Only Truvada is FDA approved in these populations.<br>• If patient has low bone mineral density or renal function that would preclude Truvada use, but has risk factors for HIV, refer the patient to a specialist for PrEP management. | Truvada |
| NSAID use<br>• If patient is male or a male to female transgender woman, consider Descovy | Descovy |
| Patient has some kidney impairment (CrCl <60mL/min) but is not under care of nephrologist.<br>• If patient is male or male to female transgender woman, consider Descovy | Descovy |
| Patient has decreased bone mineral density or on medications that affect bone mineral density.<br>• If patient is male or male to female transgender woman, consider Descovy. | Descovy |
| Patient is pregnant or breastfeeding<br>• Descovy has not been studied in these populations. Truvada is approved in these populations. | Truvada |

*generic versions are acceptable in all cases if available.

**Counseling (at minimum):**

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/PEP and alternative dosing regimens (i.e. PrEP on demand, PrEP 2-1-1)
- Individualized strategies for optimum adherence
- Behaviorally based adherence improvement strategies, such as pairing medication with established part of daily routine, pill boxes, reminder for daily dose
- Signs/symptoms of acute HIV infection and recommended actions
- Appropriate counseling regarding on-going risk for HIV and other STI acquisition
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care.
- The importance and requirement of testing for HIV, renal function, hepatitis B, hepatitis C and sexually transmitted diseases

**Documentation:**

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Regulation 18VAC110-21-46.

**Referrals to primary care provider:**

- (note 1) If a patient tests positive for HIV infection or has signs or symptoms of acute HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 2) If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 3) If a patient test has abnormal renal values and/or signs of acute renal injury, refer for urgent evaluation.
- (note 4) If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- (note 5) If a patient tests positive for Hepatitis C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- (note 6) If a female patient becomes pregnant while on PrEP, refer for care.

# Provider Notification - DRAFT
## Pre-Exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV)

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____
Dear Provider_____ (name) (____) _____-_____ (FAX)
Your patient _____ (name) _____/_____/_____ (DOB) has been initiated treatment for HIV Pre-Exposure Prophylaxis (PrEP) by _____. This regimen was filled on _____/_____/_____ (Date) and follow-up HIV testing is recommended in approximately 90 days _____/_____/_____ (Date)

**This regimen consists of the following (check one):**

- ☐ Truvada (emtricitabine/tenofovir disoproxil fumarate) 200/300mg tablets
  - Take one tablet by mouth daily for 90 days
- ☐ Descovy (emtricitabine/tenofovir alafenamide) 200/25mg tablets
  - Take one tablet by mouth daily for 90 days

**Your patient has been tested for and/or indicated the following:**

| Test Name | Date of Test | Result | Needs referral |
|---|---|---|---|
| • HIV ag/ab (4th gen): | _____/_____/_____ | ☐ *reactive* ☐ *indeterminate* ☐ negative | ☐ *Yes* |
| • Syphilis/Treponemal antibody: | _____/_____/_____ | ☐ *reactive* ☐ *indeterminate* ☐ negative | ☐ *Yes* |
| • Hepatitis B surface antigen: | _____/_____/_____ | ☐ *positive* ☐ negative | ☐ *Yes* |
| • Gonorrhea/Chlamydia: | _____/_____/_____ | | ☐ *Yes* |
| Urinalysis result: ☐ *reactive* ☐ *indeterminate* ☐ negative | Pharyngeal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative | Rectal test result: ☐ *reactive* ☐ *indeterminate* ☐ negative | |
| • Renal function (CrCl): ☐ CrCl >60mL/min | _____/_____/_____ ☐ CrCl 30mL/min - 60mL/min | _____ mL/min ☐ *CrCl <30mL/min* | ☐ *Yes* |
| • Signs/symptoms of STI not otherwise specified: | _____/_____/_____ | ☐ *present* | ☐ *Yes* |
| • Condomless sex in past two weeks | _____/_____/_____ | ☐ *yes* | ☐ *Yes* |

We recommend evaluating the patient, confirming the results, and treating as necessary. *Listed below are some key points to know about PrEP.*

**Provider pearls for HIV PrEP:**

- Truvada is not recommended for CrCl less than 60 mL/min. Please contact the pharmacy if this applies to your patient and/or there is a decline in renal function. Descovy may be a better option.
- Truvada and Descovy are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PrEP.
- NSAIDs should be avoided while patients are taking HIV PrEP to avoid drug-drug interactions with Truvada.
- Truvada is a first line option for Hepatitis B treatment. This is not a contraindication to PrEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- A positive STI test is not a contraindication for PrEP.

**Pharmacy monitoring of HIV PrEP:**

- The pharmacy initiating treatment and dispensing PrEP conducts and/or reviews results of HIV testing, STI testing, and baseline testing as part of their patient assessment.
- Patients who test reactive or indeterminate for HIV, gonorrhea/chlamydia, syphilis, or Hepatitis B will be referred to your office for evaluation, diagnosis, and treatment.
- Your office may take over management of this patient's HIV PrEP from the pharmacy at any time.

If you have additional questions, please contact the prescribing pharmacy, or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (855) 448-7737. For information about PrEP, please visit the CDC website.

# VIRGINIA BOARD OF PHARMACY

## Preventive Care

## HIV Post-Exposure Prophylaxis (PEP) Statewide Protocol

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

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

### STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized PEP Patient Intake Form (pg. 2)
- Utilize the standardized PEP Assessment and Treatment Care Pathway (pg. 3-5)
- Utilize the standardized PEP Patient Informational Handout (pg. 7)
- Utilize the standardized PEP Provider Fax (pg. 8)

### PHARMACIST EDUCATION AND TRAINING

- Prior to issuing a prescription to initiate treatment with, dispensing, or administering controlled substances for post-exposure prophylaxis under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use and shall have completed a comprehensive training program related to the prescribing and dispensing of HIV prevention medications, to include related trauma-informed care.

# Post-Exposure Prophylaxis (PEP) Self-Screening Patient Intake Form - DRAFT

## (CONFIDENTIAL-Protected Health Information)

Date ____/____/_____ Date of Birth ____/____/_____ Age____

Legal Name_____ Preferred Name _____

Sex Assigned at Birth (circle) M / F Gender Identification (circle) M / F / Other____

Preferred Pronouns (circle) She/Her/Hers, He/Him/His, They/Them/Their, Ze/Hir/Hirs, Other_____

Street Address _____

Phone ( ) _____ Email Address _____

Healthcare Provider Name _____ Phone ( ) _____ Fax ( ) _____

Do you have health insurance? Yes / No Insurance Provider Name _____

Any allergies to medications? Yes / No If yes, please list _____

**Background Information:**

| | | |
|---|---|---|
| 1. | Do you think you were exposed to Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 2. | What was the date of the exposure? | ___/___/___ |
| 3. | What was the approximate time of the exposure? | ___:___ *AM/PM* |
| 4. | Was your exposure due to unwanted physical contact or a sexual assault? | □ Yes □ No □ Not sure |
| 5. | Was the exposure through contact with any of the following body fluids? Select any/all that apply:<br>□ Blood □ Tissue fluids □ Semen □ Vaginal secretions □ Saliva □ Tears □ Sweat □ Other (please specify):_____ | □ Yes □ No □ Not sure |
| 6. | Did you have vaginal or anal sexual intercourse without a condom? | □ Yes □ No □ Not sure |
| 7. | Did you have oral sex without a condom with visible blood in or on the genitals or mouth of your partner? | □ Yes □ No □ Not sure |
| 8. | Did you have oral sex without a condom with broken skin or mucous membrane of the genitals or oral cavity of your partner? | □ Yes □ No □ Not sure |
| 9. | Were you exposed to body fluids via injury to the skin, a needle, or another instrument or object that broke the skin? | □ Yes □ No □ Not sure |
| 10. | Did you come into contact with blood, semen, vaginal secretions, or other body fluids of one of the following individuals?<br>□persons with known HIV infection<br>□men who have sex with men with unknown HIV status<br>□persons who inject drugs<br>□sex workers | □ Yes □ No □ Not sure |
| 11. | Did you have another encounter that is not included above that could have exposed you to high risk body fluids? Please specify:_____ | Yes □ No □ Not sure |

**Medical History:**

| | | |
|---|---|---|
| 12. | Have you ever been diagnosed with Human Immunodeficiency Virus (HIV)? | □ Yes □ No □ Not sure |
| 13. | Are you seeing a provider for management of Hepatitis B? | □ Yes □ No □ Not sure |
| 14. | Have you ever received immunization for Hepatitis B? If yes, indicate when:_____<br>If no, would you like a vaccine today? *Yes/No* | □ Yes □ No □ Not sure |
| 15. | Are you seeing a kidney specialist? | □ Yes □ No □ Not sure |
| 16. | Are you currently pregnant? | □ Yes □ No □ Not sure |
| 17. | Are you currently breast-feeding? | □ Yes □ No □ Not sure |
| 18. | Do you take any of the following over-the-counter medications or herbal supplements? □ Orlistat (Alli®) □ aspirin ≥ 325 mg □ naproxen (Aleve®) □ ibuprofen (Advil®) □ antacids (Tums® or Rolaids®), □ vitamins or multivitamins containing iron, calcium, magnesium, zinc, or aluminum | □ Yes □ No □ Not sure |
| 19. | Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here: _____ | □ Yes □ No □ Not sure |

Signature_____ Date_____

# Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)- DRAFT
## Assessment and Treatment Care Pathway
### (CONFIDENTIAL-Protected Health Information)

Name: _____ Date of Birth:____/____/_____ Today's Date:____/____/_____

| | | |
|---|---|---|
| 1. Is the patient less than 18 years old? | | Notes: |
| ☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health clinic | ☐ No: Go to #2 | |
| 2. Was the patient a survivor of sexual assault? | | Notes: |
| ☐ Yes: If the patient experienced a sexual assault, continue on with the algorithm (Go to #3) and then refer the patient to the emergency department for a sexual assault workup.** | ☐ No: Go to #3 | |
| 3. Is the patient known to be HIV-positive? | | Notes: PEP is a time sensitive treatment with evidence supporting use <72 hours from time of exposure. |
| ☐Yes: Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist or public health clinic. | ☐No: Go to #4. Conduct 4th generation HIV fingerstick test if available (optional). | |
| 4. What time did the exposure occur? | | Notes: |
| ☐ >72 hours ago: PEP not recommended. Do not prescribe PEP. Refer patient to local primary care provider, infectious disease specialist, or public health department. | ☐ ≤72 hours ago: go to #5 | |
| 5. Was the exposure from a source person known to be HIV-positive? | | |
| ☐ Yes: Go to #6 | ☐ No: Go to #7 | |
| 6. Was there exposure of the patient's vagina, rectum, eye, mouth, other mucous membrane, or non-intact skin, or percutaneous contact with the following body fluids: | | Notes: The fluids listed on the far left column are considered high risk while the fluids on the right column are only considered high risk if contaminated with blood. |
| Please check any/all that apply:<br>☐Blood<br>☐Semen<br>☐Vaginal secretions<br>☐Rectal secretions<br>☐Breast milk<br>☐Any body fluid that is visibly contaminated with blood<br><br>If any boxes are checked, go to #9. | Please check any/all that apply (*Note: only applicable if not visibly contaminated with blood*):<br>☐Urine<br>☐Nasal Secretions<br>☐Saliva<br>☐Sweat<br>☐Tears<br>☐None of the above<br><br>Go to #7 | |
| 7. Did the patient have receptive/insertive anal/vaginal intercourse without a condom with a partner of known or unknown HIV status? | | Notes: This type of exposure puts the patient at a high risk for HIV acquisition |
| ☐ Yes: Go to #9 | ☐ No: Go to #8 | |

## Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)- DRAFT Assessment and Treatment Care Pathway

**(CONFIDENTIAL-Protected Health Information)**

| | | |
|---|---|---|
| 8. Did the patient have receptive/insertive intercourse without a condom with mouth to vagina, anus, or penis (with or without ejaculation) contact with a partner of known or unknown HIV status? | | Notes: Consider calling the HIV Warmline (888) 448-4911 for guidance. |
| ☐ Yes: Please check all that apply and go to #9:<br>☐Was the source person known to be HIV-positive?<br>☐Were there cuts/openings/sores/ulcers on the oral mucosa?<br>☐Was blood present?<br>☐Has this happened more than once without PEP treatment?<br>☐None of the above | ☐ No: Use clinical judgement. Risk of acquiring HIV is low. Consider referral. If clinical determination is to prescribe PEP then continue to #9. | |
| 9. Does the patient have an established primary care provider for appropriate follow-up? –OR- Can the pharmacist directly refer to another local contracted provider or public health department for appropriate follow-up? | | Notes: Connection to care is critical for future recommended follow-up. |
| ☐ Yes: Go to #10 | ☐ No: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. | |
| 10. Does the patient have history of known Hepatitis B infection (latent or active)? | | Notes: Tenofovir disoproxil fumarate treats HBV, therefore once stopped and/or completed, the patient could experience an acute Hepatitis B flare. |
| ☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. | ☐ No. Go to #11 | |
| 11. Has the patient received the full Hepatitis B vaccination series? ☐Yes ☐No<br>Verify vaccine records or VIIS. Dates:_____ | | |
| ☐ Yes: Go to #13 | ☐ No: Go to #12 | |
| 12. Review the risks of hepatitis B exacerbation with PEP with the patient. Offer vaccine if appropriate and go to #13.<br>☐Vaccine administered<br>Lot:_____ Exp:_____ Signature:_____ | | |
| 13. Does the patient have known chronic kidney disease or reduced renal function? | | Notes: emtricitabine and tenofovir disoproxil fumarate requires renal dose adjustment when the CrCl <50 mL/min |
| ☐ Yes: Do not prescribe PEP. Refer patient to local primary care provider (PCP), emergency department (ED), urgent care, infectious disease specialist, or public health dept. | ☐ No: PEP prescription recommended. See below for recommended regimen(s) and counseling points. Patient must be warm referred to appropriate provider following prescription of PEP for required baseline and follow-up testing. Pharmacist must notify both the provider and patient. | |

# Post-exposure Prophylaxis (PEP) of Human Immunodeficiency Virus (HIV)- DRAFT
## Assessment and Treatment Care Pathway
(CONFIDENTIAL-Protected Health Information)

RECOMMENDED REGIMEN:

| Medication | Age/Weight | Dose | Duration | Notes |
|---|---|---|---|---|
| emtricitabine 200mg/tenofovir disoproxil fumarate 300mg (Truvada or generic)<br><br>PLUS<br><br>raltegravir 400mg<br><br>OR<br><br>dolutegravir 50mg | ≥18 years | Once daily No refills<br><br>Twice daily No refills<br><br>Once daily No refills | 28 days | • Dosing adjustments with renal dysfunction if CrCl <60 ml/min.<br>• Dolutegravir should not be used in pregnant women.<br>• If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then the "alternate regimens" per CDC guidelines should be referenced and used.<br>• Other FDA-approved regimens can be used if they become available. Formulation cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.<br>• Although labeling is for 28 day supply, 30 days is recommended for prescribing due to the products being available only in 30-day packaging and high cost of the medications which could provide a barrier to availability and care. If able, 28-day regimens are appropriate if the pharmacist/pharmacy is willing to dispense as such.<br>• Pregnancy is not a contraindication to receive PEP treatment as Truvada® and Isentress® are preferred medications during pregnancy. If the patient is pregnant, please report their demographics to the Antiretroviral Pregnancy Registry: http://www.apregistry.com<br>• If the patient is breastfeeding, the benefit of prescribing PEP outweigh the risk of the infant acquiring HIV. Package inserts recommend against breastfeeding. "Pumping and dumping" may be considered. Consider consulting with an infectious disease provider, obstetrician, or pediatrician for further guidance. |

COUNSELING POINTS (at minimum):

- Proper use of medication dosage, schedule, and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function , hepatic function , hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

PHARMACIST MANDATORY FOLLOW-UP:

- The pharmacist will contact the patient's primary care provider or other appropriate provider to provide written notification of PEP prescription and to facilitate establishing care for baseline testing such as SCr, 4th generation HIV Antigen/Antibody, AST/ALT, and Hepatitis B serology. *(sample info sheet available)*
- The pharmacist will provide a written individualized care plan to each patient. *(sample info sheet available)*
- The pharmacist will contact the patient approximately 1 month after initial prescription to advocate for appropriate provider follow-up after completion of regimen.

Pharmacist Signature_____Date____/____/_____

Pharmacy Name: _____
Pharmacy Address: _____
Pharmacy Phone Number: _____

## This page contains important information for you; please read it carefully.

You have been prescribed Post-Exposure Prophylaxis (PEP) to help prevent Human Immunodeficiency Virus (HIV). Listed below are ~~the medications and directions you have been prescribed,~~ some key points to remember about these medications, and a list of next steps that will need to be done in order to confirm the PEP worked for you.

### ~~Medications: You must start these within 72 hours of your exposure~~

- ~~Truvada (emtricitabine/tenofovir disoproxil) 200 mg/300 mg – take 1 tablet by mouth daily for 30 days,~~ **~~AND~~**
- ~~Isentress (raltegravir) 400 mg – take 1 tablet by mouth twice daily for 30 days~~

### Key Points

- You must start the medications within 72 hours of your exposure.
- Take every dose. If you miss a dose, take it as soon as you remember.
  - If it is close to the time of your next dose, just take that dose. Do not double up on doses to make up for the missed dose.
- Do not stop taking ~~either~~ the medication without first asking your doctor or pharmacist.
- ~~Truvada and Isentress don't have side effects most of the time.~~ The most common side effects (if they do happen) are stomach upset. Taking ~~Truvada and Isentress~~ the medication with food can help with stomach upset. Over-the- counter nausea and diarrhea medications are okay to use with PEP if needed.
- Avoid over-the-counter pain medications like ibuprofen or naproxen while taking PEP.

### Follow-up and Next Steps

1. Contact your primary care provider to let them know you have been prescribed PEP because they will need to order lab tests and see you. The pharmacy cannot do these lab tests.
2. Our pharmacist will contact your doctor (or public health office if you do not have a primary doctor) to let them know what labs they need to order for you.
3. The tests we will be recommending to check at 6 weeks and at 3 months are listed below. The listed labs will involve a blood draw. Your provider may choose to do more tests as needed.
   - ☐ HIV antigen/antibody 4th generation
   - ☐ Hepatitis B surface antigen and surface antibody
   - ☐ Hepatitis C antibody
   - ☐ Treponema pallidum antibody
   - ☐ Comprehensive metabolic panel
4. If you think that you might still be at risk of HIV infection after you finish the 30-day PEP treatment, talk to your doctor about starting Pre-exposure prophylaxis (PrEP) after finishing PEP.

# Provider Notification
## Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV) - DRAFT

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

Dear Provider_____ (name), (____) _____ -_____ (FAX)

Your patient _____(name) _____/_____/_____ (DOB) has been initiated treatment for HIV Post-Exposure Prophylaxis (PEP) at _____ Pharmacy.

**This regimen consists of:**

- ~~Truvada (emtricitabine/tenofovir disoproxil) 200/300mg tablets - one tab by mouth daily for 30 days~~ AND
- ~~Isentress (raltegravir) 400mg tablets - one tab by mouth twice daily for 30 days.~~

_____

_____

This regimen was initiated on _____(Date).

We recommend an in-clinic office visit with you or another provider on your team within 1-2 weeks of starting HIV PEP. Listed below are some key points to know about PEP and which labs are recommended to monitor.

**Provider pearls for HIV PEP:**

- ~~Truvada~~ Emtricitabine/tenofovir disoproxil fumarate needs renal dose adjustments for CrCl less than 50 mL/min. Please contact the pharmacy if this applies to your patient.
- ~~Truvada~~ Etricitabine/tenofovir disoproxil fumarate and ~~Isentress~~ raltegravir are both safe in pregnancy. If your patient is pregnant or becomes pregnant, they may continue PEP for the full 30 days.
- NSAIDs should be avoided while patients are taking HIV PEP to avoid drug-drug interactions with ~~Truvada~~ emtricitabine/tenofovir disoproxil fumarate.
- ~~Truvada~~ Emtricitabine/tenofovir disoproxil fumarate is a first line option for Hepatitis B treatment. This is not a contraindication to PEP use, but we recommended you refer Hepatitis B positive patients to an infectious disease or gastroenterology specialist.
- If your patient continues to have risk factors for HIV exposure, consider starting Pre-exposure prophylaxis (PrEP) after the completion of the 30-day PEP treatment course.

We recommend ordering the following labs at **6 weeks** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis B surface antigen and surface antibody
- ☐ Hepatitis C antibody
- ☐ Comprehensive metabolic panel
- ☐ Treponema pallidum antibody as appropriate
- ☐ Pregnancy test as appropriate
- ☐ STI screening as appropriate (chlamydia, gonorrhea at affected sites)

We recommend ordering the following labs at **3 months** after the initiation date for HIV PEP:

- ☐ HIV antigen/antibody (4th gen) test
- ☐ Hepatitis C antibody

## Provider Notification
## Post-Exposure Prophylaxis (PEP) for Human Immunodeficiency Virus (HIV) - DRAFT

Pharmacy Name:_____
Pharmacy Address:_____
Pharmacy Phone:_____ Pharmacy Fax: _____

If you have further questions, please contact the pharmacy or call the HIV Warmline. The HIV Warmline offers consultations for providers from HIV specialists and is available every day at: (888) 448-4911. For more information about PEP, please visit the CDC website at cdc.gov/hiv/basics/pep.html.

## 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

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

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

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

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

**INCLUSION CRITERIA**

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

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

**EXCLUSION CRITERIA**

Individuals meeting any of the following criteria:

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

**CONSIDERATIONS**

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

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

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

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

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

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

**MEDICATIONS**

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

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

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

**PROCEDURES FOR INITIATION OF TB SCREENING**

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

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

**PROCEDURES FOR MONITORING AND FOLLOW UP**

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

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

**COUNSELING REQUIREMENTS**

Individuals receiving TST will receive counseling regarding:

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

**DOCUMENTATION**

Pharmacists will document via prescription or medical record each person who

receives a TST under this protocol including:

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

**NOTIFICATION AND REFERRAL**

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

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

# VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM - DRAFT
## (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□ |

**Adopted by Virginia Board of Pharmacy:** **Effective Date:**

| | | |
|---|---|---|
| 9. | Have you ever had a documented prior positive test for TB infection?<br>If yes, date of positive test (if known):_____ Type of Test: ☐ TST/IGRA ☐ TST<br>Reading:_____mm<br>If yes to prior positive test, did you have a chest radiograph performed after the positive test?<br>CXR date (if known):_____ Results: ☐ Normal ☐ Abnormal<br>If chest radiograph was normal after positive test, did you receive LTBI treatment? | Yes ☐ No☐<br><br>Yes ☐ No☐<br><br>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?<br>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?<br>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?<br>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?<br>***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?<br>Have you received medical care within the last two years?<br>***If NO to both questions, patient is considered medically underserved.*** | Yes ☐ No ☐<br>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?<br>***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:<br>- Low body weight due to chronic malabsorption syndromes?<br>- Lung disease silicosis caused by breathing in tiny bits of silica?<br>- Diabetes?<br>- End stage renal disease or on hemodialysis?<br>- Head or neck cancer?<br>- Leukemia?<br>- Lymphoma?<br>- Hematologic or reticuloendothelial disease? | <br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □ |
| 24. | Have you ever had any of the following procedures:<br>- Gastrectomy?<br>- Intestinal bypass?<br>- Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)? | <br>Yes □ No □<br>Yes □ No □<br>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.

**Adopted by Virginia Board of Pharmacy:** **Effective Date:**

## 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.

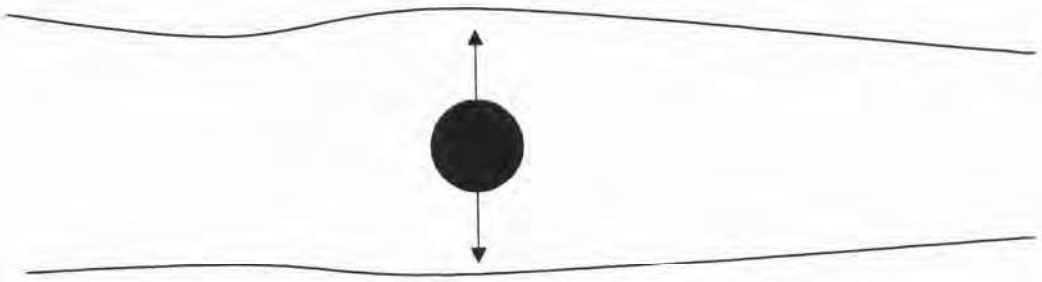
**Classification of the Tuberculin Skin Test Reaction[1]**

| ≥5 mm Induration | ≥10 mm Induration | ≥15 mm Induration |
|---|---|---|
| Considered positive in the following persons:<br>• Persons living with the human immunodeficiency virus (HIV)<br>• Recent contacts of a person with Tuberculosis (TB) disease<br>• Persons with a chest radiography (CXR) findings suggestive of previous TB disease<br>• Patients with organ transplants<br>• 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:<br>• 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<br>• Persons with substance use disorders<br>• Mycobacteriology laboratory personnel<br>• Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities<br>• 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<br>• Persons <90% of ideal body weight<br>• Children aged <5 years<br>• 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/s3/6[illegible]08/2021-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

## 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

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

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

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

**INCLUSION CRITERIA**

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

**EXCLUSTION CRITERIA**

Individuals meeting any of the following criteria:

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

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

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

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

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

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

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

**CONSIDERATIONS**

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

**MEDICATIONS**

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

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

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

**PROCEDURES FOR INITIATION OF TB SCREENING**

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

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

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

**PROCEDURES FOR MONITORING AND FOLLOW UP**

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

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

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

**COUNSELING REQUIREMENTS**

Individuals receiving TST will receive counseling regarding:

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

**DOCUMENTATION**

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

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

**NOTIFICATION AND REFERRAL**

Prior to screening the patient for TB, the patient must complete and sign the Patient

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

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

# VIRGINIA BOARD OF PHARMACY TUBERCULOSIS RISK ASSESSMENT FORM - DRAFT
## (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□ |

**Adopted by Virginia Board of Pharmacy:** **Effective Date:**

| | | |
|---|---|---|
| 9. | Have you ever had a documented prior positive test for TB infection?<br>If yes, date of positive test (if known):_____ Type of Test: ☐ TST/IGRA ☐ TST<br>Reading:_____mm<br>If yes to prior positive test, did you have a chest radiograph performed after the positive test?<br>CXR date (if known):_____ Results: ☐ Normal ☐ Abnormal<br>If chest radiograph was normal after positive test, did you receive LTBI treatment? | Yes ☐ No☐<br><br><br>Yes ☐ No☐<br><br>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.<br>If YES to prior positive TB test, and NO subsequent chest radiograph performed, refer patient to PCP.<br>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.<br>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.<br>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?<br>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?<br>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?<br>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.<br>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.<br>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?<br>***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?<br>Have you received medical care within the last two years?<br>***If NO to both questions, patient is considered medically underserved.*** | Yes ☐ No ☐<br>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.<br>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?<br>***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:<br>- Low body weight due to chronic malabsorption syndromes?<br>- Lung disease silicosis caused by breathing in tiny bits of silica?<br>- Diabetes?<br>- End stage renal disease or on hemodialysis?<br>- Head or neck cancer?<br>- Leukemia?<br>- Lymphoma?<br>- Hematologic or reticuloendothelial disease? | <br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □<br>Yes □ No □ |
| 24. | Have you ever had any of the following procedures:<br>- Gastrectomy?<br>- Intestinal bypass?<br>- Solid organ transplant (e.g., kidney, liver, heart, lung, intestines, pancreas)? | <br>Yes □ No □<br>Yes □ No □<br>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.

**Adopted by Virginia Board of Pharmacy:** **Effective Date:**

## 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.

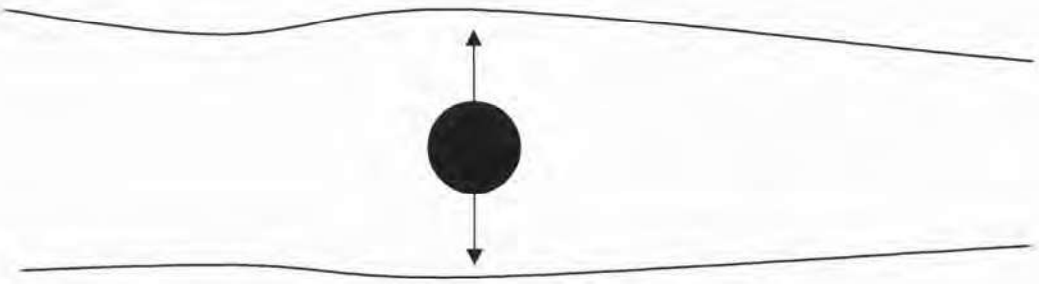
**Classification of the Tuberculin Skin Test Reaction[1]**

| ≥5 mm Induration | ≥10 mm Induration | ≥15 mm Induration |
|---|---|---|
| Considered positive in the following persons:<br>• Persons living with the human immunodeficiency virus (HIV)<br>• Recent contacts of a person with Tuberculosis (TB) disease<br>• Persons with a chest radiography (CXR) findings suggestive of previous TB disease<br>• Patients with organ transplants<br>• 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:<br>• 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<br>• Persons with substance use disorders<br>• Mycobacteriology laboratory personnel<br>• Residents and employees of high-risk congregate settings such as nursing homes, homeless shelters, or correctional facilities<br>• 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<br>• Persons <90% of ideal body weight<br>• Children aged <5 years<br>• 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.

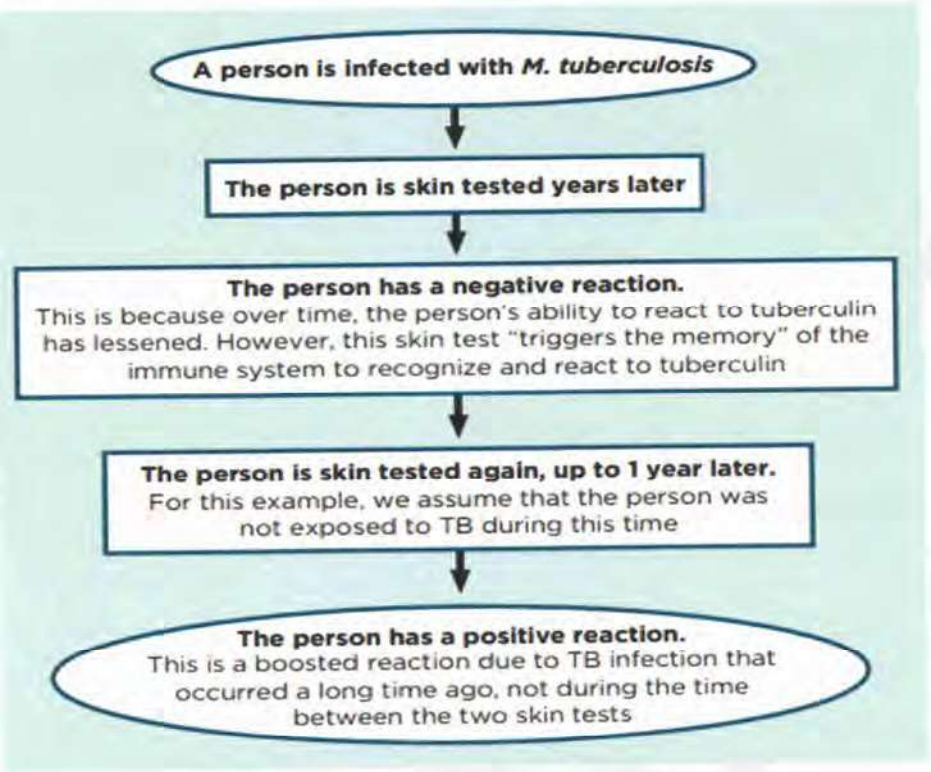



**Figure 2: Two-Step TST Testing**

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.**