COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Public Hearing and Full Board Meeting

June 15, 2015

9:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances:
Ellen B. Shinaberry, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Possible scheduling of the following substances:
  - N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA) — 1-4
  - methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)- 3-methylbutanoate (other name: 5-fluoro-AMB)
  - 1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201)
  - 1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144)
  - 4-bromomethcathinone (other name: 4-BMC)
  - 4-chloromethcathinone (other name: 4-CMC)

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Ellen B. Shinaberry, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - March 11, 2015, Special Conference Committee — 5-7
  - March 23, 2015, Innovative (Pilot) Program Informal Conference Committee — 8-12
  - March 24, 2015, Full Board Meeting — 13-20
  - March 25, 2015, Special Conference Committee — 21-28
  - April 16, 2015, Telephone Conference Call — 29-31
  - April 21, 2015, Special Conference Committee — 32-33
  - May 8, 2015, Telephone Conference Call — 34-35
  - May 11, 2015, Regulation Committee — 36-42
  - May 13, 2015, Telephone Conference Call — 43-51

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

DHP Director's Report: David Brown, DC

- Pharmacy Benefit Managers

Regulatory Actions: Elaine Yeatts/Caroline Juran

- Consideration of Any Scheduling Action from Public Hearing 52-54
- Regulatory Update 55
- Revenue and Expenditure Analysis 56
- Report from Regulation Committee
  - Closed System Transfer Devices to Extend BUD of Single Dose Vials
  - 2016 Legislative Proposals:
    - Third Party Logistic Providers, Wholesale Distributors, Track and Trace Requirements 57-74
    - Nonresident Medical Equipment Suppliers
    - PTCB Requirement 75
  - Additional Legislative Issues Considered: 76-77
    - VAWD Accreditation
    - Separate License for Pharmacies Performing Sterile Compounding
  - Recommended Legislative Proposals from PMP Advisory Committee:
    - Expanded Access and Reporting Requirements 78-83

New Business: Caroline D. Juran/Elaine Yeatts

- Adoption of Naloxone Protocol:
  - HB 1458 84-90
  - Draft Naloxone Protocol 91-92
- Request from VPhA to Amend Guidance Document 110-36 93
- 2014 Virginia Workforce Report, Elizabeth Carter, PhD, Executive Director, HWDC
  - Pharmacist Report 94-122
  - Pharmacy Technician Report 123-151

Reports:

- Chairman's Report – Ellen B. Shinaberry
- Report on Board of Health Professions - Ellen B. Shinaberry
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day
- Executive Director's Report –Caroline D. Juran

Election of Officers – Chairman and Vice-Chairman

Consideration of consent orders

Adjourn

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

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on June 15, 2015** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 1, 2015 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified six (6) compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. Other drugs of this type have been placed in Schedule I in previous legislative sessions. A brief description and chemical name for each compound is as follows:

1. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA)**

   ADB-CHMINACA is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

2. **methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)- 3-methylbutanoate (other name: 5-fluoro-AMB)**

   5-fluoro-AMB is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

3. **1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201)**

   NM-2201 is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

4. **1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144)**

   FUB-144 is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

5. **4-bromomethcathinone (other name: 4-BMC)**

   4-bromomethcathinone is classified as a substituted cathinone, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

6. **4-chloromethcathinone (other name: 4-CMC)**

4-chloromethcathinone is classified as a substituted cathinone, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of Board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

§ 54.1-3443. Board to administer article.

A. The Board shall administer this article and may add substances to or deschedule or reschedule all substances enumerated in the schedules in this article pursuant to the procedures of the Administrative Process Act (§ 2.2-4000 et seq.). In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;

2. The scientific evidence of its pharmacological effect, if known;

3. The state of current scientific knowledge regarding the substance;

4. The history and current pattern of abuse;

5. The scope, duration, and significance of abuse;

6. The risk to the public health;

7. The potential of the substance to produce psychic or physical dependence; and

8. Whether the substance is an immediate precursor of a substance already controlled under this article.

B. After considering the factors enumerated in subsection A, the Board shall make findings and issue a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Courts of Justice and Senate Courts of

3

Justice Committees of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to Schedule I or II. Nothing in this subsection shall preclude the Board from adding substances to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 120 days from publication in the Federal Register of the final order designating a substance as a controlled substance or rescheduling or descheduling a substance without following the provisions specified in subsections A and B.

F. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

G. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, March 11, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Empsy Munden, Committee Chair

MEMBERS PRESENT: Jody H. Allen, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

DIE K. BLAISE
License Number 0202-205672

Die K. Blaise did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 20, 2015, Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Blaise's legal address of record.

Closed Meeting: Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Die K. Blaise. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee voted to refer this matter to a formal hearing.

LaShawn A. Bailey-Jones
License Number 0202-011004

LaShawn A. Bailey- Jones appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 20, 2015, Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of LaShawn A. Bailey-Jones. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee voted to close this matter with no violation.

HAWSATOU BARRY
Pharmacy Technician Applicant

Hawsatou Barry appeared to discuss her application for registration as a pharmacy technician and to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the February 23, 2015, Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Hawsatou Barry. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations

Reconvene:

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

Decision:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that approved Ms. Barry's application.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Barry, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Ms. Barry within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 1:30 p.m.

_____
Empsy Munden, Chair

_____
Date

_____
Cathy M. Reiniers-Day
Deputy Executive Director

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Monday, March 23, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: The meeting was called to order at 1:00 p.m.

PRESIDING: Empsy Munden, Committee Chairperson

MEMBERS PRESENT: Ellen B. Shinaberry

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager

Pharmacy Central Distribution-
Parallon Supply Chain Solutions, HCA

The purpose of the informal conference was to act upon the Application of Parallon Supply Chain Solutions for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-20-490(C) (1)(2) and 18VAC110-20-460(A). Present for the meeting from Parallon Supply Chain Solutions were Kim Biggers-Hayes – Division Director for pharmacy services, Parallon, Noel Hodges – COO, Parallon, Robin Sayles – Director of pharmacy, John Randolph Medical Center, Corey Winston – Director of Consolidated Service Center Operations, Parallon, Jennifer Scales-Hill – Director of Pharmacy, HCA Retreat, Demetrus Garrett – Pharmacy Manager, CSC Parallon, and Sherone Ruggs – Division Director of Pharmacy Operations, Parallon.

Parallon Supply Chain Solutions, which is owned by Healthcare Corporation of America (HCA), requested a waiver of 18 VAC 110-20-490 (C) that requires the delivery record of drugs placed into an automated dispensing device (ADD) in a hospital to include the initials of the pharmacist at the hospital that checked the drugs to be removed from the pharmacy and the delivery record for accuracy. Additionally, a waiver was requested of 18 VAC 110-20-460 (A) that requires a pharmacist to check all Schedule II - VI drugs prior to delivery as nursing unit floor stock, plus the requirement of initialing or signing manually, or electronically, the record of distribution verifying the accuracy of

distribution of Schedule II - IV drugs.

For the purpose of this pilot program, the Central Shared Services warehouse (permit number 0216-000033), which is owned by HCA and provides drugs via intra-company sales to HCA hospitals, intends to distribute individual quantities of Schedule VI drugs necessary to replenish specifically identified ADDs located at thirteen hospitals and three stand-alone emergency departments owned by HCA (facility). A Virginia-licensed pharmacist at the Central Shared Services warehouse will perform a 100% check of all drugs prior to the drugs being placed in a secured tote and delivered directly to facility pharmacy department. Pharmacy technicians at the facility, using barcode scanning, will directly restock the ADD with the medications that were picked, verified and secured at the warehouse. The drugs will not be checked and verified by a pharmacist at the facility to which they are delivered.

Ms. Biggers-Hayes provided an overview of the Pharmacy Central Distribution operation with assistance from Mr. Winston, Mr. Garrett, Ms. Ruggs and Mr. Hodges. They provided answers to questions the Board and staff members had with regard to the process of Pharmacy Central Distribution to facility pharmacy departments.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for Pharmacy Central Distribution – Parallon Supply Chain Solutions. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., and Beth O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Munden stated the Committee shall offer a consent order that approves the innovative (pilot) program for a period of three (3) years from the date the Order is entered by the Board with the following terms and conditions that were read by Ms. Juran:

1. The approval of this innovative (pilot) program is limited to Schedule VI drugs.
2. The Central Shared Services warehouse shall deliver the drugs directly to the pharmacy at each facility.
3. A pharmacist at the Central Shared Services warehouse shall verify 100% of all drugs distributed to the pharmacy at a facility to be placed into an ADD.
4. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from a pharmacy to be placed in an ADD to include the initials of the pharmacist checking shall be waived for those drugs received from the Central Shared Services warehouse.
5. The requirement in 18 VAC 110-20-460 (A) of the Regulations for a pharmacist to check all drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution shall be waived for the drugs received from the Central Shared Services warehouse to be placed in an ADD.
6. The Central Shared Services warehouse shall maintain a record of all drugs distributed to facilities to be placed in an ADD. The record shall include the date; drug name, dosage form, and strength; quantity; facility name, hospital unit, a unique identifier for the specific device receiving the drug; and initials of the pharmacist checking the drugs for accuracy.
7. The pharmacy at each facility shall maintain a record of the initials of the person loading the automated dispensing device.
8. All records required by this section shall be maintained at the address of the applicable warehouse or facility for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an

exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

9. Each facility receiving drugs from the Central Shared Services warehouse to be placed in an ADD shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices at a facility is less than 90% for any quarter, the pharmacy at that facility shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until the Board approves Central Shared Services resuming the allowances within the innovative (pilot) program.
10. The assignment of the Meditech and Pyxis ID code shall be performed by a Virginia-licensed pharmacist employed by Parallon.
11. Central Shared Services shall submit to the Board a quarterly report which indicates for each facility the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from Central Shared Services.These reports shall be submitted in March, June, September, and December.
12. The innovative (pilot) program shall be subject to two random, unannounced inspections by the Board or its designated representative within three (3) years following implementation of the program, one inspection to take place within the first twelve (12) months of implementation. Central Shared Services shall be solely responsible for the payment of an inspection fee of $150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection.
13. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.
14. Except as specifically waived in the Consent Order, Central Shared Services and the facilities

shall maintain compliance with all applicable federal and State laws and regulations.

15. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.

ADJOURN: With all business concluded, the meeting adjourned at 4:00 p.m.

Empsy Munden, Committee Chairman

Date

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 24, 2015
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:02 a.m.

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Michael Elliott
Sheila Elliott
Dinny Li
Ryan Logan
Empsy Munden
Cynthia Warriner

MEMBERS ABSENT: Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Jamie Hoyle, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: Ms. Juran requested that the Board consider an amendment to Guidance Document 110-9 as an additional agenda topic. The agenda was amended and approved as requested.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the December 4, 2014 (Telephone Conference Call), December 9, 2014 (Public Hearing for Scheduling Certain Controlled Substances), December 9, 2014 (Full Board Meeting), December 16, 2014 (Special Conference Committee), January 22, 2015 (Special Conference Committee), February 5, 2015 (Formal Hearing) and March 11, 2015 (Special Conference Committee).

MOTION: **The Board voted unanimously to approve the minutes as presented. (motion by Warriner, second by Allen)**

PUBLIC COMMENTS:

John Beckner, representing the National Community Pharmacists Association, discussed with the Board his concerns with pharmacy benefit managers (PBMs) and the lack of oversight which impacts patient care. He stated that this warrants further discussion and requested that the Board refer the agenda topic of PBMs to the Regulation Committee for further review.

Alexander Pytlarz, representing the Virginia Pharmacists Association (VPhA), addressed the Board regarding Guidance Document 110-36 "Compliance with USP Standards for Compounding". Mr. Pytlarz requested that the Board consider adopting the guidance document as presented as it accurately represents the compounding working group's recommendation.

Susan Schriner, clinical pharmacist, Virginia Oncology Associates, encouraged the Board to consider their request for the dispensing physicians at their locations to be able to use a camera-facilitated prescription verification process.

H. Otto Waxman, pharmacist, Stoney Creek Pharmacy, expressed concerns regarding physicians dispensing as the physicians may not have sufficient time to devote to the accuracy verification process. He also stated that he had concerns with the PBMs and their impact on the services of rural pharmacies. He stated the credentialing process has become an issue and is taking too much time away from safely dispensing medication.

Scott Johnson, General Counsel, Medical Society of Virginia (MSV), thanked the Board for including his letter within the meeting agenda and stated he was ready and willing to be a resource if necessary regarding the issue involving PBMs.

David Creecy, pharmacist, Poquoson Pharmacy, stated his concerns regarding PBMs and wanted to reiterate on Mr. Beckner's comments. Mr. Creecy brought to the Board's attention the access issues, how there are no standards and there is consistent changes. He also disagrees with the constant credentialing process and how many times independent pharmacies have to be re-accredited. Mr. Creecy also stated he too has issues with camera verification of prescriptions and that the rules should stay constant across the board.

Tim Musselman, Executive Director, Virginia Pharmacist Association (VPhA), addressed concerns regarding the length of time that some of the draft regulations have been either at the Secretary's office or the Governor's office. He also expressed concerns with the issue of physicians dispensing using a camera to verify dispensed prescriptions as the process did not appear to provide adequate supervision as required in regulation. Mr. Musselman also stated that he often receives negative comments from VPhA membership regarding PBM practices. He

encouraged the Board to address the issue and consider regulating PBMs to the extent that is consistent with the Board's jurisdiction.

Hunter Jamerson, Counsel, Epic Pharmacies, stated that he concurred with the concerns expressed by the VPhA on the matter of PBMs as PBMs are effectively unregulated. He stated many community pharmacies are having a difficult time with the credentialing process, it is creating a patient access issue, and that the patients are the ones who are ultimately suffering. He expressed concern for the PBMs ability to designate drugs in a specialty tier, often requiring these drugs to be dispensed by mail order pharmacies owned by the PBMs, and concerns for mail order pharmacies to satisfy a bona fide pharmacist-patient relationship.

DHP DIRECTOR'S REPORT:

Dr. Brown was unable to attend the meeting due to a scheduling conflict. Jamie Hoyle, Chief Deputy Director, DHP, provided the Director's report. Ms. Hoyle began by offering her gratitude to Ms. Juran and Ms. Yeatts for their participation in a successful legislative session. She stated that the department was increasing their efforts in providing training for staff and investigators. Training for board members on disciplinary topics will be held in September. Ms. Hoyle reported that the Citizen Advocacy Center was contracted to conduct an audit of the Health Practitioners Monitoring Program (HPMP). They are beginning their audit with a focus on nursing and medicine cases. A report with findings and recommendations will be available in May.

REPORT:

VCU SCHOOL OF PHARMACY:

Ms. Shinaberry stated that the Board recently invited the deans of the Virginia schools of pharmacy to provide a report to the Board of their activities during one of the 2015 full board meetings. Joseph T. DiPiro, Dean, VCU School of Pharmacy and Tom Reinders, Associate Dean for Admissions and Student Services, appeared this day and provided the Board with a handout outlining current information regarding the school of pharmacy. Currently, there are 70 faculty members, 140 PharmD students, 85 graduate students and satellite programs located at Inova-Fairfax in Virginia. Dean DiPiro also addressed the multiple achievements made by faculty and staff. He reported there have been ongoing position recruitments at the school. A center for compounding practice and research has been added to the school and they are currently recruiting for a director of the program. Regarding the VCU School of Pharmacy class of 2018, it is 64% female, 36% male, mean age of 23 years, 76% Virginia residents and 97% hold baccalaureate degrees. Currently, the school of pharmacy meets all 30 standards of accreditation, and was commended in two areas of teaching methods and assessments regarding faculty collegiality to develop new methods of teaching. The accreditation has been extended a full 8 years until 2023 by the Accreditation Council for Pharmacy Education Board (ACPE).

REGULATORY ACTIONS:

- LEGISLATIVE UPDATE:

Ms. Yeatts reported that this was a busy General Assembly session. She reviewed the handout in the agenda packet and indicated that several bills submitted by DHP were passed. Ms. Yeatts also stated that the majority of the agency's bills are pharmacy-related and many will require action by the Regulation Committee. Unless otherwise authorized, bills passed will become effective July 1, 2015. Ms. Yeatts and Ms. Juran confirmed for Ms. Warriner, therefore, that the requirement to perform a perpetual inventory of hydrocodone-containing products takes effect July 1, 2015 when the State law placing hydrocodone-containing products into Schedule II becomes effective.

- REGULATION UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet.

- AMENDMENT OF 18VAC 110-20-727; PHARMACISTS REPACKAGING FOR CLIENTS OF A CSB OR BHA:

Ms. Yeatts stated that staff recently identified an error in 18VAC 110-20-727 as there is no section G, H or J in 18VAC 110-20-725. She requested that the Board amend 18VAC 110-20-727 regarding pharmacists repackaging for clients of a CSB or BHA.

MOTION:

The Board voted unanimously to amend 18VAC 110-20-727 as presented regarding pharmacists repackaging for clients of a CSB or BHA. (motion by Munden, second by Allen)

NEW BUSINESS:

DISCUSS CONSTITUENT CONCERN RAISED WITH SENATOR WARNER'S OFFICE REGARDING PHARMACY BENEFIT MANAGER OVERSIGHT:

Ms. Juran provided an overview of the letter sent from Senator Mark Warner to Ms. Shinaberry requesting an appropriate response to concerns with PBMs that were expressed by John Frye, Pharmacist, Rocky Mount Family Pharmacy. In the letter, Mr. Frye states the PBM discriminates against independent pharmacies by requiring a different credentialing process than that which required for larger chain pharmacies. During the discussion, members acknowledged that not all PBM activities are within the Board's legal scope of authority. There was some focus of discussion on patient safety, security of the prescription department, and patient access to drugs. It was suggested that the NABP PBM Task Force Report be utilized as a resource. Ms. Shinaberry stated that the request for the Regulatory Committee to review this matter should be more general in nature and not limited to specific subjects.

MOTION:

The Board voted unanimously to refer the concerns of pharmacy benefit manager oversight to the Regulation Committee in May for a more thorough review. (motion by Munden, second by M. Elliott)

CONSIDER OF ADOPTION OF NOIRA FOR DRUG DISPOSAL

Ms. Juran reviewed with the Board the Drug Enforcement Administration's (DEA) final ruling regarding the disposal of pharmaceutical controlled substances. Ms. Juran stated that currently a pharmacy may collect and dispose of controlled substances under federal regulations, however, there is no direct authority for the Board to regulate this process or address issues of non-compliance. It was recommended that the Board adopt a Notice of Intended Regulatory Action (NOIRA) which would directly authorize the Board to regulate the drug disposal process in accordance with federal regulation.

MOTION:

The Board voted unanimously to adopt a NOIRA requiring compliance with the federal rules regarding the collection and disposal of controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010. (motion by S. Elliott, second by Li)

CONSIDER USE OF CAMERA-FACILITATED PRESCRIPTION VERIFICATION PROCESS BY PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES:

Ms. Juran reviewed with the Board a request made by Virginia Oncology Associates that would allow their physicians licensed to dispense drugs to use a camera-facilitated prescription verification process. The process is somewhat akin to the Walgreens camera verification system that the Board previously deemed met compliance with regulation, albeit there are differences. Ms. Juran suggested that if the Board could not reach consensus on whether the verification process met compliance with current regulation, it could consider recommending that Virginia Oncology Associates apply for an innovative "pilot" program. Among the concerns voiced by the Board: lack of supervision of the person assisting the physician with the dispensing process; camera not interfaced with dispensing software; communications sent via email; lack of drug security; lack of process for ensuring correct drugs are placed in the correct patient's bag. No action was taken on the matter. It was recommended that Virginia Oncology Associates consider strengthening the intended verification process prior to possibly applying for an innovative pilot program.

STAFF REQUEST TO CONSIDER PARTICIPATING IN THE MULTISTATE PHARMACY JURISPRUDENCE EXAMINATION (MPJE):

Ms. Juran requested that the Board consider moving from Virginia contracting to administer its own Federal and State Drug Law Exam (FSDLE) to participating in the NABP Multistate Pharmacy Jurisprudence Examination (MPJE). Currently, Virginia is one of three states that do not participate in the MPJE. The contract with the current testing administrator expires in June 2015 and can be extended for only one additional year prior to issuing a Request for Proposal (RFP) for a testing administrator. Ms. Juran explained that staff workload has steadily increased in recent years while resources remain limited. Overseeing the administration of the jurisprudence examination is labor-intensive and costly due to the number of meetings required for exam development. Staff has also noticed fewer companies have been bidding on the examination contracts, possibly due to the relatively small number of exams administered annually. She then provided a brief comparison between the MPJE and FSDLE.

MOTION:

The Board voted unanimously to extend the contract for the Virginia FSDLE for one year and approve staff working with NABP to transition to the MPJE. (motion by S. Elliott, second by Munden)

AMEND GUIDANCE DOCUMENT 110-36

Ms. Juran discussed the proposed amendment to Guidance Document 110-36 to more accurately reflect the recommendation offered by the Compounding Work Group which met during the summer of 2014.

MOTION:

The Board voted unanimously to amend Guidance Document 110-36 as presented. (motion by Warriner, second by Boone)

AMEND GUIDANCE DOCUMENT 110-9

Ms. Juran discussed the proposed amendment to Guidance Document 110-9 which is consistent with the current inspection report.

MOTION:

The Board voted unanimously to adopt the amendment to Guidance Document 110-9 as presented. (motion by Munden, second by Warriner)

IDENTIFY SUBJECTS FOR POSSIBLE 2016 LEGISLATIVE PROPOSALS:

- IMAPACT OF DRUG SUPPLY CHAIN SECURITY ACT
- PHARMACIST ACCESS TO PMP

It was requested that the Board identify subjects for possible 2016 legislative proposals. The Drug Supply Chain Security Act prohibits boards of pharmacy from licensing third party logistic providers (3PL) as wholesale distributors. Additionally, it preempts state pedigree requirements that differ from the federal track and trace requirements. Thus, Virginia law may need amending. Another subject discussed involves limitations on when pharmacists may access the PMP. This subject is being discussed within the Governor's Task Force on Prescription Drug and Heroin Abuse. Ralph Orr, Program Director for the PMP stated that the PMP committee was meeting later this month and will consider drafting a legislative proposal to allow pharmacists to have broader access to the PMP and not simply when presented a prescription for dispensing or when serving as a physician's delegate.

REPORTS:

CHAIRMAN'S REPORT:

Ms. Shinaberry gave a brief report on upcoming events. May 16th-May 20th is the NABP 111th Annual meeting being held in New Orleans, Louisiana. She and Ms. Juran will be attending. Ms. Shinaberry stated that anyone who would like to provide comments on any of the resolutions that will be voted on at the meeting should send those comments to Ms. Juran by April 30th. She also congratulated current and past members and staff for being selected to receive the NABP Fred T. Mahaffey award during the awards dinner to be held on May 19th. This award is presented to a board that has substantially contributed to the protection of the public health and welfare through the enforcement of state and federal laws and regulations. Virginia is specifically recognized for its efforts to address concerns with compounding.

BOARD OF HEALTH PROFESSIONS:

Ms. Shinaberry gave an update on the Board of Health Professions. The last meeting was cancelled due to snow, however; the review committee is scheduled to meet next month to discuss scope of practice for dental hygienists.

PRESCRIPTION MONITORING PROGRAM:

Ralph Orr, Program Manager for the Prescription Monitoring Program (PMP), gave an overview of the program's current activity. Mr. Orr stated as of now, 5696 pharmacists are registered and 199 pharmacist delegates are registered. In the year 2014, 25% of all requests were made by pharmacists. Currently 1.1 to 1.2 million prescriptions records are being processed monthly. Mr. Orr stated that the PMP is planning an archive system to reduce the size of the program's database to increase speed and efficiency. The retention schedule will be 2 years active, 3 years inactive and after 5 years removed from database. Mr. Orr stated that they are working on a project to place morphine equivalent score information on the PMP. This will include the conversion score which is calculated by strength. This may help practitioners when looking at patients records and preventing an overdose. The higher the score, the higher the overdose risk. He also discussed the automatic registration of pharmacists on the PMP. Those pharmacists that are not already registered will become automatically registered and be sent an email to activate their account. There are currently 13,500 licensed pharmacists and it is crucial that pharmacists add or update their email address by August. Mr. Orr stated that the Board of Medicine is giving money to help develop a resource website which will assist practitioners on how to use the morphine daily dose scores, access the PMP and information on the collaborative process.

LICENSURE PROGRAM:

Mr. Johnson reported the Board currently licenses 34,066 individuals and facilities. The Board issued 848 licenses and registrations for the period of December 1, 2014 through February 28, 2015. Inspectors conducted 302 facility inspections including 151 routine inspections of pharmacies: 35 (23%) resulted in no deficiency, 56 (37%) with deficiencies and 60 (40%) with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

DISCIPLINARY PROGRAM:

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran congratulated the Board again on being selected to receive the Fred T. Mahaffey award that is given every year at the NABP annual meeting. Ms. Juran discussed her involvement with the Governor's Task Force on Prescription Drug and Heroin Abuse. A third meeting of the Storage and Disposal Workgroup will convene in mid-April. The minutes and agendas for all Task Force and Workgroup meetings can be accessed on the DHP homepage. One of the focal points for the Storage

and Disposal workgroup has been to find ways to increase drug collection boxes at law enforcement agencies throughout Virginia. Ms. Juran stated that she and Mr. Johnson attended an NABP meeting in January to consider amendments to the Verified Pharmacy Provider inspection report. The goal was to modify the VPP to present a more uniform inspection report that could potentially be adopted by all 50 states. NABP intends to release this document at the annual meeting. Ms. Juran also stated that she participated on the NABP Law and Legislative Committee in January. Pharmacy renewals have gone smoothly which includes renewals from December, February and April. The 50-State Intergovernmental meeting hosted by the FDA was last week in which she and Mr. Johnson both attended. There was excellent discussion regarding the draft MOU for interstate compounding. Ms. Juran reported that she served as a panelist for the draft information sharing documents, to include the proposed changes to their 20.88 agreement. She also stated that Virginia is fortunate to have a good working relationship with FDA and that several members of Board staff, herself included, and inspectors are commissioned with the FDA which allows them to receive non-public information from the FDA. Ms. Juran also addressed the possibility for the board to send renewal notices via email later this year. Several other boards have utilized this process for several years now and it has reduced their mailing costs. The individual or facility would receive an email that would alert them to go online and renew their license or permit. If the license is not renewed within a specified time period, a paper renewal notification will be mailed to the licensee.

CONSIDERATION OF CONSENT ORDERS

There were no consent orders for consideration at this time.

ADJOURN:

With all business concluded, the meeting concluded at approximately 12:10pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, March 25, 2015
Commonwealth Conference Center
Second Floor
Hearing Room 5

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 10:00 a.m.

PRESIDING: Ryan K. Logan, Committee Chair

MEMBERS PRESENT: Michael I. Elliott, Committee Member

STAFF PRESENT: J. Samuel Johnson, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist
Beth L. O'Halloran, Individual Licensing Manager

THE COMMUNITY FREE CLINIC OF NEWPORT NEWS
Permit Number 0201004399

Brian E. Logue, former Pharmacist In Charge, appeared with Golden Bethune-Hill, Executive Director of the Board, to discuss allegations that The Community Free Clinic of Newport News may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 25, 2015 notice.

Closed Meeting: Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of The Community Free Clinic of Newport News. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order and that no sanction be imposed.

As provided by law, this decision shall become a final Order thirty (30) days after service of such

Order on The Community Free Clinic of Newport News, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from The Community Free Clinic of Newport News within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

WESTWOOD PHARMACY CLINICAL SERVICES
Permit Number 0201003985

Shubhro Pal, Pharmacist In Charge, appeared with Shannon Dowdy, Pharmacist, to discuss allegations that Westwood Pharmacy Clinical Services may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 25, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Westwood Pharmacy Clinical Services. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Westwood Pharmacy Clinical Services, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Westwood Clinical Pharmacy Services within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

LEWISGALE MEDICAL CENTER
Permit Number 0201001043

Anita M. Atkins, Pharmacist In Charge, appeared to discuss allegations that LewisGale Medical Center may have violated certain laws and regulations governing the conduct of pharmacy as stated in the February 22, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of LewisGale Medical Center. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on LewisGale Medical Center unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from LewisGale Medical Center within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

SEVEN CORNERS PHARMACY
Permit Number 0201002487

Tien Viet Hoang, Pharmacist In Charge, appeared with Amy Vu, business manager, to discuss allegations that Seven Corners Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as

stated in the February 25, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Seven Corners Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Seven Corners Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Seven Corners Pharmacy within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

HELEN BLAND
Pharmacy Technician
Registration Number 0230020119

Ms. Helen Bland, Pharmacy technician, failed to appear to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 4, 2014 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Helen Bland. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting

was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Ms. Bland, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Ms. Bland within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

TABITHA D. BROWN
Pharmacy Technician
Registration Number 0230014089

Ms. Tabitha Brown, Pharmacy technician, failed to appear to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 4, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Tabitha D. Brown. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue

an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Ms. Brown, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Ms. Brown within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

AIKINS W. DEBRAH
Pharmacy Technician
Registration Number 0230007710

Ms. Aikins Debrah, Pharmacy technician, failed to appear to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the march 4, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Aikins W. Debrah. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Ms. Debrah, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Ms. Debrah within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

LAWRENCE W. ENG
Pharmacist
License Number 0202010380

Mr. Lawrence Eng, Pharmacist, failed to appear to discuss allegations that he may have violated certain laws and regulations governing the conduct of pharmacy as stated in the March 4, 2015 notice.

Closed Meeting

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Lawrence Eng. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order

As provided by law, this decision shall become a final Order thirty (30) days after service of such
Order on Mr. Eng, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Eng within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 3:15 p.m.

Ryan Logan, Chair

J. Samuel Johnson
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, April 16, 2015

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on April 16, 2015, at 3:00 p.m., to consider two summary suspensions.

PRESIDING: Ellen B. Shinaberry, Chair

MEMBERS PRESENT:
Jody H. Allen
Dinny Li
Ryan K. Logan
Empsy Munden
Rebecca Thornbury

MEMBERS ABSENT:
Melvin L. Boone, Sr.
Michael I. Elliott
Sheila K. W. Elliott
Cindy Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
Jim E. Rutkowski, Assistant Attorney General

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

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

WESTBURY PHARMACY Permit No. 0201-002508	Wayne T. Halbleib presented a summary of the evidence in this case.
Closed Session:	Upon a motion by Ms. Munden and duly seconded by Ms. Thornbury, the Board voted 6-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Westbury Pharmacy. Additionally, he moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.
Reconvene:	The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.
MOTION:	Upon a motion by Ms. Munden, and duly seconded by Mr. Logan, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued conduct of a pharmacy by Westbury Pharmacy poses a substantial danger to the public; and therefore, the permit of Westbury Pharmacy to conduct a pharmacy be summarily suspended.
FAIZ ANTHONY OLEY, JR. License No: 0202-010741	Wayne T. Halbleib presented a summary of the evidence in this case.
Closed Session:	Upon a motion by Ms. Munden and duly seconded by Ms. Thornbury, the Board voted 6-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Faiz Anthony Oley, Jr. Additionally, he moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.

Reconvene:	The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.
MOTION:	Upon a motion by Ms. Munden, and duly seconded by Mr. Logan, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice of Faiz Anthony Oley, Jr., poses a substantial danger to the public; and therefore, the license of Faiz Anthony Oley, Jr., to practice pharmacy be summarily suspended.
ADJOURN:	With all business concluded, the telephone conference call adjourned at 4:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Ellen B. Shinaberry, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, April 21, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Cindy Warriner, Committee Chair

MEMBERS PRESENT: Ryan Logan, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

Janet R. Underhill
License Number 0202-207242

Janet R. Underhill appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 30, 2015, Notice.

Closed Meeting: Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Janet R. Underhill. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to accept the voluntary surrender of Ms. Underhill's pharmacist license and to indefinitely suspend same.

Tiffany F. Vincent
License Number 0202-206843

Tiffany F. Vincent appeared with Lorraine Vincent, her mother, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the March 16, 2015, Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Tiffany F. Vincent. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee voted to issue an Order reprimanding Ms. Vincent.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Agee, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Agee within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN:

With all business concluded, the meeting adjourned at 2:15 p.m.

Cindy Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, May 8, 2015

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

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

TIME & PURPOSE: A quorum of the Board convened at 12:00 p.m. on Wednesday, May 8, 2015, by telephone conference call in order to consider a settlement proposal for cases currently pending before the Board.

PRESIDING: Empsy Munden, Vice-Chair

MEMBERS PRESENT:
Jody Allen
Sheila Elliott
Ellen Shinaberry
Rebecca Thornbury
Cindy Warriner

STAFF PRESENT:
Caroline Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
Jim Rutkowski, Senior Assistant Attorney General

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

With six (6) board members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

WESTBURY PHARMACY
Permit #0201-002508

Mr. Halbleib presented a summary of the evidence in this case.

Closed Session:

Upon a motion by Ms. Allen and duly seconded by Ms. Warriner, the Board voted 6-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Westbury Pharmacy. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.

Reconvene:	The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session. The Board requested that another telephone conference call be scheduled to discuss this matter.
FAIZ A. OLEY, JR. License #0202-010741	Mr. Halbleib presented a summary of the evidence in this case.
Closed Session:	Upon a motion by Ms. kAllen and duly seconded by Ms. Warriner, the Board voted 6-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Faiz A. Oley, Jr. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.
Reconvene:	The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session. The Board requested that another telephone conference call be scheduled to discuss this matter.
ADJOURN:	1:05 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Empsy Munden, Vice Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

May 11, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:05AM.

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
Michael Elliott
Ryan Logan
Empsy Munden
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Jim Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather W. Hurley, Administrative Assistant

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

PUBLIC COMMENT: Stephen F. Eckel, Clinical Associate Professor, Vice-Chair, Graduate and Post-Graduate Education, Division of Practice Advancement and Clinical Education for University of North Carolina School of Pharmacy addressed the Board concerning the topic of the use of closed system transfer devices (CSTD) to extend beyond use dates (BUD) of single dose vials. Dr. Eckel requested that board guidance not be made stricter than USP Chapter 797 and allow for the use of CSTDs to extend the use of SDVs beyond 6 hours when punctured and stored within an ISO 5 environment. He indicated this can be beneficial during drug shortages. He reported that the University of North Carolina has been conducting research with CSTDs to extend BUDs and it has shown no sign of contamination. This research has been forwarded to the USP and Dr. Eckel stated he has had continuous open dialogues with them.

Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) brought four issues to the committee's attention. First was the topic of issuing of a separate license for sterile compounding. Mr. Musselman requested that if such a requirement is approved it should apply to non-resident pharmacies as well as the in-state pharmacies. Secondly, he stated that VPhA supported amending the law for the registration of pharmacy technicians that would require them to take the Pharmacy Technician Certification Board exam (PTCB). However, the pharmacy technicians currently registered with the Board should be grandfathered. Thirdly, he commented regarding the Prescription Monitoring Program draft legislative proposal that would change the reporting time from 7 days to 24 hours. He requested that the committee consider an allowance for vendors to assist the pharmacies so that they could meet the 24 hour deadline. Lastly, he spoke on the subject of the

pharmacy benefit management companies (PBMs) and stated that the major concern is the clinical aspect. He stated that there have been issues with delays in treatment because of the PBMs and their prior authorization system. The question to be addressed is who is making the decisions regarding the patient's care and who has the oversight. Mr. Musselman referenced regulations where he feels the Board has jurisdiction to regulate the PBMs. He requested that the committee recommend proposed regulations that would allow the Board to take regulatory action against PBMs.

Otto Wachsmann, Jr., Stony Creek Pharmacy, addressed the committee with his concerns regarding PBMs and the impact they have on the small rural pharmacies. Mr. Wachmann stated he knew of several rural pharmacies closing down due to mail order pharmacies taking over. There have been issues with the PBMs calling patients at work and on their cell phones, asking them to use the mail order pharmacies instead of going to their local community pharmacy. He also addressed the issue of the pre-authorization process being cumbersome and it may take the patient days to get their medication. Mr. Wachsmann stated that patient safety is in jeopardy and that there needs to be oversight by the Board of Pharmacy.

Adam Chesler, Director of Strategic Alliances, Pharmacy Technician Certification Board (PTCB) stated that he would be available to answer any questions the committee may have regarding the PTCB exam and what is required of PTCB pharmacy technicians. He explained that currently PTCB does not require a training program, but he agrees that having pharmacy technicians PTCB certified will assist with standardizing educational requirements across the board. PTCB will require completion of an ASHP-accredited training program beginning in 2020.

Hunter Jamerson, Esq., Macaulay & Burtch, representing the Virginia Academy of Family Physicians commented that he has been currently working closely with health plans on prior authorization issues. Mr. Jamerson also briefly discussed a letter that he submitted on behalf of EPIC Pharmacies, a network that consists of over 300 community pharmacies in the Commonwealth. Their concerns are the credentialing processes, the increase of drugs classified in a "specialty" drug tier and how the PBMs inform their patients that they have to use mail order pharmacies to obtain these "specialty" drugs. A majority of the community pharmacies are unable to participate in a PBM network. This creates limits on where the patient can get their prescriptions, therefore, compromising patient access. EPIC requests that the Board regulate the PBMs as well, not just the mail order pharmacies.

Kerri Musselman, Director of Bon Secours Pharmacy, expressed concerns with PBMs based on personal experiences involving prior authorizations and certain drugs inexplicably being deemed specialty drugs. She indicated it was a difficult process to navigate as a pharmacist and expressed concern for those patients who do not have her level of understanding of PBMs. She feared these patients may not being able to receive their medications in a timely manner.

David Creecy, Poquoson Pharmacy, shared concerns regarding PBMs. He stated that there were issues with drug accessibility as well as patient safety. There is also the concern with people having to pay out of pocket who cannot afford their medication, but cannot wait for approval of a prior authorization. Mr. Creecy gave several examples of patient safety issues that include being denied their medication, not being given the correct medication, or not being trained on how to use the medication properly. Mr. Creecy requests that the mail order pharmacies or non-resident pharmacies be held to the same standards as in-state pharmacies when it comes to inspections and sterile compounding.

USE OF CLOSED SYSTEM TRANSFER DEVICES TO EXTEND BEYOND USE DATES OF SINGLE DOSE VIALS:

The committee discussed the compounding working group's recommendation to amend Guidance Document 110-36 to prohibit the use of closed system transfer devices (CSTD) to extend the beyond use dates of single dose vials beyond 6 hours when punctured and stored within a ISO class 5 environment. A response from USP in the agenda packet was also highlighted which indicated that USP does not address the use of CSTDs to extend BUDs of single dose vials. Ms. Shinaberry recommended that CSTDs be allowed to extend BUDs of single dose vials if site-specific testing was maintained to demonstrate its successful use to safely extend the BUD without contamination. Ms. Juran indicated she would contact USP to ensure this recommendation would be consistent with USP allowances and determine what criteria should be included in any site-specific testing. Information will be shared with the full board at the June board meeting.

EMERGENCY REGULATIONS FOR OUTSOURCING FACILITIES:

Ms. Yeatts reviewed HB 1739 with the committee regarding the statutory framework. She reported that the Board may begin drafting regulations, but may not adopt them until after July 1, 2015 when HB 1739 becomes effective. Therefore, the earliest the Board can adopt regulations will be at the September full board meeting.

MOTION:

The committee voted unanimously to recommend the following amendments to the draft proposed regulations for outsourcing facilities:

- **In 18VAC110-20-215 C, 2, b, strike "active" in the first two lines, add an "s" to "ingredient", and add "or lot number" at the end of subsection. (motion by Warriner, second by Elliott)**

MOTION:

The committee voted unanimously to recommend to the full board at the September 2015 full board meeting that it adopt the draft proposed regulations for outsourcing facilities as amended. (motion by Munden, second by Elliott)

EMERGENCY REGULATIONS FOR

Ms. Yeatts reviewed with the committee HB 2192 which passed during the 2015 General Assembly session and the draft proposed regulations

PERMITTING DISPENSING FACILITIES FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES:

included in the agenda packet.

MOTION:

The committee voted unanimously to strike section B within the proposed 18VAC 110-30-20 concerning the alarm requirements for physicians who dispense no more than five different topical Schedule VI drugs for cosmetic use and for staff to continue to follow guidance on this subject within Guidance Document 110-12. (motion by Shinaberry, second by Munden)

MOTION:

The committee voted unanimously to amend 18VAC110-30-90 number 5 to clarify "immediate vicinity" by replacing the terms with "twenty feet" and adding at the end of the phrase "and not located within an exam room or restroom." (motion by Logan, second by Munden)

MOTION:

The committee voted unanimously to increase the proposed renewal permit fee in 18VAC110-30-15 C, 2 to $240 and to recommend to the full board at the September 2015 full board meeting to adopt the proposed regulations regarding the licensing of physician dispensing locations as amended. (motion by Shinaberry, second by Munden)

REGULATIONS FOR PACE FACILITIES:

The committee reviewed HB 1733 that was approved during the 2015 General Assembly session regarding PACE facilities. Ms. Yeatts stated that that the current regulations for Community Services Boards (CSBs) and Behavioral Health Authorities (BHAs) could be amended to include PACE facilities. The committee was presented with the draft regulatory language for consideration.

MOTION:

The committee voted unanimously to recommend to the full board in September 2015 to adopt the proposed regulations for PACE facilities. (motion by Munden, second by M. Elliott)

POSSIBLE LEGISLATIVE PROPOSALS:

Third Party Logistic Providers, Wholesale Distributors, Track and Trace Requirements, etc.:

Ms. Juran presented to the committee possible legislative proposals for the upcoming General Assembly session. The proposals were on the following topics: replace current pedigree requirements with a requirement for wholesale distributors to comply with federal track and trace requirements; create licensure categories for third-party logistic providers, non-resident third-party logistic providers, non-resident manufacturers, and nonresident medical equipment suppliers; whether wholesale distributors should be required to obtain Verified-Accredited Wholesale Distributors accreditation (VAWD); clarification that a manufacturer may ship without obtaining a wholesale distributor permit; and, the consideration of creating a separate permit for those pharmacies that compound sterile drugs. The Board requested counsel to research

whether the Board may identify sterile compounding pharmacies through a subcategory of the pharmacy permit in regulation, in lieu of creating a new licensing category in statute. The Board also requested staff to research definitions for "co-licensed partner" and "track and trace" that could be incorporated into the proposed legislative proposal.

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt the legislative proposal, with definitions for "co-licensed partner" and "track and trace" to be added, to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in 54.1-3410.2 F. (motion by Shinaberry, second by Munden)

Nonresident Medical Equipment Suppliers:

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would create a new licensing category for nonresident medical equipment suppliers. (motion by Elliott, second by Shinaberry)

Separate License for Pharmacies Performing Sterile Compounding:

MOTION:

The committee voted unanimously to request counsel to research whether the board could identify pharmacies that perform sterile compounding through a subcategory of the pharmacy permit via regulation, in lieu of creating a separate licensing category. (motion by Munden, second by Shinaberry)

- Consideration to require VAWD for wholesale distributors and/or manufacturers:

Ms. Juran gave a brief overview of the Verified-Accredited Wholesale Distributors (VAWD) accreditation that is offered through the National Association of the Boards of Pharmacy (NABP). The committee determined that it would not recommend to the full board at this time to require VAWD since regulations supporting the Drug Supply Chain Security Act have not been fully implemented, but that the Board may wish to revisit this topic in the future.

- PMP legislation:

Ralph A. Orr, Program Manager, Prescription Monitoring Program (PMP) gave a brief update on the PMPs current legislative proposals for the 2016 General Assembly. The PMP advisory committee recommended a legislative proposal to amend §54.1-2523 to expand a pharmacist's ability to access PMP data when consulting on a specific patient and not simply dispensing a drug. Mr. Orr also stated that the PMP committee recommends changing the reporting requirement from within 7 days of dispensing to within 24 hours of dispensing. With respect to the proposal for reporting within 24 hours of dispensing or the next business day whichever comes later, the committee questioned whether the language referred to the next business day for the Department

or the dispenser. Additionally, the committee questioned if simply requiring reporting within 24 hours was sufficient and therefore, the PMP may wish to consider deleting the allowance for reporting within the next business day.

CONSIDER REQUIREMENT FOR PHARMACY TECHNICIAN CERTIFICATION BOARD (PTCB):

Ms. Juran reminded the committee that the full board briefly discussed at the December 2014 full board meeting whether it should require PTCB certification as a prerequisite for pharmacy technician registration and referred the matter to the Regulation Committee for further consideration. The committee discussed minimal educational standards for pharmacy technicians, grandfathering those already registered as pharmacy technicians, and the possible elimination of the state and ExCPT pharmacy technician exams. There was consensus that a pharmacy technician should still be allowed to enroll in a Board-approved pharmacy technician training program and perform duties of a pharmacy technician for up to 9 months while working to complete the process for obtaining board registration as a pharmacy technician. Those pharmacy technicians already registered should not be required to obtain PTCB certification. Additionally, there was agreement that the allowance for a limited-use pharmacy technician registration for practicing in a free clinic should remain and that the fee for the initial PTCB examination should be waived, along with initial application fee for board registration and subsequent renewals fees.

MOTION:

The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would amend 54.1-3321 to require new applicants for registration as a pharmacy technician to obtain certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite to registration and allow the fee for the initial PTCB examination to be waived, along with the initial application fee for board registration and subsequent renewals fees, for a limited-use pharmacy technician registration. (motion by Munden, second by Logan)

OVERSIGHT OF PHARMACY BENEFITS MANAGERS:

Ms. Warriner reviewed the comments and concerns made regarding Pharmacy Benefit Managers (PBMs). Many of the comments provided referenced concerns with patient safety, an increased number of drugs requiring prior authorizations or classified as specialty drugs, and patient access to medications. Ms. Warriner stated she participated on a NABP Task Force in October 2014 concerning PBMs. The committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage. Ms. Juran stated that this is a large, complex subject affecting multiple healthcare professions, not simply pharmacists, and any oversight would likely involve multiple governing bodies. She recommended the committee consider asking Dr. Brown or Secretary Hazel to form a work group of various stakeholders to review the possible lack of oversight for PBMs. After discussion, Dr. Brown agreed that he and Ms. Juran would contact Secretary Hazel to explore possible next steps.

ADJOURN:

With all business concluded, the meeting adjourned at 2:28pm.

Cynthia Warriner, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

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

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

TIME & PURPOSE: A quorum of the Board convened at 1:00 p.m. on Wednesday, May 13, 2015, by telephone conference call in order to consider a settlement proposal for cases currently pending before the Board.

PRESIDING: Empsy Munden, Vice-Chair

MEMBERS PRESENT:
Melvin Boone
Sheila Elliott
Ryan Logan
Ellen Shinaberry
Rebecca Thornbury
Cindy Warriner

STAFF PRESENT:
Caroline Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
Jim Rutkowski, Senior Assistant Attorney General

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

With seven (7) board members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

WESTBURY PHARMACY
Permit #0201-002508

Mr. Halbleib presented a summary of the evidence in this case.

Closed Session: Upon a motion by Ms. Shinaberry and duly seconded by Ms. Warriner, the Board voted 7-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of

Virginia for the purpose of deliberation to reach a decision in the matter of Westbury Pharmacy. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.

Reconvene: The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

MOTION: Upon a motion by Ms. Shinaberry and duly seconded by Ms. Elliott, the Board voted 7-0 in favor of the motion that, according to the evidence presented, following the summary suspension of Westbury Pharmacy's permit to conduct a pharmacy in Virginia, the Board agreed to enter into a Consent Order with Findings of Fact, Conclusions of Law and sanctions as stated in Attachment I.

FAIZ A. OLEY, JR.
License #0202-010741

Mr. Halbleib presented a summary of the evidence in this case.

Closed Session: Upon a motion by Ms. Shinaberry and duly seconded by Ms. Warriner, the Board voted 7-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Faiz A. Oley, Jr. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.

Reconvene: The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Caroline Juran departed at 3:10 p.m.

MOTION: Upon a motion by Ms. Warriner and duly seconded by Mr. Logan, the Board voted 7-0 in favor of the motion that, according to the evidence presented, following the summary suspension of Mr. Oley's license to practice pharmacy in Virginia, the Board agreed to enter into a Consent Order with Findings of Fact, Conclusions of Law and sanctions as stated in Attachment II.

ADJOURN: 3:20 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Empsy Munden, Vice Chair

Date

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Westbury Pharmacy holds permit number 0201-002508 issued by the Board to conduct a pharmacy in the Commonwealth of Virginia on August 8, 1980. By Order of the Board, the permit was summarily suspended on April 17, 2015.

2. Westbury Pharmacy entered into a Consent Order with the Board on August 23, 2013, for two major deficiencies identified during an inspection conducted on November 30, 2012. The first deficiency was the perpetual inventory was not being maintained or monitored as required in violation of 18 VAC 110-20-240 of the Board's Regulations Governing the Practice of Pharmacy ("Regulations"). The second deficiency was there was no documentation of initial and semi-annual media-fill testing for persons performing high-risk level compounding of sterile products in violation of § 54.1-3410.2 of the Code of Virginia (1950), as amended ("Code"). Under the terms of the Consent Order, Westbury Pharmacy acknowledged the deficiencies, paid a monetary penalty of $5,250, and agreed to submit documentation showing corrective action.

3. Westbury Pharmacy also entered into a Consent Order with the Board on February 19, 2014, for six deficiencies identified during inspections conducted on November 30, 2012 and July 24, 2013, concerning non-compliance with applicable law and regulations governing compounded drug products. Under the terms of the Consent Order, Westbury Pharmacy acknowledged the deficiencies and paid a monetary penalty of $7,750.

4. Unannounced inspections of Westbury Pharmacy on May 21 and 29, 2014, and on February 3 and 5, 2015, and a drug audit on May 29, 2014, disclosed the following deficiencies:

a. Westbury Pharmacy violated § 54.1-3316(2) and (7) of the Code, and 18 VAC 110-20-25(6) of the Regulations in that it failed to take the necessary steps to prevent the diversion of controlled substances. Specifically, between May 2012 and on or about July 29, 2014, the pharmacy lost 25,804 tablets of oxycodone 30mg (Schedule II), 21,901 tablets of oxycodone/APAP 10/325mg (Schedule II), 1,962 tablets of oxycodone/APAP 7.5/325mg (Schedule II), 561 tablets of methadone 10mg (Schedule II), 60mg of fentanyl citrate powder (Schedule II), and 261 tablets of hydrocodone/APAP 5/325 (Schedule III) due in part to theft by an employee.

b. Westbury Pharmacy violated § 54.1-3316(1), (2), (7), and (13) of the Code and 18 VAC 110-20-25(6) and 18 VAC 110-20-200(B) of the Regulations in that the Schedule II drugs were not securely stored. The drugs could be removed from the storage cabinet when it was locked.

c. Westbury Pharmacy violated § 54.1-3316(1), (7), and (13) of the Code and 18 VAC 110-20-190(B) and (C) of the Regulations in that:

i. The access code to the alarm system and the key to the code were posted on the alarm control panel in full view of all employees.

ii. Between January 26, 2015, and February 3, 2015, a pharmacy clerk and a pharmacy technician deactivated the pharmacy alarm on multiple occasions, and five unlicensed individuals had access to the pharmacy department when a pharmacist was not present.

d. Westbury Pharmacy violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-240(A)(1) of the Regulations in that the perpetual inventory was not being maintained as required. The Pharmacist-in-Charge was aware that the computer system was not keeping accurate records of the inventories between June 2012 and May 2014, and he simply adjusted the totals listed in the computer system to account for any discrepancies between the theoretical and physical counts. This deficiency was noted previously in an inspection summary dated November 30, 2012.

e. Westbury Pharmacy violated § 54.1-3316(7) and § 54.1-3410.2(E) and (I)(4) of the Code and 18 VAC 110-20-321 of the Regulations in that:

i. Between January 6, and February 11, 2014, a pharmacy technician performed high-risk compounding on 24 occasions before passing his initial media-fill testing.

ii. A pharmacist and pharmacy technician performing high-risk compounding had not completed their semi-annual media-fill testing or gloved finger tip testing as required by the United

States Pharmacopeia-National Formulary ("USP-NF") within the required time period. This deficiency was noted previously in an inspection summary dated November 30, 2012.

f. Westbury Pharmacy violated § 54.1-3316(7) and § 54.1-3410.2(D), (E) and (I)(1) and (2) of the Code and 18 VAC 110-20-321 of the Regulations in that between May 22, 2012, and July 31, 2014, multiple sterile and non-sterile compounding records for single patient, single prescription and batch compounded products were not initialed by a pharmacist.

g. Westbury Pharmacy violated § 54.1-3316(7) and § 54.1-3410.2(E) of the Code and 18 VAC 110-20-321 of the Regulations in that between January 1, 2014 and August 14, 2014, sterile products containing tacrolimus (Schedule VI), a hazardous drug, were compounded in the same hood as non-hazardous drugs.

h. Westbury Pharmacy violated § 54.1-3316(7) of the Code and 18 VAC 110-20-140(A) of the Regulations in that remodeling applications were not filed with the Board when the following changes were made:

i. The security system was changed in January 2013.

ii. The following structural changes were made to the prescription department after August 2014:

a. A new door was installed to the entrance of the prescription department from the warehouse storage area;

b. Two new doors with badge access scanners were installed to the rear left and front right side of the prescription department;

c. The locking glass doors that protected the Schedule II drugs were replaced with glass doors at the ends of the Schedule II aisles. The doors could only be opened by badge scanner access. The tops of the Schedule II bays were enclosed with wire and a 360 degree video surveillance system was installed.

i. Westbury Pharmacy violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(B) and (C) of the Regulations in that prescriptions requiring refrigeration or freezing were stored in an area accessible to the public.

j. Westbury Pharmacy violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(C) of the Regulations in that controlled paraphernalia, flu vaccines, a vial of clonidine (Schedule VI) injectable, and a tube of lidocaine-prilocaine (Schedule VI) ointment were stored in areas outside of the previously approved drug storage area.

k. Westbury Pharmacy violated § 54.1-3316(7) and § 54.1-2521(A), (B) and (C) of the Code and 18 VAC 76-20-40(A), (B), (D) and (E) of the Regulations in that between May 20, 2012 and July 8, 2014, incorrect and incomplete data was sent to the Virginia Prescription Monitoring Program, including failure to list a drug, listing an incorrect practitioner, and failure to name a drug product for compounded agents.

l. Westbury Pharmacy violated § 54.1-3316(7) and § 54.1-3404(B) of the Code in that the biennial inventory for Schedule III through V drugs taken May 20, 2012, could not be located.

m. Westbury Pharmacy violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-200(D) of the Regulations in that over one hundred seventy-one (171) expired drugs were in the pharmacy mixed in with the drug stock.

n. Westbury Pharmacy violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(A) and (B) of the Regulations in that:

i. At least twenty-one (21) bottles of medication were labeled as containing one type of medication, but contained medication from two different manufacturers.

ii. At least sixty-five (65) bottles and one blister pack of medication either were unlabeled or did not include either the drug name, an expiration date, a lot number, or a quantity. Three of the bottles contained multiple types of pills, and four bottles contained more medication than listed on the label.

iii. At least one hundred twenty-four (124) bottles of medication, thirteen (13) of them Schedule II drugs, contained pills in excess of the amount listed on the bottle label.

iv. One bottle labeled as containing Afeditab CR (nifedipine, Schedule VI) 60mg contained tablets from three different manufacturers. One of the tablets was amitriptyline (Schedule VI).

o. Westbury Pharmacy violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(D) of the Regulations in that medication returned by patients or their relatives after it had left the pharmacy premises and medication that was returned before it left the pharmacy was placed back in stock medicine bottles on the shelf.

p. Westbury Pharmacy violated § 54.1-3316(1) and (7), § 54.1-3410.2(B) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D), 18 VAC 110-20-321 and 18 VAC 110-20-355(A) and (B) of the Regulations in that forty-three (43) compounded drugs either were expired, lacked lot numbers, or had no expiration dates and no compounding records.

q. Westbury Pharmacy violated § 54.1-3316(5), (7) and (13) of the Code in that:

i. Pharmacy employees engaged in a pattern of waiving and discounting co-pays for certain individuals, primarily those who ordered compounded pain medication, and fraudulently reporting them as paid to the insurance company.

ii. Pharmacy employees engaged in a pattern of charging insurance company co-pays when the patients did not pick up the medication.

r. On November 6, 2014, Westbury Pharmacy incurred and subsequently paid an audit chargeback of $278,770.06 and audit fee of $41,815.51 to CVS/Caremark following an audit for the two-year period between March 19, 2012 and March 17, 2014. The audit concerned both inaccurate claim submissions and copayment collections.

s. On April 17, 2015, the Board's Order of Summary Suspension issued to Westbury Pharmacy was hand-delivered to Joseph A. Oley, Pharmacist-in-Charge, Westbury Pharmacy. A sign prepared by Board staff was placed on the door at the entrance of the pharmacy notifying patients that Westbury Pharmacy was unable to dispense medications. An inventory of all drugs in the pharmacy was conducted. Unsealed bottles of drugs as well as containers in the "Will Call Area" of the pharmacy department were embargoed. Approximately 3,904 open containers and unsealed bottles of drugs were embargoed.

SANCTIONS

It is hereby ORDERED that the permit of Westbury Pharmacy be, and hereby is, REVOKED. Upon entry of this Order, the permit of Westbury Pharmacy will be recorded as revoked and no longer current.

It is further ORDERED that Westbury Pharmacy will ensure, after it has obtained authorization to do so from all relevant governmental agencies, that all embargoed drugs in open containers and unsealed bottles are destroyed and that all costs associated with the drugs' destruction will be paid for by Westbury Pharmacy.

It is further ORDERED that Westbury Pharmacy shall pay a monetary penalty in the amount of Sixty-Five Thousand Fifty Dollars ($65,050.00). Such payment shall be made within thirty (30) days of the date this Order is entered and shall be made by cashier's check or money order made payable to the "Treasurer of Virginia."

At such time as Westbury Pharmacy is able to resume the competent conduct of pharmacy with reasonable skill and safety to patients, it may petition for the reinstatement of its permit. Pursuant to § 54.1-2408.2 of the Code, should Westbury Pharmacy seek reinstatement of its permit after three years, it shall be responsible for any fees that may be required for the reinstatement of its permit prior to issuance of its permit to resume practice. The reinstatement of Westbury Pharmacy's permit shall require the affirmative vote of three-fourths of the members at a meeting of the Board.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Faiz A. Oley, Jr. holds license number 0202-010741 issued by the Board to practice as a pharmacist in the Commonwealth of Virginia. Said license was summarily suspended on April 17, 2015.

2. Pursuant to an Order of the Board of Pharmacy entered on December 12, 2006, Mr. Oley was required to complete the Accreditation Council for Pharmacy Education ("ACPE") approved continuing pharmacy education courses, *Controlled Substance Prescriptions and Pain Management: Striking a Balance* and *Substance Abuse: Guidelines for Professionals.* These courses were required due to Mr. Oley allowing hydrocodone/APAP (C-III), diazepam (C-IV) and butalbital/APAP (C-VI) to be dispensed to a patient without proper authorization from the prescribing physician and for refilling a patient's prescriptions for hydrocodone/APAP and butorphanol (C-VI) early.

3. During the course of Mr. Oley's employment as Pharmacist-in-Charge of Westbury Pharmacy, Richmond, Virginia ("Westbury"), unannounced inspections of Westbury on May 21 and 29, 2014, and on February 3 and 5, 2015, and a drug audit on May 29, 2014, disclosed the following deficiencies:

a. Mr. Oley violated § 54.1-3316(2) and (7) of the Code and 18 VAC 110-20-25(6) of the Regulations Governing the Practice of Pharmacy ("Regulations"), in that he failed to take the necessary steps to prevent the diversion of controlled substances. Specifically, between May 2012 and July 29, 2014, the pharmacy lost 25,804 tablets of oxycodone 30mg (Schedule II), 21,901 tablets of oxycodone/APAP 10/325mg (Schedule II), 1,962 tablets of oxycodone/APAP 7.5/325mg (Schedule II), 561 tablets of methadone 10mg (Schedule II), 60mg of fentanyl citrate powder (Schedule II), and 261 tablets of hydrocodone/APAP 5/325 (Schedule III) due in part to theft by an employee.

b. Mr. Oley violated § 54.1-3316(1), (2), (7), and (13) of the Code and 18 VAC 110-20-25(6) and 18 VAC 110-20-200(B) of the Regulations in that the Schedule II drugs were not securely stored. The drugs could be removed from the storage cabinet when it was locked.

c. Mr. Oley violated § 54.1-3316(1), (7), and (13) of the Code and 18 VAC 110-20-190(B) and (C) of the Regulations in that:

i. The access code to the alarm system and the key to the code were posted on the alarm control panel in full view of all employees.

ii. Between January 26, 2015, and February 3, 2015, a pharmacy clerk and a pharmacy technician deactivated the pharmacy alarm on multiple occasions, and five unlicensed individuals had access to the pharmacy department when a pharmacist was not present.

d. Mr. Oley violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-240(A)(1) of the Regulations in that the perpetual inventory was not being maintained as required. He was aware that the computer system was not keeping accurate records of the inventories between June 2012 and May 2014 and he simply adjusted the totals listed in the computer system to account for any discrepancies between the theoretical and physical counts. This deficiency was previously noted in an inspection summary dated November 30, 2012.

e. Mr. Oley violated § 54.1-3316(7) and § 54.1-3410.2(E) and (I)(4) of the Code and 18 VAC 110-20-321 of the Regulations in that:

i. Between January 6 and February 11, 2014, a pharmacy technician performed high-risk compounding on 24 occasions before passing his initial media-fill testing.

ii. A pharmacist and pharmacy technician performing high-risk compounding had not completed their semi-annual media-fill testing or gloved finger tip testing as required by the United States Pharmacopeia–National Formulary ("USP-NF") within the required time period. This deficiency was previously noted in an inspection summary dated November 30, 2012.

f. Mr. Oley violated § 54.1-3316(7) and § 54.1-3410.2(D), (E) and (I)(1) and (2) of the Code and 18 VAC 110-20-321 of the Regulations in that between May 22, 2012, and July 31, 2014, multiple sterile and non-sterile compounding records for single patient, single prescription and batch compounded products were not initialed by a pharmacist.

g. Mr. Oley violated § 54.1-3316(7) and § 54.1-3410.2(E) of the Code and 18 VAC 110-20-321 of the Regulations in that between January 1, 2014 and August 14, 2014, sterile products containing tacrolimus (Schedule VI), a hazardous drug, were compounded in the same hood as non-hazardous drugs.

h. Mr. Oley violated § 54.1-3316(7) of the Code and 18 VAC 110-20-140(A) of the Regulations in that remodeling applications were not filed with the Board when the following changes were made:

i. The security system was changed in January 2013.

ii. The following structural changes were made to the prescription department after August 2014:

a. A new door was installed to the entrance of the prescription department from the warehouse storage area;

b. Two new doors with badge access scanners were installed to the rear left and front right side of the prescription department;

c. The locking glass doors that protected the Schedule II drugs were replaced with glass doors at the ends of the Schedule II aisles. The doors could only be opened by badge scanner access. The tops of the Schedule II bays were enclosed with wire and a 360 degree video surveillance system was installed.

i. Mr. Oley violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(B) and (C) of the Regulations in that prescriptions requiring refrigeration or freezing were stored in an area accessible to the public.

j. Mr. Oley violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(C) of the Regulations in that controlled paraphernalia, flu vaccines, a vial of clonidine (Schedule VI) injectable, and a tube of lidocaine-prilocaine (Schedule VI) ointment were stored in areas outside of the previously approved drug storage area.

k. Mr. Oley violated § 54.1-3316(7) and § 54.1-2521(A), (B) and (C) of the Code and 18 VAC 76-20-40(A), (B), (D) and (E) of the Regulations in that between May 20, 2012 and July 8, 2014, incorrect and incomplete data was sent to the Prescription Monitoring Program, including failure to list a drug, listing an incorrect practitioner, and failure to name a drug product for compounded agents.

l. Mr. Oley violated § 54.1-3316(7) and § 54.1-3404(B) of the Code in that the biennial inventory for Schedule III through V drugs taken on May 20, 2012, could not be located.

m. Mr. Oley violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-200(D) of the Regulations in that over one hundred seventy-one (171) expired drugs were in the pharmacy mixed in with the drug stock.

n. Mr. Oley violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(A) and (B) of the Regulations in that:

i. At least twenty-one (21) bottles of medication were labeled as containing one type of medication, but contained medication from two different manufacturers.

ii. At least sixty-five (65) bottles and one blister pack of medication either were unlabeled or did not include either the drug name, an expiration date, a lot number, or a quantity. Three of the bottles contained multiple types of pills, and four bottles contained more medication than listed on the label.

iii. At least one hundred twenty-four (124) bottles of medication, thirteen (13) of them Schedule II drugs, contained pills in excess of the amount listed on the bottle label.

iv. One bottle labeled as containing Afeditab CR (nifedipine, Schedule VI) 60mg contained tablets from three different manufacturers. One of the tablets was amitriptyline (Schedule VI).

o. Mr. Oley violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(D) of the Regulations in that medication returned after it had left the pharmacy by patients or their relatives and medication that was returned before it left the pharmacy was placed back in stock medicine bottles on the shelf.

p. Mr. Oley violated § 54.1-3316(1) and (7), § 54.1-3410.2(B) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D), 18 VAC 110-20-321 and 18 VAC 110-20-355(A) and (B) of the Regulations in that forty-three (43) compounded drugs either were expired, lacked lot numbers, or had no expiration dates and no compounding records.

q. Mr. Oley violated § 54.1-3303(A) and § 54.1-3316(5), (7) and (13) of the Code in that he returned drugs that were not picked up to the drug stock and still charged the insurance company.

r. Mr. Oley violated § 54.1-3316(7) and § 54.1-3410(A)(2) of the Code and 18 VAC 110-20-290(C) of the Regulations in that between July 9, 2012 and May 6, 2014, he filled 11 Schedule II prescriptions as emergency fills when they were all called in by the prescribers' agent and the quantities dispensed were for the entire amount instead of just enough to allow the prescription to be physically presented at the pharmacy.

s. Mr. Oley violated § 54.1-3316(2) and (7), § 54.1-3408.03(A) and § 54.1-3410(A) of the Code and 18 VAC 110-20-25(10) and 18 VAC 110-20-270(C) of the Regulations in that between December 23, 2013, and April 11, 2014, he dispensed four Schedule II prescriptions where he made changes to the prescriptions without receiving prior approval from the prescriber.

SANCTIONS

It is hereby ORDERED that:

1. The license of Faiz A. Oley, Jr. be, and hereby is, REVOKED.

2. Upon entry of this Order, the license of Mr. Oley will be recorded as revoked and no longer current. During the period of revocation, a pharmacist-in-charge or pharmacist on duty shall not permit Mr. Oley to have access to the prescription department or controlled substances of any pharmacy in accordance with revised 18 VAC 110-20-190 of the Regulations, as approved by the Governor and submitted to the Virginia Register of Regulations on May 11, 2015.

3. Faiz A. Oley, Jr. shall be assessed a monetary penalty of Fifty-Five Thousand Fifty Dollars ($55,050.00). Such payment shall be made within thirty (30) days of the date this Order is entered and shall be made by cashier's check or money order made payable to the "Treasurer of Virginia."

4. Pursuant to § 54.1-2408.2 of the Code, should Mr. Oley seek reinstatement of his license after three years, he shall be responsible for any fees that may be required for the reinstatement of his license prior to issuance of his license to resume practice. The reinstatement of Mr. Oley's license shall require the affirmative vote of three-fourths of the members at a meeting of the Board.

Agenda Item: Adoption of Regulation to Schedule certain chemicals in Schedule I of the Drug Control Act

Staff Note:

There was a Public Hearing conducted at 9:00 this morning pursuant to requirements of § 54.1-3443 of the Drug Control Act.

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of Code section § 54.1-3443

Copy of regulation to schedule certain chemicals

Board action:

Adoption of section 18VAC110-20-322. Placement of chemicals in Schedule I. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

Project 4220 - none

BOARD OF PHARMACY

Placement of chemicals in Schedule I

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

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

1. Cannabimimetric agents:

~~1. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA)~~

~~2. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB)~~

~~3. 3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA)~~

a. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA)

b. methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)- 3-methylbutanoate (other name: 5-fluoro-AMB)

c. 1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201)

d. 1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144)

2. Substituted cathinones:

a. 4-bromomethcathinone (other name: 4-BMC)

b. 4-chloromethcathinone (other name: 4-CMC)

B. The placement shall remain in effect until ~~July 28, 2016~~ February 8, 2017 unless enacted into law in the Drug Control Act.

Board of Pharmacy

Chart of Regulatory Actions as of June 8, 2015

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Prohibition against incentives to transfer prescriptions [Action 4186] NOIRA - *At Secretary's Office for 353 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Collection sites for disposal of unused drugs [Action 4337] NOIRA - *Register Date: 6/1/15* *Comment: 6/1/15 to 7/1/15*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 760 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Maintaining floor stock of certain drugs onsite at correctional facilities [Action 4157] Fast-Track - *Register Date: 6/1/15* *Effective: 7/16/15*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Nonresident pharmacy renewal date and access by suspended pharmacists to prescription department [Action 4215] Fast-Track - *Register Date: 6/1/15* *Effective: 7/16/15*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Drugs and emergency medical services agencies [Action 4216] Fast-Track - *Register Date: 6/1/15* *Effective: 7/16/15*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Final - *Register Date: 6/1/15* *Effective: 7/1/15*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	(E) Correction of error [Action 4335] Final - *Register Date: 5/18/15* *Effective: 6/17/15*

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

MEMORANDUM

TO: Members, Board of Pharmacy

FROM: David E. Brown, D.C.

DATE: May 6, 2015

SUBJECT: Revenue and Expenditure Analysis

Virginia law requires that an analysis of revenues and expenditures of each regulatory board be conducted at least biennially. If revenues and expenditures for a given board are more than 10% apart, the Board is required by law to adjust fees so that the fees are sufficient, but not excessive, to cover expenses. The adjustment can be either an increase or decrease.

The Board of Pharmacy ended the 2012 - 2014 biennium (July 1, 2012, through June 30, 2014) with a cash balance of $2,384,739. Current projections indicate that expenditures for the 2014 - 2016 biennium (July 1, 2014, through June 30, 2016) will exceed revenue by approximately $658,655. When combined with the Board's $2,384,739 cash balance as of June 30, 2014, the Board of Pharmacy projected cash balance on June 30, 2016, is $1,726,084.

We recommend that no action to change license fees be taken at this time.

We are grateful for continued support and cooperation as we work together managing the fiscal affairs of the Board and the Department.

Please do not hesitate to call me if you have questions.

cc: Caroline Juran, Executive Director
Jaime Hoyle, Chief Deputy Director
Jason Brown, Deputy Director of Administration
Charles E. Giles, Budget Manager
Elaine Yeatts, Senior Policy Analyst

Agenda Item: Legislative Proposals

Enclosed:

- Copy of bill proposing Virginia licensure for third party logistics providers and non-resident manufacturers, etc.
- Copy of bill proposing registration of non-resident medical equipment suppliers
- Copy of bill proposing requirement for PTCB certification for registration as a pharmacy technician

Staff note (excerpts from Regulation Committee minutes):

- The committee voted unanimously to recommend to the full board in June 2015 to adopt the legislative proposal, with definitions for "co-licensed partner" and "track and trace" to be added, to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in 54.1-3410.2 F.
- The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would create a new licensing category for nonresident medical equipment suppliers
- The committee voted unanimously to recommend to the full board in June 2015 to adopt a legislative proposal that would amend 54.1-3321 to require new applicants for registration as a pharmacy technician to obtain certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite to registration and allow the fee for the initial PTCB examination to be waived, along with the initial application fee for board registration and subsequent renewals fees, for a limited-use pharmacy technician registration.

Board Action:

Motions for each proposal on whether to request introduction of the draft legislation for the 2016 Session of the General Assembly

Board of Pharmacy

2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending sections §§ 54.1-3307, 54.1-3401, 54.1-3410.2, 54.1-3435, 54.1-3435.01, 54.1-3435.1, and 54.1-3437 and by adding sections numbered §§ 54.1-3435.5, 54.1-3435.6 and 54.1-3442.1, pertaining to registration of nonresident manufacturers and nonresident third-party logistics providers, permitting of third-party logistics providers and a requirement for wholesale distributors to comply with federal track and trace requirements.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3307, 54.1-3401, 54.1-3410.2, 54.1-3435, 54.1-3435.01, 54.1-3435.1, and 54.1-3437 of the *Code of Virginia* be amended and reenacted and that §§ 54.1-3435.5, 54.1-3435.6 and 54.1-3442 be enacted as follows:

§ 54.1-3307. Specific powers and duties of Board.

A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.

The Board's regulations shall include criteria for:

1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.

2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.

3. Controls and safeguards against diversion of drugs or devices.

4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.

5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.

6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.

7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.

9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.

~~B. The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353(e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.~~

C. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

~~D. For the purposes of this section:~~

~~"Normal distribution channel" means a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer, through acquisition and sale by one wholesale distributor as defined in § 54.1-3401, that is not exempted pursuant to § 54.1-3401.1, to a chain pharmacy warehouse to its intracompany pharmacies; or a chain of custody for a prescription drug from initial sale by a pharmaceutical manufacturer to a chain pharmacy warehouse to its intracompany pharmacies.~~

~~"Pedigree" means a paper document or electronic file recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer through acquisition and sale by any wholesale distributor, as defined in § 54.1-3401 and not exempted pursuant to § 54.1-3401.1, until sale to a pharmacy or other person dispensing or administering the controlled substance. Returns from a pharmacy to the originating wholesale distributor or pharmaceutical manufacturer shall not be subject to the pedigree requirements of this section.~~

§ 54.1-3401. Definitions.

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

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262 (k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a party that, with another party or parties, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with the U. S. Food and Drug Administration's' implementation of the federal Prescription Drug Marketing Act.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which

has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"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 that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall

only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

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

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

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262 (k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement,

or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures to include a manufacturer's co-licensed partner or repackager..

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not

be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353 (b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning -- may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262 (a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262 (k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"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."

"Third-party logistics provider" means an entity that provides or coordinates warehousing, or other logistics services of a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of a drug or device, but does not take ownership of the product, nor has responsibility to direct the sale or disposition of the product.

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

"Warehouser" means any person, other than a wholesale distributor, manufacturer, or third-part logistics provider, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, ~~manufacturers; repackers;~~ own-label distributors; private-label distributors; jobbers; brokers; ~~warehouses, including manufacturers' and distributors' warehouses,~~ chain drug warehouses conducting wholesale distributions~~, and wholesale drug warehouses~~; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition. This term shall not include a manufacturer or a third-party logistics provider.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

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

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

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

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

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

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

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

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

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

Pharmacists shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate

beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

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

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

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

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

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

2. Are manufactured by an establishment that is registered by the FDA; or

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

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

H. Pharmacists shall not engage in the following:

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

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a

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

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

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

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

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

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

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to

include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

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

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

§ 54.1-3435. License to act as wholesale distributor; renewal; fee.

It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public. A wholesale distributor shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

E. A nonresident wholesale distributor shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

§ 54.1-3435.1. Denial, revocation, and suspension of license as wholesale distributor, ~~or of~~ registration as a nonresident wholesale distributor, third-party logistics provider, nonresident third-party logistics provider, manufacturer, and nonresident manufacturer.

A. The Board may deny, revoke, suspend, or take other disciplinary actions against a wholesale distributor license, ~~or~~ nonresident wholesale distributor registration, third-party logistics provider, nonresident third-party logistics provider, manufacturer, and nonresident manufacturer as provided for in § 54.1-3316 or the following:

1. Any conviction of the applicant, licensee, or registrant under federal or state laws relating to controlled substances, including, but not limited to, drug samples and wholesale or retail prescription drug distribution;

2. Violations of licensing requirements under previously held licenses;

3. Failure to maintain and make available to the Board or to federal regulatory officials those records required to be maintained by wholesale distributors of prescription drugs; or

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal Prescription Drug Marketing Act of 1987 (21 U.S.C. §§ 333, 353 and 381) and Part 205 of Chapter 21 of the Code of Federal Regulations.

B. Wholesale drug distributors, nonresident wholesale distributors, third-party logistics providers, nonresident third-party logistics providers, manufacturers, and nonresident manufacturers shall allow the Board or its authorized agents to enter and inspect, at reasonable times and in a reasonable manner, their premises and delivery vehicles, and to audit their records and written operating procedures. Such agents shall be required to show appropriate identification prior to being permitted access to wholesale drug distributors' premises and delivery vehicles.

§ 54.1-3435.5. Permitting of third-party logistics provider; renewal.

A. It shall be unlawful for any person to possess or distribute prescription drugs as a third-party logistics provider in this Commonwealth without a valid, unrevoked permit issued by the Board. The third-party logistics provider shall renew such permit annually on a date determined by the Board in regulation and shall notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted.

B. The Board shall promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by third-party logistics providers as it deems necessary to prevent diversion of prescription drugs and to protect the public.

§ 54.1-3435.6. Registration of nonresident third-party logistics provider; renewal.

A. Any third-party logistics provider located outside this Commonwealth who ships prescription drugs into this Commonwealth shall be registered with the Board. The nonresident third-party logistics provider shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within thirty days of any substantive change in the information previously submitted.

B. The nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a third-party logistics provider with the Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

§ 54.1-3437. Permit to manufacture drugs.

It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs. Such permit shall allow the distribution of the drug to anyone other than the end user without the need to obtain a wholesale distributor permit.

§ 54.1-3442.1 Registration of nonresident manufacturer; renewal.

A. Any manufacturer located outside this Commonwealth who ships prescription drugs into this Commonwealth shall be registered with the Board. The nonresident manufacturer shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within thirty days of any substantive change in the information previously submitted.

B. The nonresident manufacturer shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located or current registration as a manufacturer or repackager with the Food and Drug Administration and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of shipments into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

Board of Pharmacy
2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by adding a section numbered § 54.1-3435.3.01 pertaining to registration of non-resident medical equipment suppliers.

Be it enacted by the General Assembly of Virginia:
1. That § 54.1-3435.3.01 of the *Code of Virginia* is enacted as follows:

§ 54.1-3435.3.01 Registration of non-resident medical equipment suppliers; renewal; fee.

A. Any person located outside this Commonwealth, with the exception of a non-resident pharmacy registered pursuant to § 54.1-3434.1, who ships, mails, or delivers to a consumer in this Commonwealth, pursuant to a lawful order of a prescriber, any hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, or solutions for peritoneal dialysis shall be registered with the Board. The registration as a nonresident medical equipment supplier shall be renewed annually on or before January 1 of each year with payment of a fee specified by the Board in regulation. The registrant shall notify the Board within thirty days of any substantive change in the information previously submitted.

B. The nonresident medical equipment supplier shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located if required by the resident state, and shall furnish proof of such upon application and at each renewal. If the resident state does not require licensure or registration of persons engaged in direct consumer supply of the items listed in subsection A of this section, the applicant or registration holder shall furnish proof that it meets the minimum requirements of law and regulation for medical equipment suppliers in Virginia.

C. Records of distribution of any item listed in subsection A of this section into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

Board of Pharmacy

2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending section § 54.1-3321 pertaining to registration of pharmacy technicians.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3321 of the *Code of Virginia* is amended as follows:

§ 54.1-3321. Registration of pharmacy technicians.

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

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

2. The preparation of prescription labels or patient information;

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

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

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

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

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

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

76

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and ~~has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he~~ holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

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

2. That the provisions of this act shall become effective on July 1, 2017.

Agenda Item: **Legislative Proposals from the PMP**

Enclosed:

- Copy of bill relating to PMP information to pharmacists for clinical consultation
- Copy of bill proposing transmission of data within 24 hours of dispensing

Staff note:

These are legislative proposals from the PMP for the 2016 Session of the General Assembly. The Board may vote to support or to receive as information.

Prescription Monitoring Program

2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending section § 54.1-2523, relating to disclosure of information from the Prescription Monitoring Program to pharmacists for the purpose of clinical consultation.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2523 of the *Code of Virginia* is amended and reenacted as follows:

§ 54.1-2523. Confidentiality of data; disclosure of information; discretionary authority of Director.

A. All data, records, and reports relating to the prescribing and dispensing of covered substances to recipients and any abstracts from such data, records, and reports that are in the possession of the Prescription Monitoring Program pursuant to this chapter and any material relating to the operation or security of the program shall be confidential and shall be exempt from the Virginia Freedom of Information Act (§ 2.2-3700 et seq.) pursuant to subdivision 15 of § 2.2-3705.5. Further, the Director shall only have discretion to disclose any such information as provided in subsections B and C.

B. Upon receiving a request for information in accordance with the Department's regulations and in compliance with applicable federal law and regulations, the Director shall disclose the following:

1. Information relevant to a specific investigation of a specific recipient or of a specific dispenser or prescriber to an agent who has completed the Virginia State Police Drug Diversion School designated by the superintendent of the Department of State Police or designated by the chief law-enforcement officer of any county, city, or town or campus police department to conduct drug diversion investigations pursuant to § 54.1-3405.

2. Information relevant to an investigation or inspection of or allegation of misconduct by a specific person licensed, certified, or registered by or an applicant for licensure, certification, or registration by a health regulatory board; information relevant to a disciplinary proceeding before a health regulatory board or in any subsequent trial or appeal of an action or board order to designated employees of the Department of Health Professions; or to designated persons

operating the Health Practitioners' Monitoring Program pursuant to Chapter 25.1 (§ 54.1-2515 et seq.).

3. Information relevant to the proceedings of any investigatory grand jury or special grand jury that has been properly impaneled in accordance with the provisions of Chapter 13 (§ 19.2-191 et seq.) of Title 19.2.

4. Information relevant to a specific investigation of a specific recipient, dispenser, or prescriber to an agent of a federal law-enforcement agency with authority to conduct drug diversion investigations.

C. In accordance with the Department's regulations and applicable federal law and regulations, the Director may, in his discretion, disclose:

1. Information in the possession of the program concerning a recipient who is over the age of 18 to that recipient. The information shall be mailed to the street or mailing address indicated on the recipient request form.

2. Information on a specific recipient to a prescriber, as defined in this chapter, for the purpose of establishing the treatment history of the specific recipient when such recipient is either under care and treatment by the prescriber or ~~the~~ when a prescriber is consulting on or initiating treatment of ~~such~~ a specific recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the prescriber from the Prescription Monitoring Program.

3. Information on a specific recipient to a dispenser for the purpose of establishing a prescription history to assist the dispenser in determining the validity of a prescription in accordance with § 54.1-3303 ~~when the recipient is seeking a covered substance from the dispenser or the facility in which the dispenser practices~~ or to a pharmacist for the purpose of providing clinical consultation on the care and treatment of the recipient. In a manner specified by the Director in regulation, notice shall be given to patients that information may be requested by the dispenser from the Prescription Monitoring Program.

4. Information relevant to an investigation or regulatory proceeding of a specific dispenser or prescriber to other regulatory authorities concerned with granting, limiting or denying licenses, certificates or registrations to practice a health profession when such regulatory authority licenses such dispenser or prescriber or such dispenser or prescriber is seeking licensure by such other regulatory authority.

5. Information relevant to an investigation relating to a specific dispenser or prescriber who is a participating provider in the Virginia Medicaid program or information relevant to an investigation relating to a specific recipient who is currently eligible for and receiving or who has been eligible for and has received medical assistance services to the Medicaid Fraud Control Unit of the Office of the Attorney General or to designated employees of the Department of Medical Assistance Services, as appropriate.

6. Information relevant to determination of the cause of death of a specific recipient to the designated employees of the Office of the Chief Medical Examiner.

7. Information for the purpose of bona fide research or education to qualified personnel; however, data elements that would reasonably identify a specific recipient, prescriber, or dispenser shall be deleted or redacted from such information prior to disclosure. Further, release of the information shall only be made pursuant to a written agreement between such qualified personnel and the Director in order to ensure compliance with this subdivision.

8. Information relating to prescriptions for covered substances issued by a specific prescriber, which have been dispensed and reported to the Program, to that prescriber.

D. The Director may enter into agreements for mutual exchange of information among prescription monitoring programs in other jurisdictions, which shall only use the information for purposes allowed by this chapter.

E. This section shall not be construed to supersede the provisions of § 54.1-3406 concerning the divulging of confidential records relating to investigative information.

F. Confidential information that has been received, maintained or developed by any board or disclosed by the board pursuant to subsection A shall not, under any circumstances, be available for discovery or court subpoena or introduced into evidence in any medical malpractice suit or other action for damages arising out of the provision of or failure to provide services. However, this subsection shall not be construed to inhibit any investigation or prosecution conducted pursuant to Article 1 (§ 18.2-247 et seq.) of Chapter 7 of Title 18.2.

Prescription Monitoring Program

2016 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending section § 54.1-2521, relating to transmission of prescription data from dispensers to the Prescription Monitoring Program.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2521 of the *Code of Virginia* is amended and reenacted as follows:

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.

2. The recipient's date of birth.

3. The covered substance that was dispensed to the recipient.

4. The quantity of the covered substance that was dispensed.

5. The date of the dispensing.

6. The prescriber's identifier number.

7. The dispenser's identifier number.

8. The method of payment for the prescription.

9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

82

10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. Data shall be transmitted to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later.

~~C.~~ D. The reports required herein shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

2. That the provisions of this act shall become effective on January 1, 2017.

83

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 8.01-225 and 54.1-3408 of the Code of Virginia, relating to prescription, distribution, and administration of naloxone or other opioid antagonist.

[H 1458]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 8.01-225 and 54.1-3408 of the Code of Virginia are amended and reenacted as follows:

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

A. Any person who:

1. In good faith, renders emergency care or assistance, without compensation, to any ill or injured person (i) at the scene of an accident, fire, or any life-threatening emergency; (ii) at a location for screening or stabilization of an emergency medical condition arising from an accident, fire, or any life-threatening emergency; or (iii) en route to any hospital, medical clinic, or doctor's office, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such care or assistance.

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

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

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

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

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

7. Operates an AED at the scene of an emergency, trains individuals to be operators of AEDs, or orders AEDs, shall be immune from civil liability for any personal injury that results from any act or omission in the use of an AED in an emergency where the person performing the defibrillation acts as an ordinary, reasonably prudent person would have acted under the same or similar circumstances, unless such personal injury results from gross negligence or willful or wanton misconduct of the person rendering such emergency care.

8. Maintains an AED located on real property owned or controlled by such person shall be immune

from civil liability for any personal injury that results from any act or omission in the use in an emergency of an AED located on such property unless such personal injury results from gross negligence or willful or wanton misconduct of the person who maintains the AED or his agent or employee.

9. Is an employee of a school board or of a local health department approved by the local governing body to provide health services pursuant to § 22.1-274 who, while on school property or at a school-sponsored event, (i) renders emergency care or assistance to any sick or injured person; (ii) renders or administers emergency cardiopulmonary resuscitation (CPR); cardiac defibrillation, including, but not limited to, the use of an automated external defibrillator (AED); or other emergency life-sustaining or resuscitative treatments or procedures that have been approved by the State Board of Health to any sick or injured person; (iii) operates an AED, trains individuals to be operators of AEDs, or orders AEDs; or (iv) maintains an AED, shall not be liable for civil damages for ordinary negligence in acts or omissions on the part of such employee while engaged in the acts described in this subdivision.

10. Is a volunteer in good standing and certified to render emergency care by the National Ski Patrol System, Inc., who, in good faith and without compensation, renders emergency care or assistance to any injured or ill person, whether at the scene of a ski resort rescue, outdoor emergency rescue, or any other place or while transporting such injured or ill person to a place accessible for transfer to any available emergency medical system unit, or any resort owner voluntarily providing a ski patroller employed by him to engage in rescue or recovery work at a resort not owned or operated by him, shall not be liable for any civil damages for acts or omissions resulting from the rendering of such emergency care, treatment, or assistance, including but not limited to acts or omissions which involve violations of any state regulation or any standard of the National Ski Patrol System, Inc., in the rendering of such emergency care or assistance, unless such act or omission was the result of gross negligence or willful misconduct.

11. Is an employee of a school board, authorized by a prescriber and trained in the administration of insulin and glucagon, who, upon the written request of the parents as defined in § 22.1-1, assists with the administration of insulin or administers glucagon to a student diagnosed as having diabetes who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if the insulin is administered according to the child's medication schedule or such employee has reason to believe that the individual receiving the glucagon is suffering or is about to suffer life-threatening hypoglycemia. Whenever any employee of a school board is covered by the immunity granted herein, the school board employing him shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such insulin or glucagon treatment.

12. Is a school nurse, an employee of a school board, an employee of a local governing body, or an employee of a local health department who is authorized by a prescriber and trained in the administration of epinephrine and who provides, administers, or assists in the administration of epinephrine to a student believed in good faith to be having an anaphylactic reaction, or is the prescriber of the epinephrine, shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

13. Is an employee of a provider licensed by the Department of Behavioral Health and Developmental Services, or provides services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services, who has been trained in the administration of insulin and glucagon and who administers or assists with the administration of insulin or administers glucagon to a person diagnosed as having diabetes who requires insulin injections or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia in accordance with § 54.1-3408 shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if the insulin is administered in accordance with the prescriber's instructions or such person has reason to believe that the individual receiving the glucagon is suffering or is about to suffer life-threatening hypoglycemia. Whenever any employee of a provider licensed by the Department of Behavioral Health and Developmental Services or a person who provides services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services is covered by the immunity granted herein, the provider shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such insulin or glucagon treatment.

14. Is an employee of a provider licensed by the Department of Behavioral Health and Developmental Services, or provides services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services, who has been trained in the administration of epinephrine and who administers or assists in the administration of epinephrine to a

person believed in good faith to be having an anaphylactic reaction in accordance with the prescriber's instructions shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

15. In good faith ~~and without compensation,~~ *prescribes, dispenses, or* administers naloxone *or other opioid antagonist used for overdose reversal* in an emergency to an individual who is *believed to be* experiencing or ~~is~~ about to experience a life-threatening opiate overdose shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if ~~such administering person is a participant in a pilot program conducted by the Department of Behavioral Health and Developmental Services on the administration of naloxone for the purpose of counteracting the effects of opiate overdose~~ *acting in accordance with the provisions of subsection X of § 54.1-3408 or in his role as a member of an emergency medical services agency.*

B. Any licensed physician serving without compensation as the operational medical director for a licensed emergency medical services agency in the Commonwealth shall not be liable for any civil damages for any act or omission resulting from the rendering of emergency medical services in good faith by the personnel of such licensed agency unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any person serving without compensation as a dispatcher for any licensed public or nonprofit emergency services agency in the Commonwealth shall not be liable for any civil damages for any act or omission resulting from the rendering of emergency services in good faith by the personnel of such licensed agency unless such act or omission was the result of such dispatcher's gross negligence or willful misconduct.

Any individual, certified by the State Office of Emergency Medical Services as an emergency medical services instructor and pursuant to a written agreement with such office, who, in good faith and in the performance of his duties, provides instruction to persons for certification or recertification as a certified basic life support or advanced life support emergency medical services technician shall not be liable for any civil damages for acts or omissions on his part directly relating to his activities on behalf of such office unless such act or omission was the result of such emergency medical services instructor's gross negligence or willful misconduct.

Any licensed physician serving without compensation as a medical advisor to an E-911 system in the Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering medical advice in good faith to establish protocols to be used by the personnel of the E-911 service, as defined in § 58.1-1730, when answering emergency calls unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any licensed physician who directs the provision of emergency medical services, as authorized by the State Board of Health, through a communications device shall not be liable for any civil damages for any act or omission resulting from the rendering of such emergency medical services unless such act or omission was the result of such physician's gross negligence or willful misconduct.

Any licensed physician serving without compensation as a supervisor of an AED in the Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering medical advice in good faith to the owner of the AED relating to personnel training, local emergency medical services coordination, protocol approval, AED deployment strategies, and equipment maintenance plans and records unless such act or omission was the result of such physician's gross negligence or willful misconduct.

C. Any communications services provider, as defined in § 58.1-647, including mobile service, and any provider of Voice-over-Internet Protocol service, in the Commonwealth shall not be liable for any civil damages for any act or omission resulting from rendering such service with or without charge related to emergency calls unless such act or omission was the result of such service provider's gross negligence or willful misconduct.

Any volunteer engaging in rescue or recovery work at a mine, or any mine operator voluntarily providing personnel to engage in rescue or recovery work at a mine not owned or operated by such operator, shall not be liable for civil damages for acts or omissions resulting from the rendering of such rescue or recovery work in good faith unless such act or omission was the result of gross negligence or willful misconduct. For purposes of this subsection, the term "Voice-over-Internet Protocol service" or "VoIP service" means any Internet protocol-enabled services utilizing a broadband connection, actually originating or terminating in Internet Protocol from either or both ends of a channel of communication offering real time, multidirectional voice functionality, including, but not limited to, services similar to traditional telephone service.

D. Nothing contained in this section shall be construed to provide immunity from liability arising out of the operation of a motor vehicle.

E. ~~[Expired.]~~

~~F.~~ For the purposes of this section, the term "compensation" shall not be construed to include (i) the

salaries of police, fire, or other public officials or personnel who render such emergency assistance, (ii) the salaries or wages of employees of a coal producer engaging in emergency medical technician service or first aid service pursuant to the provisions of § 45.1-161.38, 45.1-161.101, 45.1-161.199, or 45.1-161.263, (iii) complimentary lift tickets, food, lodging, or other gifts provided as a gratuity to volunteer members of the National Ski Patrol System, Inc., by any resort, group, or agency, (iv) the salary of any person who (a) owns an AED for the use at the scene of an emergency, (b) trains individuals, in courses approved by the Board of Health, to operate AEDs at the scene of emergencies, (c) orders AEDs for use at the scene of emergencies, or (d) operates an AED at the scene of an emergency, or (v) expenses reimbursed to any person providing care or assistance pursuant to this section.

For the purposes of this section, an emergency medical care attendant or technician shall be deemed to include a person licensed or certified as such or its equivalent by any other state when he is performing services which he is licensed or certified to perform by such other state in caring for a patient in transit in the Commonwealth, which care originated in such other state.

Further, the public shall be urged to receive training on how to use CPR and an AED in order to acquire the skills and confidence to respond to emergencies using both CPR and an AED.

§ 54.1-3408. Professional use by practitioners.

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

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

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

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

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

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

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

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

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

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

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

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

F. Pursuant to an oral or written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize licensed athletic trainers to possess and administer topical corticosteroids, topical lidocaine, or other Schedule VI topical drugs; oxygen for use

in emergency situations; and epinephrine for use in emergency cases of anaphylactic shock.

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

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

H. Pursuant to a written order or standing protocol issued by the prescriber within the course of his professional practice, such prescriber may authorize, with the consent of the parents as defined in § 22.1-1, an employee of a school board who is trained in the administration of insulin and glucagon to assist with the administration of insulin or administer glucagon to a student diagnosed as having diabetes and who requires insulin injections during the school day or for whom glucagon has been prescribed for the emergency treatment of hypoglycemia. Such authorization shall only be effective when a licensed nurse, nurse practitioner, physician, or physician assistant is not present to perform the administration of the medication.

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

I. A prescriber may authorize, pursuant to a protocol approved by the Board of Nursing, the administration of vaccines to adults for immunization, when a practitioner with prescriptive authority is not physically present, by (i) licensed pharmacists, (ii) registered nurses, or (iii) licensed practical nurses under the immediate and direct supervision of a registered nurse. A prescriber acting on behalf of and in accordance with established protocols of the Department of Health may authorize the administration of vaccines to any person by a pharmacist, nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic under the direction of an operational medical director when the prescriber is not physically present. Emergency medical services personnel shall provide documentation of the vaccines to be recorded in the Virginia Immunization Information System.

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

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

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

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

L. This section shall not prevent the administration of drugs by a person who has satisfactorily completed a training program for this purpose approved by the Board of Nursing and who administers

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

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

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

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

O. In addition, this section shall not prevent the administration of drugs by a person to (i) a child in a child day program as defined in § 63.2-100 and regulated by the State Board of Social Services or a local government pursuant to § 15.2-914, or (ii) a student at a private school that complies with the accreditation requirements set forth in § 22.1-19 and is accredited by the Virginia Council for Private Education, provided such person (a) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, doctor of medicine or osteopathic medicine, or pharmacist; (b) has obtained written authorization from a parent or guardian; (c) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (d) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be self-administered by the child or student, or administered by a parent or guardian to the child or student.

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

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

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

prescriptions.

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

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

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

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

V. A physician assistant, nurse or a dental hygienist may possess and administer topical fluoride varnish to the teeth of children aged six months to three years pursuant to an oral or written order or a standing protocol issued by a doctor of medicine, osteopathic medicine, or dentistry that conforms to standards adopted by the Department of Health.

W. A prescriber, acting in accordance with guidelines developed pursuant to § 32.1-46.02, may authorize the administration of influenza vaccine to minors by a licensed pharmacist, registered nurse, licensed practical nurse under the direction and immediate supervision of a registered nurse, certified emergency medical technician-intermediate, or emergency medical technician-paramedic when the prescriber is not physically present.

X. Notwithstanding the provisions of § 54.1-3303 ~~and only for the purpose of participation in pilot programs conducted by the Department of Behavioral Health and Developmental Services,~~ a ~~person may obtain a prescription for a family member or a friend and may possess and administer naloxone for the purpose of counteracting the effects of opiate overdose~~, *pursuant to an oral, written or standing order issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist may dispense naloxone or other opioid antagonist used for overdose reversal and a person may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opiate overdose. Law-enforcement officers as defined in § 9.1-101 and firefighters who have completed a training program may also possess and administer naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.*

2. That an emergency exists and this act is in force from its passage.

Protocol for the Prescribing and Dispensing of Naloxone

Pharmacists shall follow this protocol when dispensing naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opiate overdose as authorized in §54.1-3408.

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling, unless pharmacist is able to verify successful completion of REVIVE! training program.
   b) The pharmacist shall provide the recipient with the current REVIVE! brochure available at _____. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

2) **Product Selection:** The pharmacist who dispenses naloxone pursuant to an oral, written or standing order shall dispense the drug and other items for the kit as prescribed and in accordance with this protocol.

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order, a pharmacist may dispense naloxone pursuant to a standing order. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   a) Name of pharmacy authorized to dispense naloxone pursuant to standing order;
   b) Contents of kit to be dispensed, to include quantity of drug and directions for administration;
   c) Prescriber's signature; and
   d) Date of issuance.

4) **Kit Contents for Intranasal or Auto-Injector Administration:**

Intranasal	Auto-Injector
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 0.4 mg/0.4 ml #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1. Kit is commercially available as a twin pack with directions for administration included.

Optional items for the kits include rescue breathing masks, and latex-free gloves.

Kits for intranasal administration may be obtained from the REVIVE! program at the Department of Behavioral Health and Developmental Services. Contact _____ for information.

5) Labeling and Records:

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation.

Protocol for Dispensing to Law-Enforcement Officers and Firefighters

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department. Training shall be conducted in accordance with policies and procedures of the law enforcement agency or fire department.

6) Resources:

a) REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at _____

b) Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742

c) Prescribe to Prevent, http://prescribetoprevent.org/pharmacists

d) Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

VIRGINIA PHARMACISTS ASSOCIATION

2530 Professional Road ~ Richmond, Virginia 23235
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@virginiapharmacists.org www.virginiapharmacists.org

June 1, 2015

Ellen Shinaberry, Pharm.D.
Chair, Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463

Dear Dr. Shinaberry,

The Virginia Pharmacists Association requests that the Board of Pharmacy adopt changes to Guidance Document 110-36 allowing for compounding pharmacies to use alternative sterility testing method so long as they meet USP <797> guidance and recommendations for using such alternative methods.

Currently the Virginia Board of Pharmacy requires compounding pharmacy to be compliant with USP <71> for sterility testing. In addition, as is stated in Guidance Document 110-36, each compounded batch must undergo sterility testing in accordance with USP Chapter <71>. USP <71> requires incubation periods of 14 days before a batch can be released and classified as "sterile".

USP <797> states that "The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein." USP <797> further states that "A method not described in the USP may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration method or the USP Direct Inoculation of the Culture Medium method where the Membrane Filtration method is not feasible."

1. Alternative testing methods are said to an effective and reliable test for the detection of microorganisms in sterile compounded preparations
2. The procedures used by such companies are said to be the same sampling protocols as the standard USP <71> tests and has been shown to detect all the standard USP test organisms
3. Alternative Testing methods are said to be more sensitive than the referenced methods used in USP <71>
4. Allows for more rapid access for patients to sterile preparations

We hope that you will consider allowances for alternative sterility testing method in Guidance Document 110-36.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

Virginia's Pharmacist Workforce: 2014

Healthcare Workforce Data Center

May 2015

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804-367-2115, 804-527-4466(fax)
E-mail: *HWDC@dhp.virginia.gov*

Follow us on Tumblr: *www.vahwdc.tumblr.com*

More than 11,000 Pharmacists 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!

Virginia Department of Health Professions

David E. Brown, D.C.
Director

Jaime H. Hoyle, J.D.
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Dr. Elizabeth Carter, Ph.D.
Executive Director

Justin Crow, MPA
Research Analyst

Laura Jackson
Operations Manager

Christopher Coyle
Research Assistant

The Board of Pharmacy

Chair

Ellen B. Shinaberry
Harrisonburg

Vice-Chair

Empsy Munden
Virginia Beach

Members

Sheila K. W. Elliott
Hampton

Melvin L. Boone, Sr.
Chesapeake

Ryan K. Logan
Fairfax

Rebecca Thornbury
Grundy

Jody H. Allen
Midlothian

Michael I. Elliott
Forest

Dinny Li
Lorton

Cynthia Warriner
Chester

Executive Director

Caroline D. Juran
Richmond

Contents

The Pharmacist Workforce: At a Glance:

The Workforce

Licensees:	13,344
Virginia's Workforce:	8,101
FTEs:	6,871

Survey Response Rate

All Licensees:	86%
Renewing Practitioners:	96%

Demographics

Female:	62%
Diversity Index:	48%
Median Age:	45

Background

Rural Childhood:	34%
HS Degree in VA:	46%
Prof. Degree in VA:	48%

Education

Baccalaureate:	46%
Ph.D./Professional:	54%

Finances

Median Inc.:	$110k-$120k
Health Benefits:	71%
Under 40 w/ Ed debt:	77%

Current Employment

Employed in Prof.:	92%
Hold 1 Full-time Job:	72%
Satisfied?:	89%

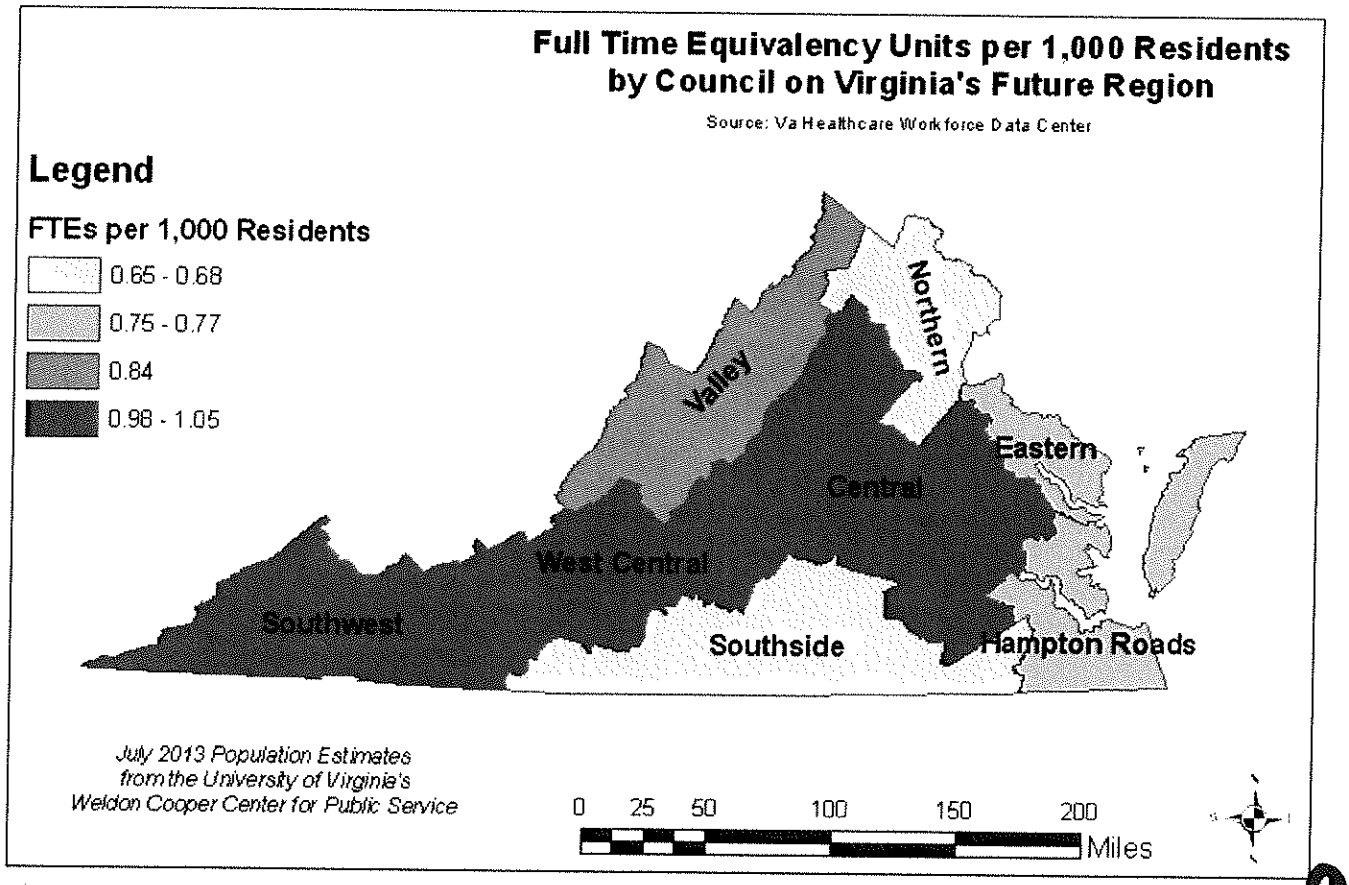
Job Turnover

Switched Jobs in 2014:	5%
Employed over 2 yrs:	63%

Primary Roles

Patient Care:	74%
Administration:	7%
Education:	1%

Source: Va. Healthcare Workforce Data Center



11,486 pharmacists voluntarily took part in the 2014 Pharmacist Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacists. These survey respondents represent 86% of the 13,344 pharmacists who are licensed in the state and 96% of renewing practitioners.

The HWDC estimates that 8,101 pharmacists 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 as an pharmacist at some point in the future. During 2014, Virginia's pharmacy workforce provided 6,871 "full-time equivalency units", which the HWDC defines simply as working 2,000 hours a year (or 40 hours per week for 50 weeks with 2 weeks off).

A majority of pharmacists are female, and the median age among those in the workforce is 45. In a random encounter between two pharmacists, there is a nearly one-in-two chance that they would be of different races or ethnicities, a measure known as the diversity index. This makes Virginia's pharmacy workforce only slightly less diverse than the state's overall population, where there is a 54% chance that two randomly chosen people would be of different races or ethnicities.

More than one-third of pharmacists grew up in a rural area, and nearly one-quarter of these professionals currently work in non-Metro areas of the state. Meanwhile, 46% of Virginia's pharmacists graduated from high school in Virginia, and 48% of pharmacists earned their initial professional degree in the state. In total, 55% of Virginia's pharmacy workforce has some educational background in the state.

A slight majority of Virginia's pharmacy workforce has earned a doctoral or other professional degree as their highest level of educational attainment. 38% of pharmacists currently carry educational debt, including more than three-quarters of those under the age of 40. The median debt burden for those pharmacists with educational debt is between $90,000 and $100,000.

92% of pharmacists are currently employed in the profession. 72% of all pharmacists hold one full-time position, and more than half of all professionals work between 40 and 49 hours per week. Over the past year, only 2% of pharmacists have been involuntarily unemployed, while another 3% of pharmacists have been underemployed.

The typical pharmacist earned between $110,000 and $120,000 last year. In addition, 84% of pharmacists who are compensated with either an hourly wage or salary at their primary work location also receive at least one employer-sponsored benefit, including 71% who receive health insurance. 89% of all pharmacists are satisfied with their current employment situation, including 49% who indicate they are "very satisfied".

More than 90% of all pharmacists work in the private sector, including 71% who work at a for-profit organization. Large community pharmacies (i.e. pharmacies with more than 10 locations) were the most common working establishment type for Virginia's pharmacy workforce, employing nearly one-third of all professionals. Hospital systems and smaller pharmacies were also common employers of Virginia's pharmacy workforce.

A typical pharmacist spends most of her time treating patients. Nearly three quarters of all pharmacists serve a patient care role, meaning that at least 60% of their time is spent in patient care activities. Meanwhile, another 7% of pharmacists served an administrative role at their primary work location.

40% of pharmacists expect to retire by the age of 65. Just 6% of the current workforce expects to retire in the next two years, while half of the current workforce expects to retire by 2039. Over the next two years, only 2% of Virginia's current pharmacy workforce expects to leave the profession, while 3% expect to leave the state entirely. Meanwhile, 10% of pharmacists plan on increasing patient care activities over the next two years, and 11% expect to pursue additional educational opportunities.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	11,900	89%
New Licensees	960	7%
Non-Renewals	484	4%
All Licensees	13,344	100%

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 86% of renewing pharmacists submitted a survey. These represent 96% of pharmacists who held a license at some point in 2014.

Response Rates			
Statistic	Non Respondents	Respondent	Response Rate
By Age			
Under 30	146	941	87%
30 to 34	241	1,681	88%
35 to 39	224	1,524	87%
40 to 44	211	1,565	88%
45 to 49	221	1,474	87%
50 to 54	183	1,212	87%
55 to 59	146	1,167	89%
60 and Over	486	1,922	80%
Total	1,858	11,486	86%
New Licenses			
Issued in 2014	265	695	72%
Metro Status			
Non-Metro	177	884	83%
Metro	927	6,700	88%
Not in Virginia	748	3,869	84%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacists

Number:	13,344
New:	7%
Not Renewed:	4%

Survey Response Rates

All Licensees:	86%
Renewing Practitioners:	96%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	11,486
Response Rate, all licensees	86%
Response Rate, Renewals	96%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2014.
2. **Target Population:** All pharmacists who held a Virginia license at some point in 2014.
3. **Survey Population:** The survey was available to those who renewed their licenses online. It was not available to those who did not renew, including some pharmacists newly licensed in 2014.

At a Glance:

Workforce

2014 Pharmacist Workforce:	8,101
FTEs:	6,871

Utilization Ratios

Licensees in VA Workforce:	61%
Licensees per FTE:	1.94
Workers per FTE:	1.18

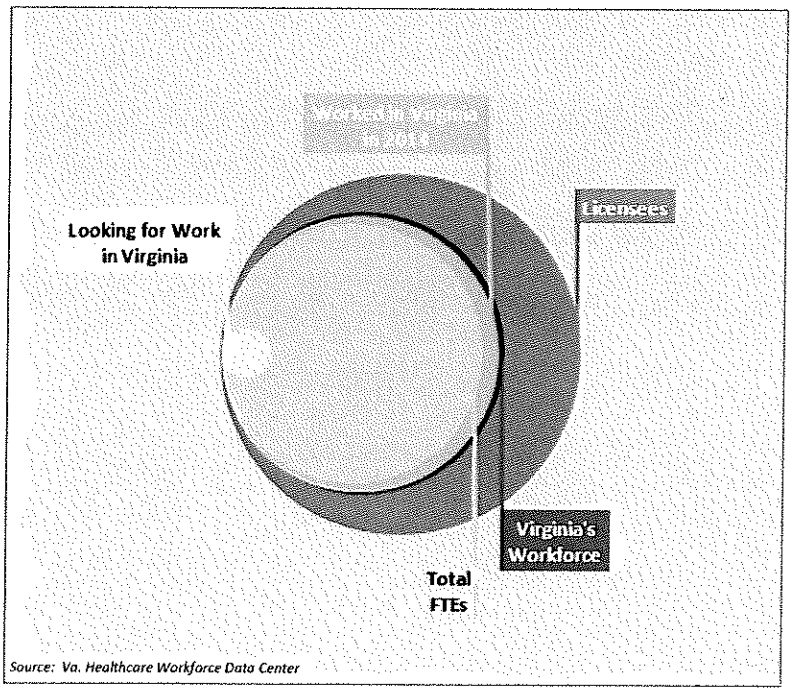
Source: Va. Healthcare Workforce Data Center

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.

Virginia's Pharmacist Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	7,858	97%
Looking for Work in Virginia	243	3%
Virginia's Workforce	8,101	100%
Total FTEs	6,871	
Licensees	13,344	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

This report uses weighting to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia Workforce only. For more information on HWDC's methodology visit: www.dhp.virginia.gov/hwdc

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	233	32%	491	68%	724	10%
30 to 34	314	28%	803	72%	1,117	15%
35 to 39	279	29%	685	71%	964	13%
40 to 44	245	27%	681	74%	926	12%
45 to 49	308	33%	634	67%	942	13%
50 to 54	252	33%	508	67%	759	10%
55 to 59	306	42%	415	58%	721	10%
60 +	896	68%	421	32%	1,317	18%
Total	2,832	38%	4,638	62%	7,470	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	62%
% Under 40 Female:	71%

Age

Median Age:	45
% Under 40:	38%
% 55+:	27%

Diversity

Diversity Index:	48%
Under 40 Div. Index:	57%

Source: Va. Healthcare Workforce Data Center

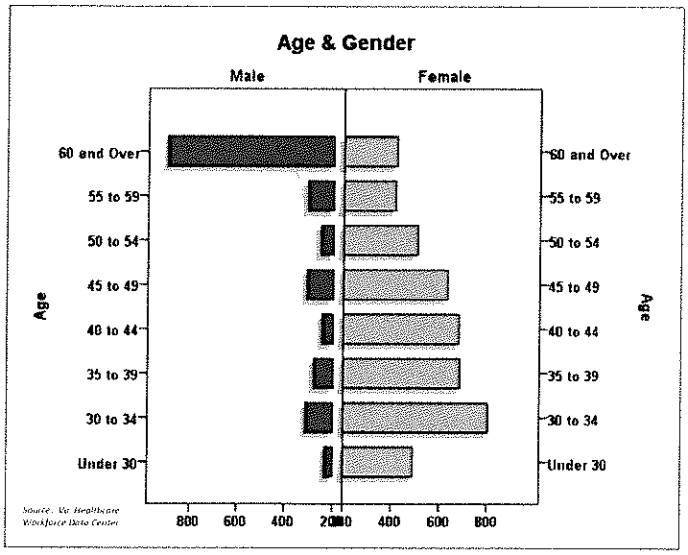
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacists		Pharmacists Under 40	
	%	#	%	#	%
White	64%	5,214	70%	1,707	61%
Black	19%	738	10%	330	12%
Asian	6%	1,156	16%	577	21%
Other Race	0%	115	2%	58	2%
Two or more races	2%	127	2%	74	3%
Hispanic	8%	108	1%	50	2%
Total	100%	7,458	100%	2,796	100%

*Population data in this chart is from the US Census, ACS 1-yr estimates, 2011 vintage.

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two pharmacists, there is a 48% chance that they would be of a different race/ethnicity (a measure known as the Diversity Index). For Virginia's population as a whole, the comparable number is 54%.

38% of pharmacists are under the age of 40, and 71% of these professionals are female. In addition, pharmacists who are under the age of 40 are slightly more diverse than Virginia's overall population.



At a Glance:

Childhood

Urban Childhood:	18%
Rural Childhood:	34%

Virginia Background

HS in Virginia:	46%
Prof. Education in VA:	48%
HS/Prof. Educ. in VA:	55%

Location Choice

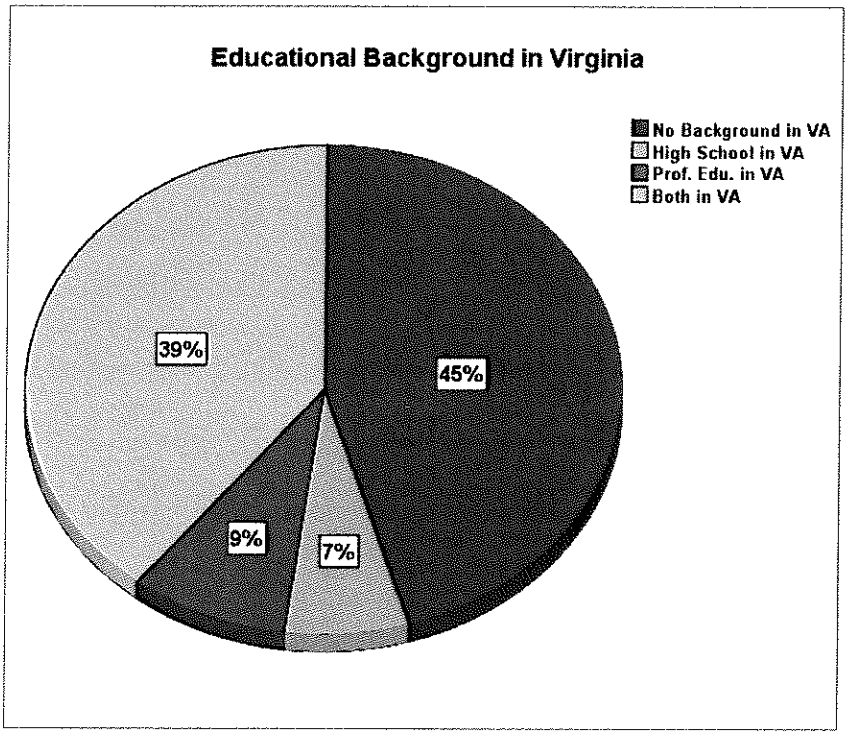
% Rural to Non-Metro:	24%
% Urban/Suburban to Non-Metro:	6%

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+	23%	55%	21%
2	Metro, 250,000 to 1 million	51%	40%	9%
3	Metro, 250,000 or less	45%	41%	14%
	Non-Metro Counties			
4	Urban pop 20,000+, Metro adj	55%	33%	12%
6	Urban pop, 2,500-19,999, Metro adj	64%	24%	12%
7	Urban pop, 2,500-19,999, nonadj	84%	10%	6%
8	Rural, Metro adj	64%	30%	6%
9	Rural, nonadj	64%	25%	12%
	Overall	**34%**	**48%**	**18%**

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

34% of pharmacists grew up in self-described rural areas, and 24% of these professionals currently work in non-Metro counties. Overall, 12% of Virginia's pharmacy workforce currently works in non-Metro counties.

Top Ten States for Pharmacy Recruitment

Rank	All Pharmacists			
	High School	#	Professional School	#
1	Virginia	3,438	Virginia	3,499
2	Outside U.S./Canada	860	Pennsylvania	523
3	Pennsylvania	476	Outside U.S./Canada	346
4	New York	359	North Carolina	300
5	Maryland	236	New York	279
6	West Virginia	232	Maryland	214
7	North Carolina	200	Massachusetts	213
8	New Jersey	170	Washington, D.C.	209
9	Ohio	149	West Virginia	201
10	Florida	108	Georgia	161

Source: Va. Healthcare Workforce Data Center

46% of Virginia's pharmacists received their high school degree in Virginia, and 48% received their initial professional degree in the state.

Among pharmacists who have been licensed in the past five years, 37% received their high school degree in Virginia, and 42% received their initial professional degree in the state.

Rank	Licensed in the Past 5 Years			
	High School	#	Professional School	#
1	Virginia	694	Virginia	769
2	Outside U.S./Canada	237	Pennsylvania	161
3	Pennsylvania	147	Outside U.S./Canada	101
4	New York	111	North Carolina	86
5	Maryland	84	New York	79
6	North Carolina	63	Maryland	75
7	New Jersey	56	West Virginia	51
8	West Virginia	45	Massachusetts	48
9	Ohio	41	Ohio	43
10	Florida	40	Washington, D.C.	40

Source: Va. Healthcare Workforce Data Center

Nearly 40% of Virginia's licensed pharmacists did not participate in Virginia's workforce in 2014. 90% of these professionals worked at some point in the past year, including 84% who currently work as pharmacists.

At a Glance:

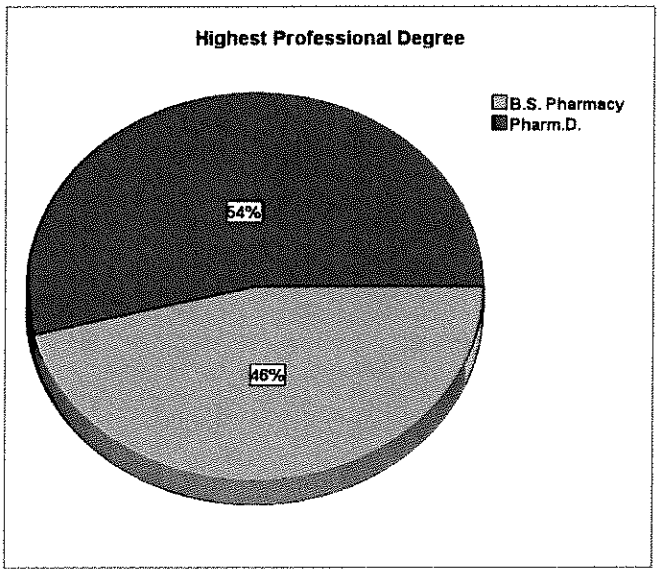
Not in VA Workforce

Total:	5,242
% of Licensees:	39%
Federal/Military:	7%
Va Border State/DC:	17%

A Closer Look:

Highest Professional Degree		
Degree	#	%
B.S. Pharmacy	3,312	46%
Pharm.D.	3,886	54%
Total	7,197	100%

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

At a Glance:

Education

B.S. Pharmacy: 46%
Pharm.D.: 54%

Educational Debt

Carry debt: 38%
Under age 40 w/ debt: 77%
Median debt: $90k-$100k

54% of pharmacists hold a Doctorate in Pharmacy as their highest professional degree, while all remaining professionals have earned a bachelor's degree in Pharmacy.

38% of pharmacists currently have educational debt, including 77% of those under the age of 40. For those with educational debt, the median debt load is between $90,000 and $100,000.

Educational Debt				
Amount Carried	All Pharmacists		Pharmacists Under 40	
	#	%	#	%
None	3,931	62%	554	23%
$20,000 or less	217	3%	112	5%
$20,001-$40,000	218	3%	134	6%
$40,001-$60,000	263	4%	175	7%
$60,001-$80,000	253	4%	167	7%
$80,001-100,000	299	5%	222	9%
$100,001-$120,000	278	4%	216	9%
$120,001-$140,000	208	3%	179	7%
$140,001-$160,000	200	3%	181	8%
$160,001-$180,000	141	2%	122	5%
$180,001-$200,000	98	2%	89	4%
Over $200,000	261	4%	238	10%
Total	6,367	100%	2,389	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Specialties

Immunization:	23%
Community Pharmacy:	10%
Compounding:	4%

Top Board Certifications

BPS - Pharmacotherapy:	5%
CCGP - Geriatrics:	1%
BPS - Ambulatory Care:	1%

Top Residencies (PGY1)

Pharmacy Practice (Post 1993):	9%
Pharmacy Practice (Pre 1993):	6%
Community Pharmacy:	6%

Source: Va. Healthcare Workforce Data Center

Board Certifications		
Certification	#	%
BPS-Pharmacotherapy	381	5%
CCGP-Geriatrics	50	1%
BPS-Ambulatory Care	44	1%
BPS-Oncology	35	0%
BPS-Nutrition	19	0%
BPS-Psychiatric	19	0%
BPS-Nuclear Pharmacy	10	0%
ABAT-Applied Toxicology	1	0%
Other Board Certification	145	2%
At Least One Certification	669	8%

Source: Va. Healthcare Workforce Data Center

PGY1		
Residency	#	%
Pharmacy Practice (Post 1993)	700	9%
Pharmacy Practice (Pre 1993)	490	6%
Community Pharmacy	475	6%
Managed Care Pharmacy	38	0%
Other	0	0%
Total	**1,703**	**21%**
PGY2		
Ambulatory Care	104	1%
Drug Information	58	1%
Internal Medicine/Cardiology	44	1%
Critical Care	40	0%
Health-system Pharmacy Administration	40	0%
Pharmacotherapy	30	0%
Oncology	27	0%
Psychiatry	24	0%
Infectious Disease	23	0%
Managed Care Pharmacy Systems	21	0%
Pediatrics	21	0%
Geriatrics	15	0%
Nuclear	12	0%
Other	202	2%
Total	**661**	**8%**

8% of pharmacists hold a board certification, including 5% who hold a certification in Pharmacotherapy. 42% also have a self-designated specialty area, including 23% who have a specialization in immunization.

At a Glance:

Employment

Employed in Profession: 92%
Involuntarily Unemployed: 1%

Positions Held

1 Full-time: 72%
2 or More Positions: 9%

Weekly Hours:

40 to 49: 53%
60 or more: 4%
Less than 30: 13%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	10	0%
Employed in a pharmacy-related capacity	6,826	92%
Employed, NOT in a pharmacy-related capacity	193	3%
Not working, reason unknown	0	0%
Involuntarily unemployed	68	1%
Voluntarily unemployed	155	2%
Retired	134	2%
Total	**7,386**	**100%**

Source: Va. Healthcare Workforce Data Center

92% of Virginia's pharmacists are currently employed in the profession, and only 1% of all pharmacy professionals are involuntarily unemployed at the moment. 72% of the state's pharmacy workforce has one full-time job, while just 9% of pharmacists have multiple positions. 53% of pharmacists work between 40 and 49 hours per week, while just 4% of pharmacy professionals work at least 60 hours per week.

Current Positions		
Positions	#	%
No Positions	357	5%
One Part-Time Position	1,025	14%
Two Part-Time Positions	164	2%
One Full-Time Position	5,206	72%
One Full-Time Position & One Part-Time Position	441	6%
Two Full-Time Positions	12	0%
More than Two Positions	34	0%
Total	**7,239**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	357	5%
1 to 9 hours	181	3%
10 to 19 hours	271	4%
20 to 29 hours	462	6%
30 to 39 hours	1,252	17%
40 to 49 hours	3,842	53%
50 to 59 hours	557	8%
60 to 69 hours	169	2%
70 to 79 hours	76	1%
80 or more hours	58	1%
Total	**7,225**	**100%**

Source: Va. Healthcare Workforce Data Center

107

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	48	1%
$50,000 or less	494	9%
$50,001-$60,000	117	2%
$60,001-$70,000	159	3%
$70,001-$80,000	143	3%
$80,001-$90,000	178	3%
$90,001-$100,000	298	5%
$100,001-$110,000	742	13%
$110,001-$120,000	887	16%
$120,001-$130,000	1,101	19%
$130,001-$140,000	746	13%
$140,001-$150,000	352	6%
More than $150,000	444	8%
Total	5,708	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $110k-120k

Benefits
Employer Health Insrnce: 71%
Employer Retirement: 73%

Satisfaction
Satisfied: 89%
Very Satisfied: 49%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	3,462	49%
Somewhat Satisfied	2,820	40%
Somewhat Dissatisfied	540	8%
Very Dissatisfied	233	3%
Total	7,056	100%

Source: Va. Healthcare Workforce Data Center

The typical pharmacist earned between $110,000 and $120,000 in 2014. Among pharmacists who received either an hourly wage or a salary as compensation at the primary work location, 71% received health insurance and 73% also had access to a retirement plan.

Employer-Sponsored Benefits			
Benefit	#	%	% of Wage/Salary Employees
Paid Vacation Leave	5,394	79%	82%
Retirement	4,806	70%	73%
Health Insurance	4,675	68%	71%
Dental Insurance	4,475	66%	69%
Paid Sick Leave	4,255	62%	65%
Group Life Insurance	3,591	53%	56%
Signing/Retention Bonus	520	8%	8%
Received At Least One Benefit	5,706	84%	86%

*From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Underemployment in Past Year		
In the past year did you . . .?	#	%
Experience Involuntary Unemployment?	152	2%
Experience Voluntary Unemployment?	267	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	254	3%
Work two or more positions at the same time?	765	9%
Switch employers or practices?	402	5%
Experienced at least 1	1,530	19%

Source: Va. Healthcare Workforce Data Center

Only 2% of Virginia's pharmacists were involuntary unemployed at some point in 2014. For comparison, Virginia's average monthly unemployment rate was 5.1%.[1]

At a Glance:

Unemployment Experience 2014

Involuntarily Unemployed: 2%
Underemployed: 3%

Stability

Switched: 5%
New Location: 22%
Over 2 years: 63%
Over 2 yrs, 2nd location: 49%

Employment Type

Salary or Wage: 92%

Source: Va. Healthcare Workforce Data Center

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	130	2%	94	9%
Less than 6 Months	612	9%	135	13%
6 Months to 1 Year	607	9%	145	14%
1 to 2 Years	1,194	17%	170	16%
3 to 5 Years	1,403	20%	232	22%
6 to 10 Years	1,229	18%	153	14%
More than 10 Years	1,755	25%	141	13%
Subtotal	6,930	100%	1,071	100%
Did not have location	286		6,980	
Item Missing	885		50	
Total	8,101		8,101	

Source: Va. Healthcare Workforce Data Center

63% of pharmacists have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.

Nearly half of all pharmacists receive a salary or commission at their primary work location, while 43% receive an hourly wage.

Employment Type		
Primary Work Site	#	%
Salary/ Commission	3,142	49%
Hourly Wage	2,805	43%
By Contract	74	1%
Business/ Practice Income	392	6%
Unpaid	41	1%
Subtotal	6,453	100%

Source: Va. Healthcare Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate ranged from 5.7% in August to 4.5% in November and December. At the time of publication, December's unemployment rate was still preliminary.

At a Glance:

Concentration

Top Region:	26%
Top 3 Regions:	69%
Lowest Region:	2%

Locations

2 or more (2014):	14%
2 or more (Now*):	14%

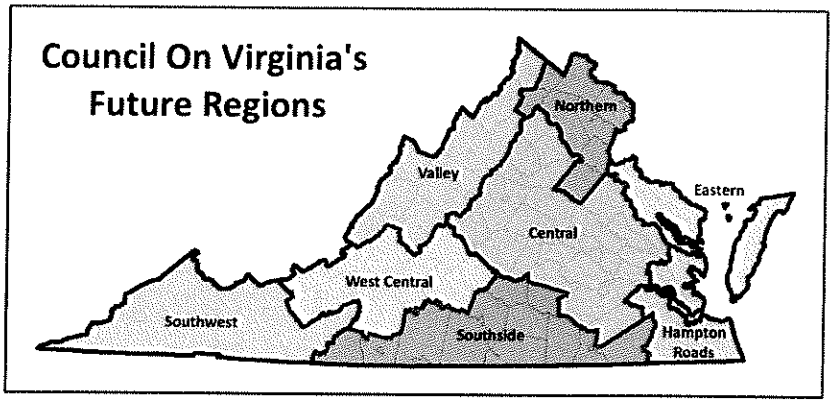
Source: Va. Healthcare Workforce Data Center

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

A Closer Look:

Regional Distribution of Work Locations				
COVF Region	Primary Location		Secondary Location	
	#	%	#	%
Central	1,682	24%	184	17%
Eastern	129	2%	24	2%
Hampton Roads	1,323	19%	180	17%
Northern	1,768	26%	275	26%
Southside	264	4%	36	3%
Southwest	408	6%	91	8%
Valley	437	6%	74	7%
West Central	785	11%	116	11%
Virginia Border State/DC	37	1%	31	3%
Other US State	53	1%	57	5%
Outside of the US	2	0%	7	1%
Total	6,888	100%	1,075	100%
Item Missing	927		44	

Source: Va. Healthcare Workforce Data Center



Number of Work Locations				
Locations	Work Locations in 2014		Work Locations Now*	
	#	%	#	%
0	284	4%	344	5%
1	6,697	83%	5,821	81%
2	568	7%	539	8%
3	352	4%	322	5%
4	43	1%	21	0%
5	21	0%	22	0%
6 or More	136	2%	94	1%
Total	8,101	100%	7,163	100%

*At the time of survey completion, December 2014.

Source: Va. Healthcare Workforce Data Center

Over the past year, 14% of Virginia's pharmacists have worked at multiple locations.

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	4,629	71%	758	74%
Non-Profit	1,387	21%	204	20%
State/Local Government	222	3%	34	3%
Veterans Administration	107	2%	5	0%
U.S. Military	134	2%	19	2%
Other Federal Gov't	65	1%	7	1%
Total	**6,544**	**100%**	**1,027**	**100%**
Did not have location	286		6980	
Item Missing	1,271		95	

At a Glance:
(Primary Locations)

Sector

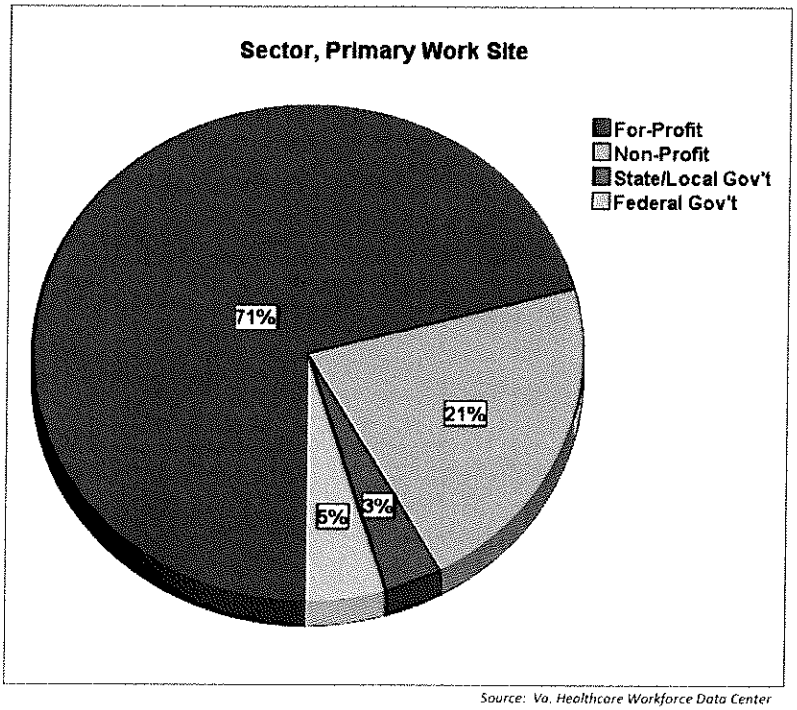
For Profit: 71%
Federal: 5%

Top Establishments

Large Chain Pharmacy (11+ Stores): 32%
Hospital/Health System (Inpatient): 23%
Independent Pharmacy (1-4 Stores): 9%

Source: Va. Healthcare Workforce Data Center

More than 90% of all pharmacists work in the private sector, including 71% who work at a for-profit company. Another 5% of pharmacists work for the federal government, while 3% work for a state or local government.

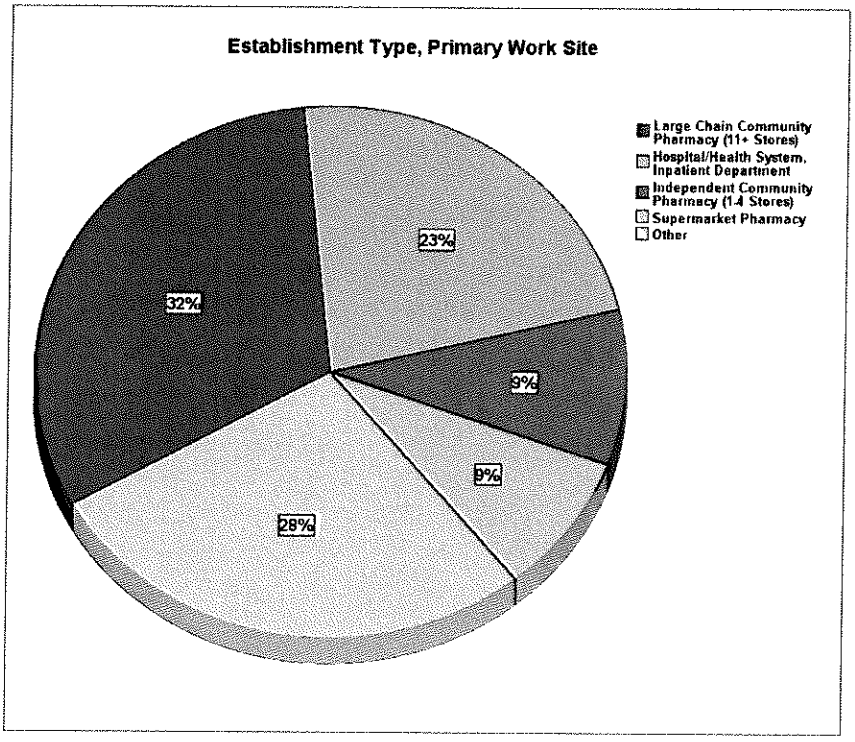


Source: Va. Healthcare Workforce Data Center

Top Location Types				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy	2,048	32%	293	29%
Hospital/Health System, Inpatient Department	1,463	23%	172	17%
Independent Community Pharmacy	610	9%	163	16%
Supermarket Pharmacy	549	9%	48	5%
Hospital/Health System, Outpatient Department	312	5%	33	3%
Mass Merchandiser (i.e. Big Box Store)	303	5%	47	5%
Nursing Home/Long-Term Care	213	3%	54	5%
Clinic-Based Pharmacy	179	3%	64	6%
Academic Institution	109	2%	31	3%
Benefit Administration	106	2%	5	0%
Home Health/Infusion	84	1%	16	2%
Mail Service Pharmacy	39	1%	8	1%
Manufacturer	34	1%	1	0%
Small Chain Community Pharmacy	29	0%	13	1%
Wholesale Distributor	5	0%	4	0%
Other	364	6%	65	6%
Total	6,447	100%	1,017	100%
Did Not Have a Location	286		6980	

Large chain community pharmacies of more than 10 stores are the most common establishment type in Virginia, employing nearly one-third of the state's pharmacy workforce.

Large chain community pharmacies of more than 10 stores were also the most common establishment type among pharmacists who also 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%
Education:	1%-9%

Roles

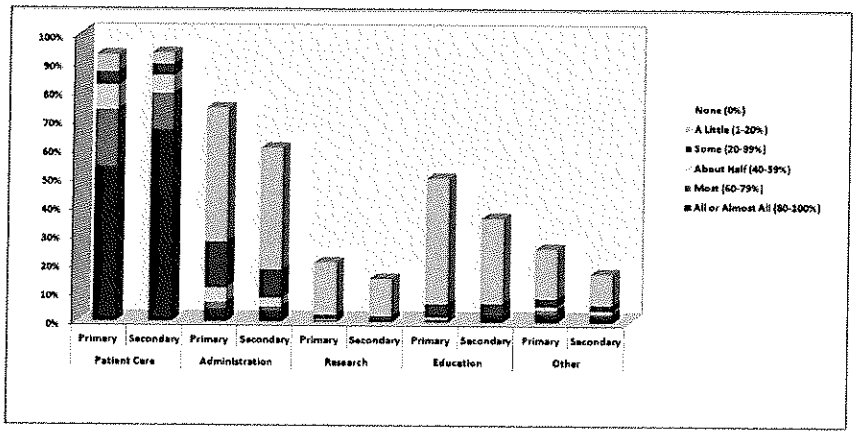
Patient Care:	74%
Administration:	7%
Education:	1%

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, nearly 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%)	54%	67%	4%	4%	0%	0%	1%	3%	3%	2%
Most (60-79%)	20%	13%	2%	2%	0%	0%	0%	0%	2%	1%
About Half (40-59%)	9%	6%	5%	3%	0%	0%	1%	0%	1%	1%
Some (20-39%)	5%	4%	16%	10%	2%	2%	5%	3%	3%	2%
A Little (1-20%)	6%	4%	47%	43%	18%	13%	44%	30%	17%	11%
None (0%)	7%	6%	26%	40%	79%	85%	50%	64%	74%	83%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	124	2%	-	-
50 to 54	189	3%	16	1%
55 to 59	596	10%	116	5%
60 to 64	1,527	25%	519	22%
65 to 69	2,196	36%	913	39%
70 to 74	781	13%	428	18%
75 to 79	216	4%	123	5%
80 or over	113	2%	63	3%
I do not intend to retire	420	7%	162	7%
Total	6,163	100%	2,340	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Retirement Expectations

All Pharmacists

Under 65: 40%

Under 60: 15%

Pharmacists 50 and over

Under 65: 28%

Under 60: 6%

Time until Retirement

Within 2 years: 6%

Within 10 years: 22%

Half the workforce: by 2039

Source: Va. Healthcare Workforce Data Center

40% of Virginia's pharmacists expect to retire before the age of 65, while 25% plan on working until at least age 70. Among pharmacists who are age 50 and over, 28% still plan on retiring by age 65, while one-third 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, 11% of pharmacists expect to pursue additional educational opportunities, and 10% also plan on increasing the number of hours that they devote to patients.

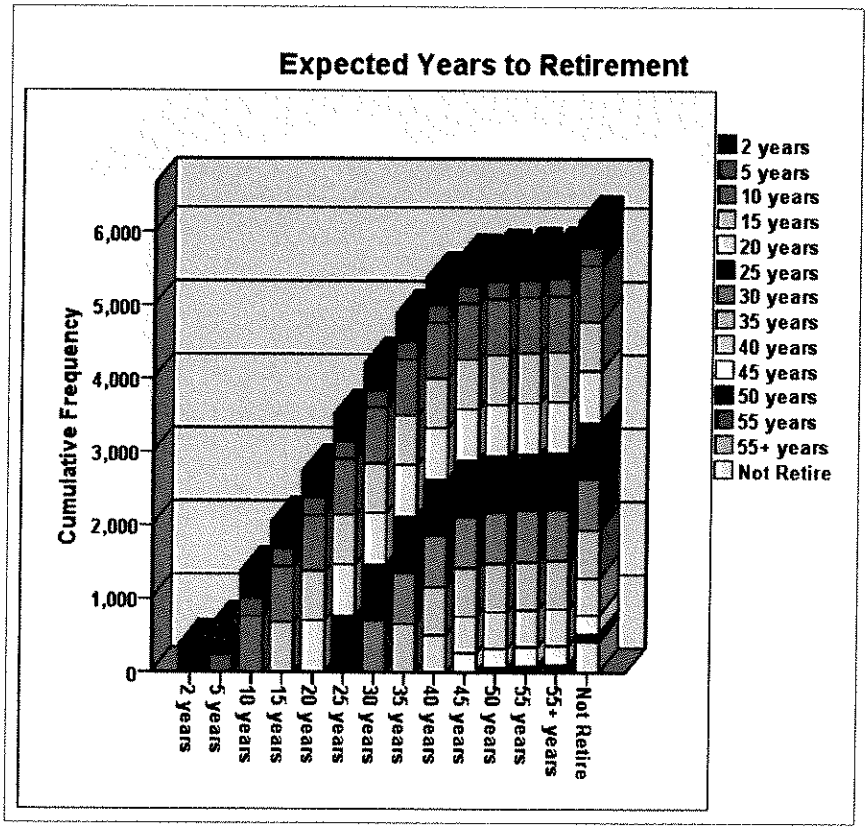
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	123	2%
Leave Virginia	249	3%
Decrease Patient Care Hours	229	3%
Decrease Teaching Hours	27	0%
Increase Participation		
Increase Patient Care Hours	774	10%
Increase Teaching Hours	463	6%
Pursue Additional Education	925	11%
Return to Virginia's Workforce	104	1%

Source: Va. Healthcare Workforce Data Center

By comparing retirement expectation to age, we can estimate the maximum years to retirement for pharmacists. Only 6% of pharmacists plan on retiring in the next two years, while 22% plan on retiring in the next ten years. Half of the current pharmacist workforce expects to be retired by 2039.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	375	6%	6%
5 years	242	4%	10%
10 years	761	12%	22%
15 years	677	11%	33%
20 years	700	11%	45%
25 years	766	12%	57%
30 years	702	11%	69%
35 years	658	11%	79%
40 years	503	8%	87%
45 years	258	4%	92%
50 years	60	1%	93%
55 years	25	0%	93%
In more than 55 years	15	0%	93%
Do not intend to retire	420	7%	100%
Total	6,163	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirements will begin to reach 10% of the current workforce starting in 2024. Retirements will peak at 12% of the current workforce around 2039 before declining to under 10% of the current workforce again around 2054.

115

At a Glance:

FTEs

Total:	6,871
FTEs/1,000 Residents:	0.832
Average:	.88

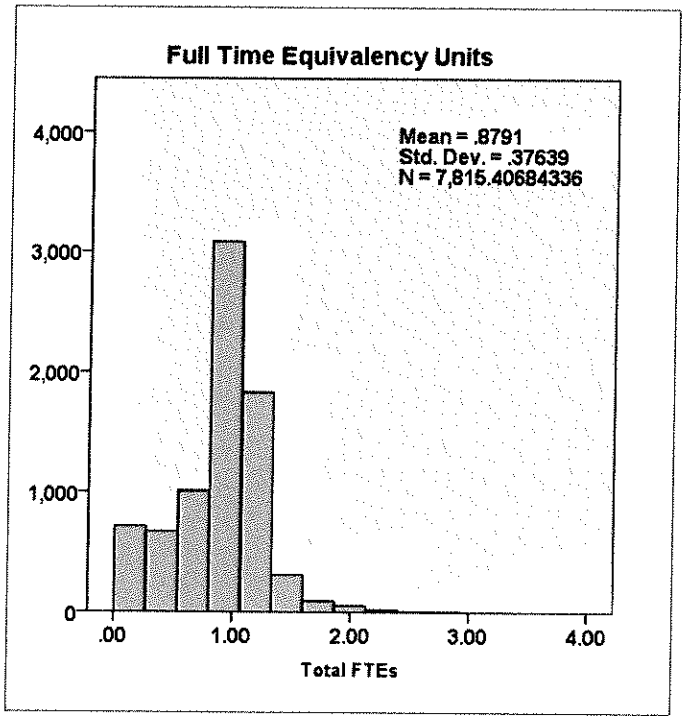
Age & Gender Effect

Age, Partial Eta^2:	Small
Gender, Partial Eta^2:	Small

Partial Eta^2 Explained:
Partial Eta^2 is a statistical measure of effect size.

Source: Va. Healthcare Workforce Data Center

A Closer Look:

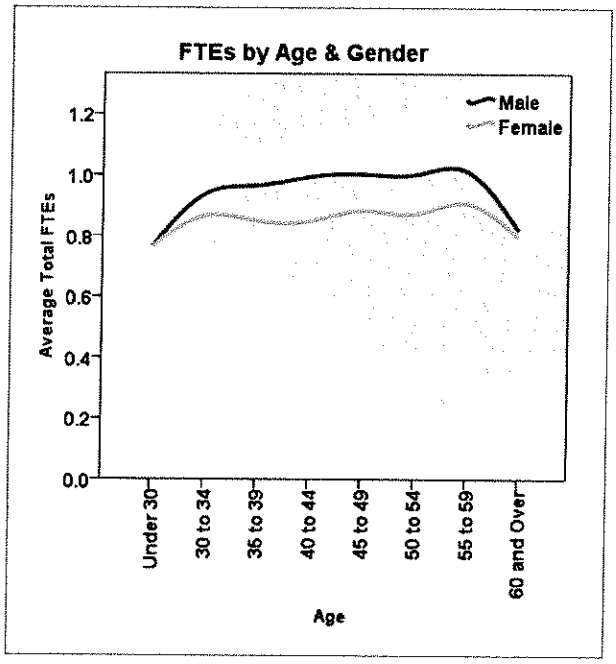


Source: Va. Healthcare Workforce Data Center

The typical pharmacist provided 0.96 FTEs in 2014, or about 37 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.[2]

Full-Time Equivalency Units	Average	Median
Age		
Under 30	0.77	0.84
30 to 34	0.89	0.96
35 to 39	0.89	0.94
40 to 44	0.90	1.01
45 to 49	0.93	0.95
50 to 54	0.92	0.97
55 to 59	0.96	1.03
60 and Over	0.80	0.83
Gender		
Male	0.92	1.01
Female	0.85	0.94

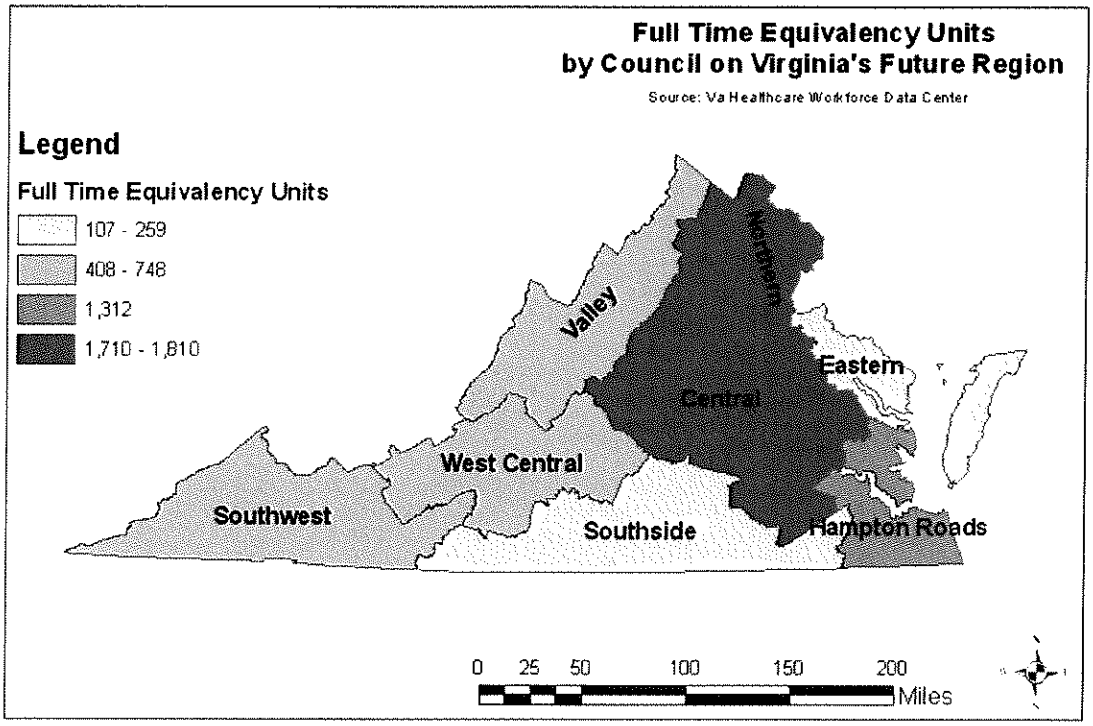
Source: Va. Healthcare Workforce Data Center

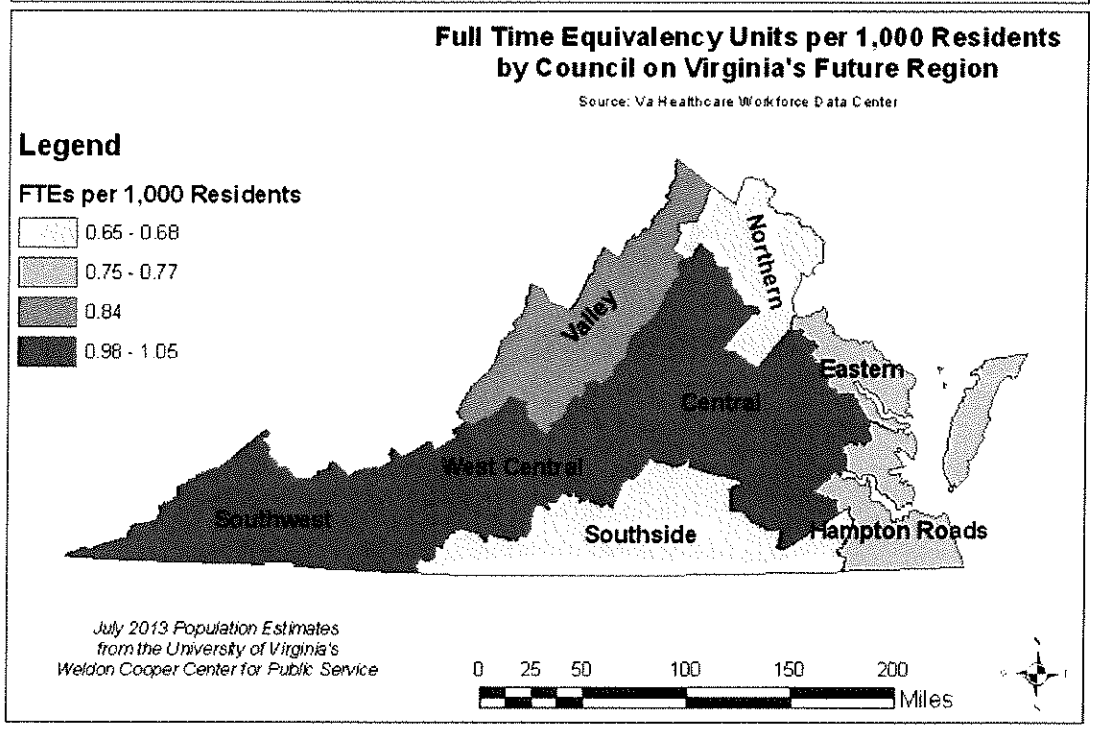


Source: Va. Healthcare Workforce Data Center

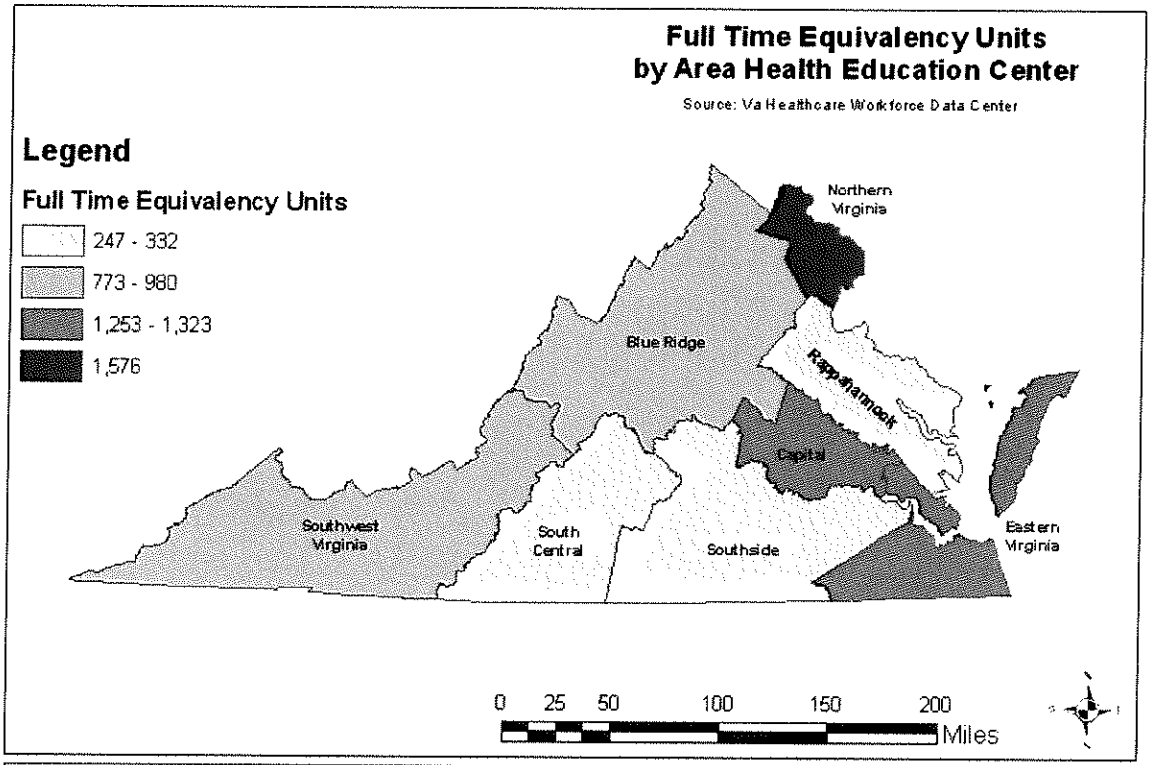
[2] Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

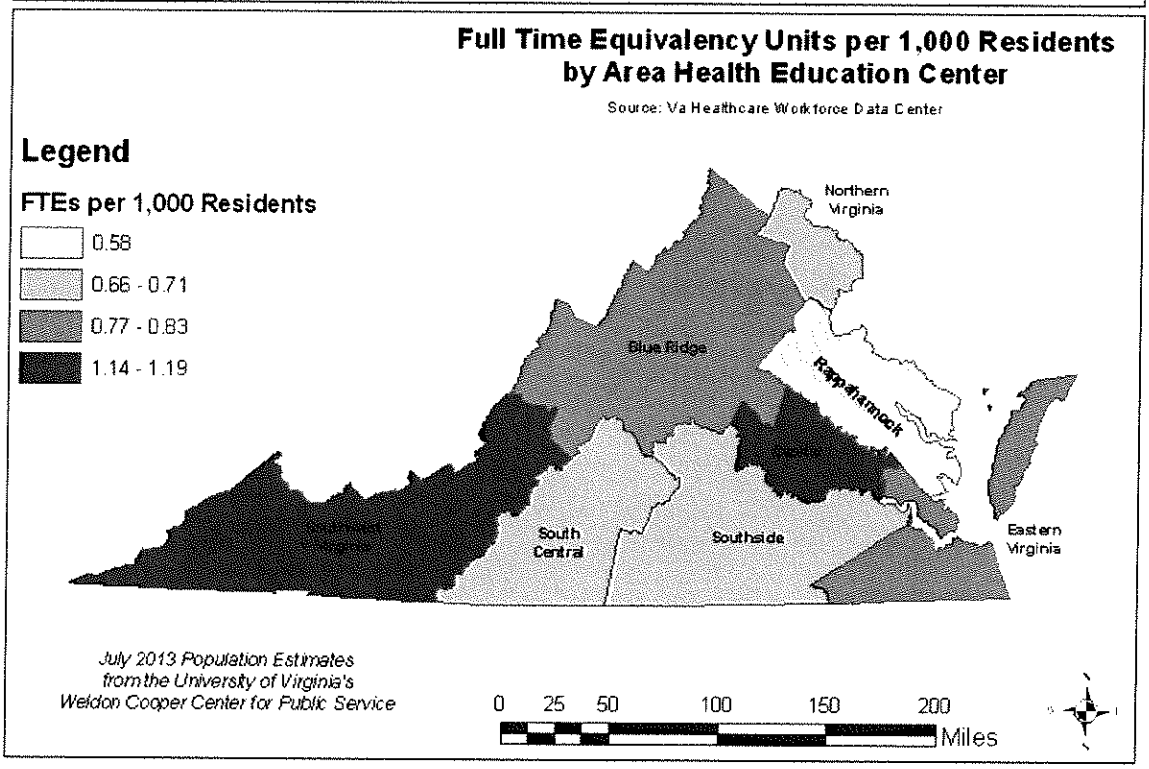
Council on Virginia's Future Regions

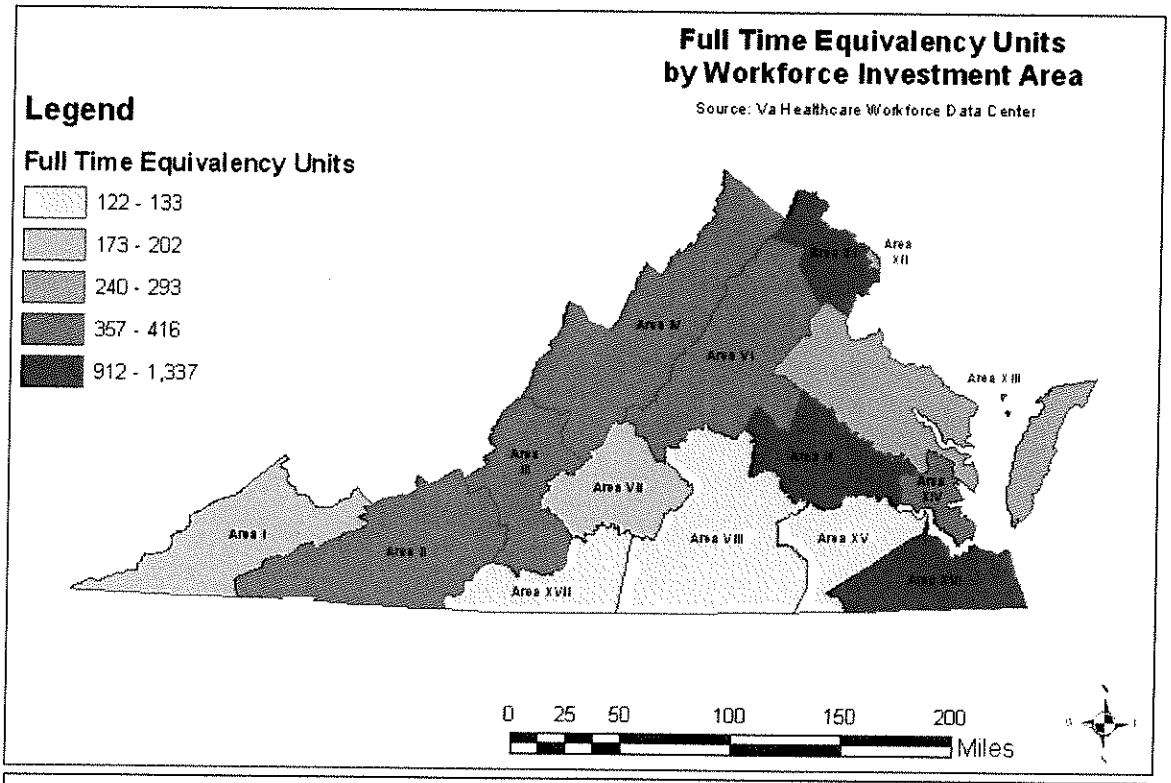


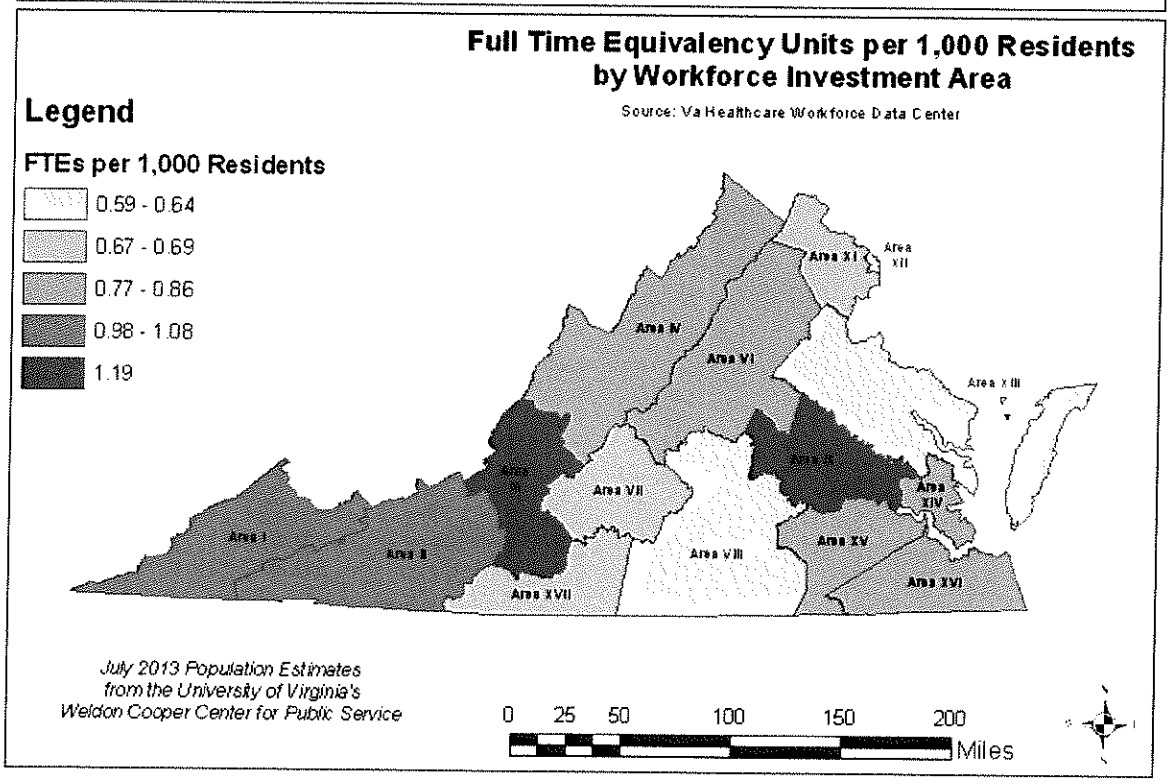


117

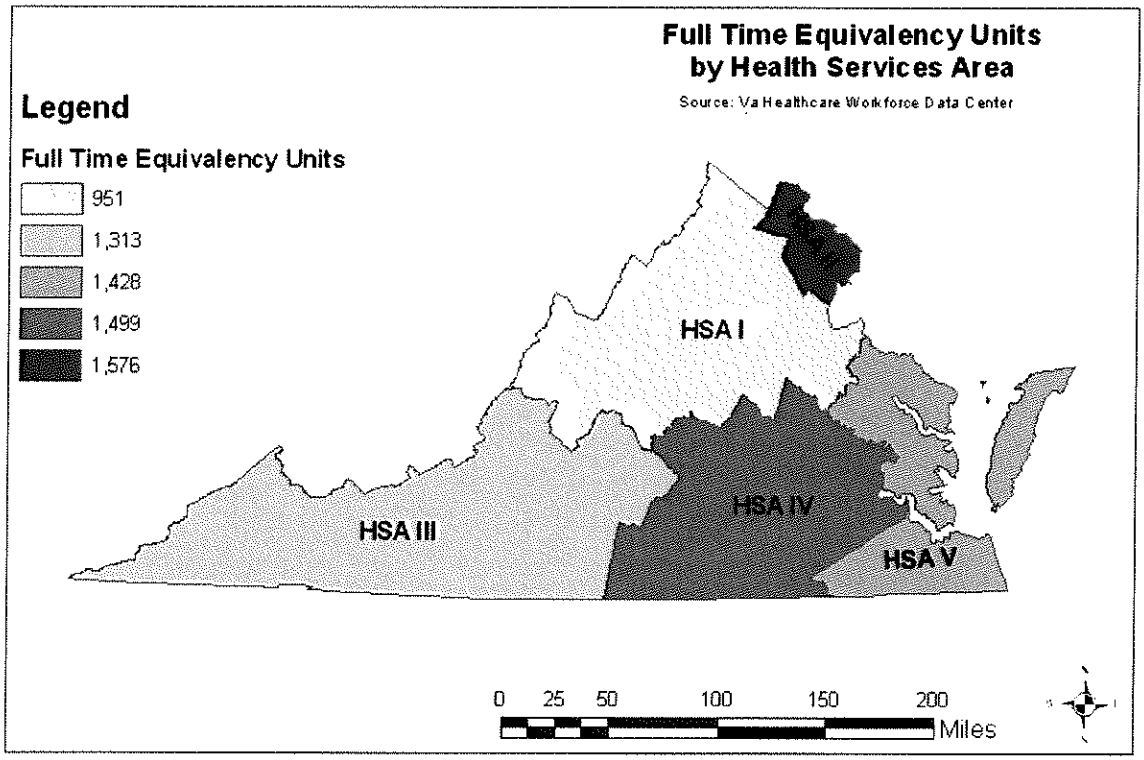

Full Time Equivalency Units
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
247 - 332
773 - 980
1,253 - 1,323
1,576
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
0 25 50 100 150 200
Miles

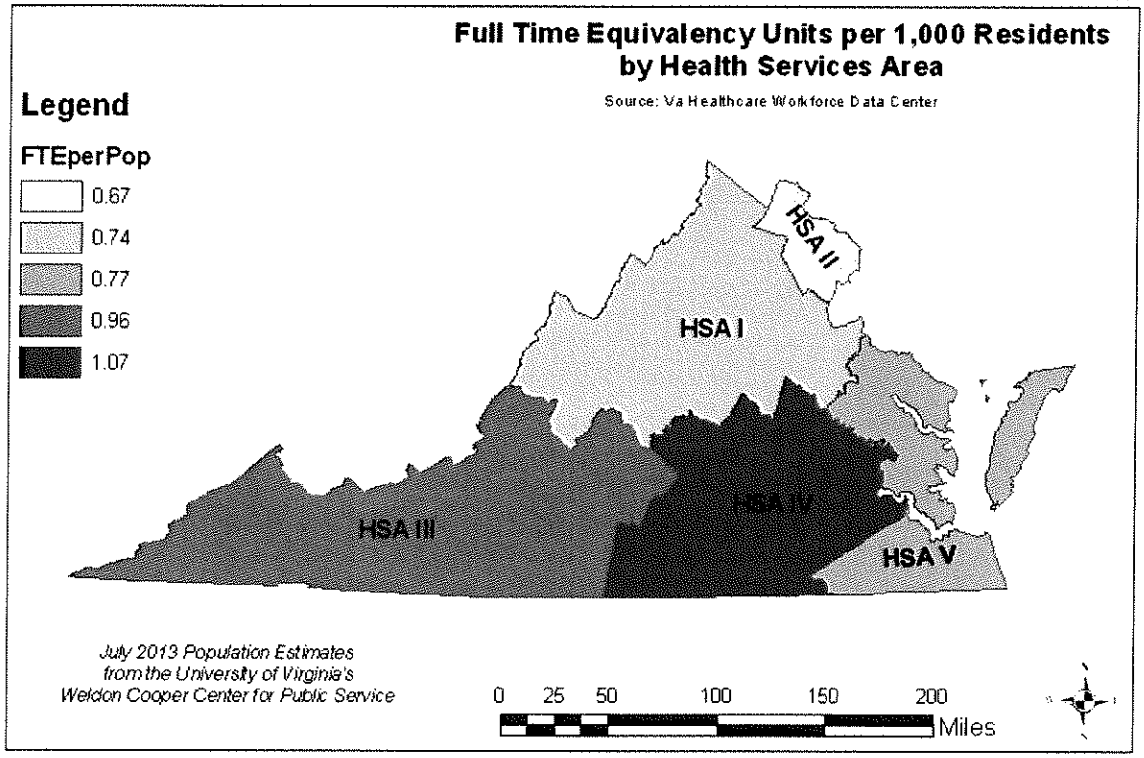

Full Time Equivalency Units per 1,000 Residents
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.58
0.66 - 0.71
0.77 - 0.83
1.14 - 1.19
Northern Virginia
Blue Ridge
Rappahannock
South Central
Southside
Eastern Virginia
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles

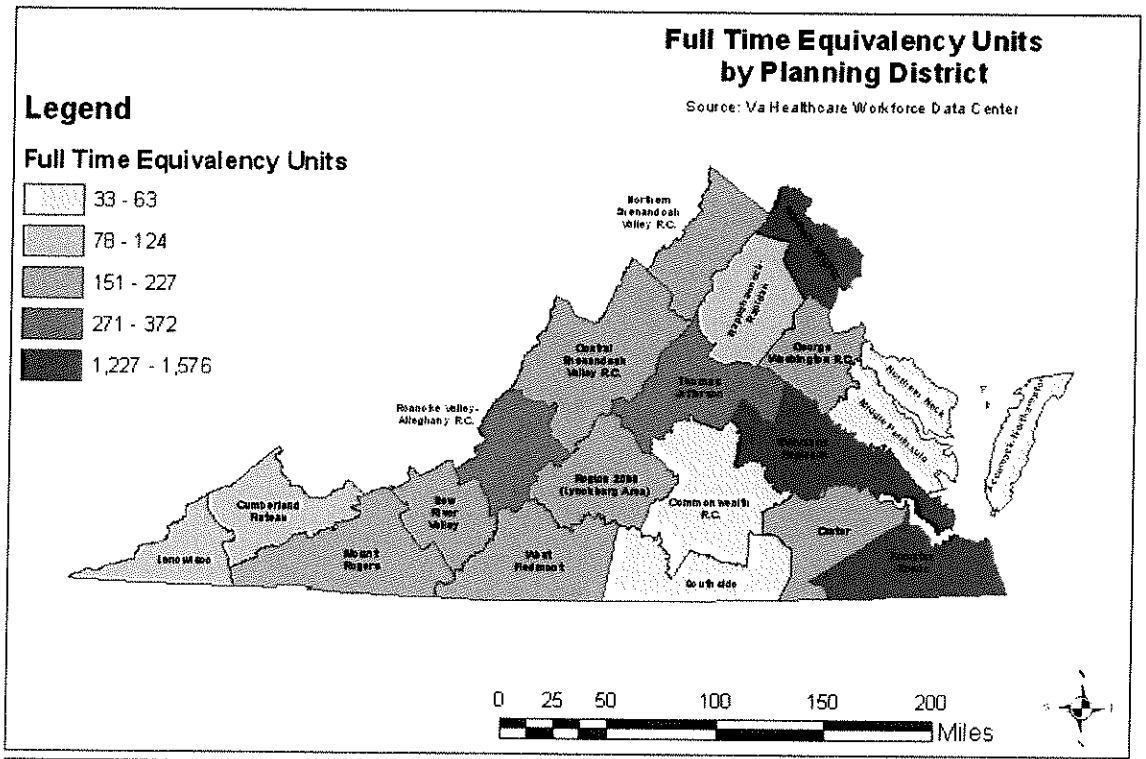

Full Time Equivalency Units
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
122 - 133
173 - 202
240 - 293
357 - 416
912 - 1,337
Area I
Area II
Area III
Area IV
Area V
Area VI
Area VII
Area VIII
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
0 25 50 100 150 200
Miles

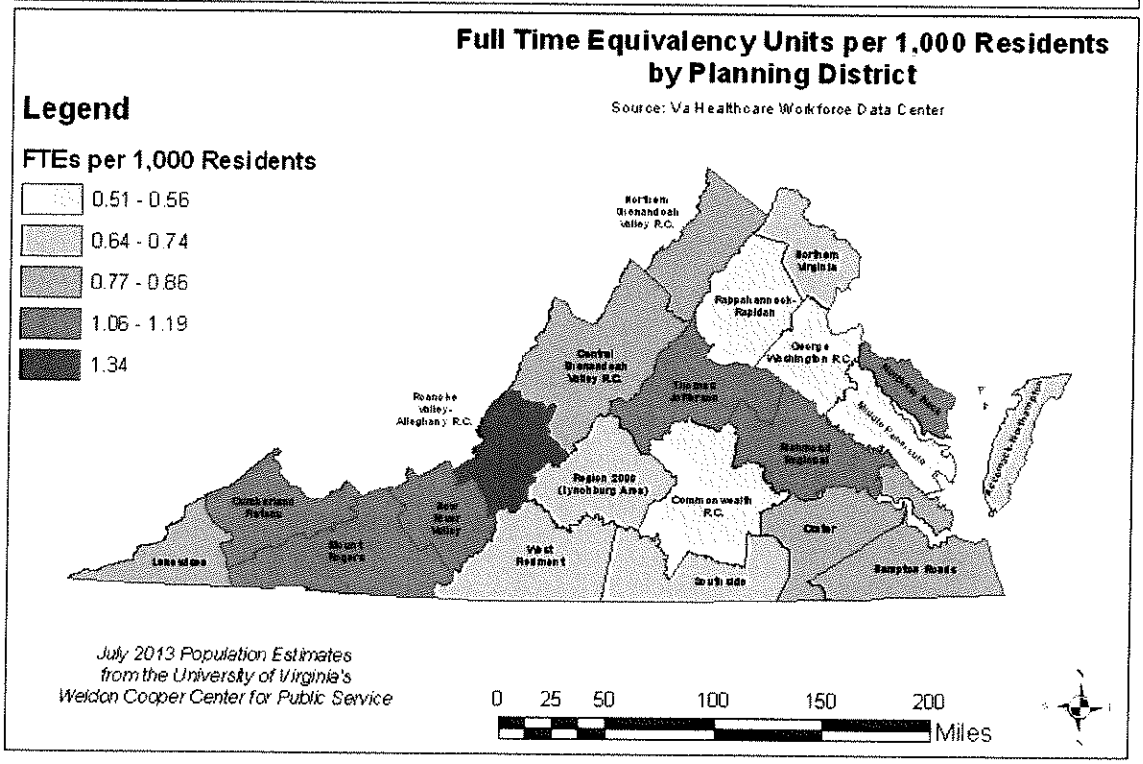

Full Time Equivalency Units per 1,000 Residents
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.59 - 0.64
0.67 - 0.69
0.77 - 0.86
0.98 - 1.08
1.19
Area I
Area II
Area III
Area IV
Area V
Area VI
Area VII
Area VIII
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles

119


Full Time Equivalency Units
by Health Services Area
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
951
1,313
1,428
1,499
1,576
HSA I
HSA II
HSA III
HSA IV
HSA V
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Health Services Area
Source: Va Healthcare Workforce Data Center
Legend
FTEperPop
0.67
0.74
0.77
0.96
1.07
HSA I
HSA II
HSA III
HSA IV
HSA V
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles


Full Time Equivalency Units
by Planning District
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
33 - 63
78 - 124
151 - 227
271 - 372
1,227 - 1,576
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Hampton Roads
Cumberland Plateau
New River Valley
Mount Rogers
West Piedmont
South side
Lenowisco
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Planning District
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.51 - 0.56
0.64 - 0.74
0.77 - 0.86
1.06 - 1.19
1.34
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
Central Shenandoah Valley R.C.
George Washington R.C.
Thomas Jefferson
Northern Neck
Middle Peninsula
Roanoke Valley-Alleghany R.C.
Richmond Regional
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Hampton Roads
Cumberland Plateau
New River Valley
Mount Rogers
West Piedmont
South side
Lenowisco
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles

Weights

Rural Status	Location Weight #	Rate	Weight	Total Weight Min	Max
Metro, 1 million+	5,820	87.47%	1.143194	1.107125	1.232837
Metro, 250,000 to 1 million	908	88.88%	1.125155	1.089655	1.213384
Metro, 250,000 or less	899	89.21%	1.120948	1.08558	1.208847
Urban pop 20,000+, Metro adj	120	85.83%	1.165049	1.12829	1.256406
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	358	84.92%	1.177632	1.140476	1.269975
Urban pop, 2,500-19,999, nonadj	257	85.21%	1.173516	1.13649	1.265537
Rural, Metro adj	225	73.78%	1.355422	1.312656	1.461707
Rural, nonadj	101	91.09%	1.097826	1.063188	1.183912
Virginia border state/DC	2,046	85.04%	1.175862	1.138762	1.268067
Other US State	2,571	82.81%	1.207609	1.169508	1.302304

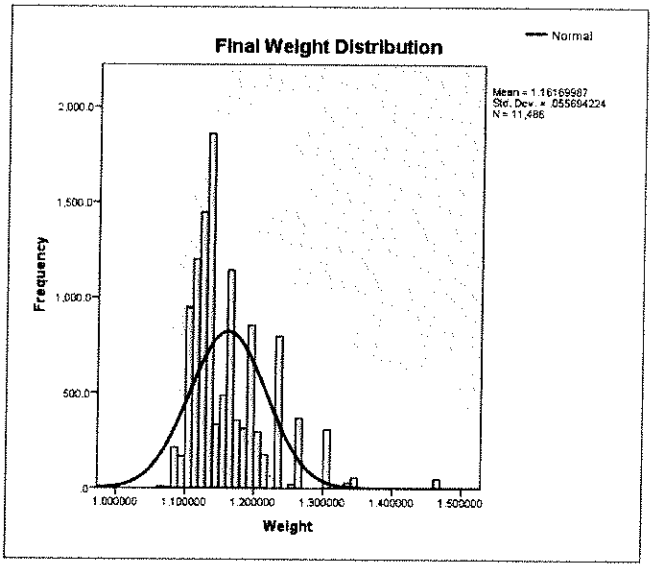
Age	Age Weight #	Rate	Weight	Total Weight Min	Max
Under 30	1,087	86.57%	1.155154	1.091582	1.347712
30 to 34	1,922	87.46%	1.143367	1.080443	1.33396
35 to 39	1,748	87.19%	1.146982	1.083859	1.338177
40 to 44	1,776	88.12%	1.134824	1.072371	1.323993
45 to 49	1,695	86.96%	1.149932	1.086647	1.34162
50 to 54	1,395	86.88%	1.15099	1.087647	1.342854
55 to 59	1,313	88.88%	1.125107	1.063188	1.312656
60 and Over	2,408	79.82%	1.252862	1.183912	1.461707

See the Methods section on the HWDC website for details on HWDC Methods:
www.dhp.virginia.gov/hwdc/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.

Overall Response Rate: 0.860761



122

Virginia's Pharmacy Technician Workforce: 2014

Healthcare Workforce Data Center

May 2015

Virginia Department of Health Professions
Healthcare Workforce Data Center
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804-367-2115, 804-527-4466(fax)
E-mail: *HWDC@dhp.virginia.gov*

Follow us on Tumblr: *www.vahwdc.tumblr.com*

More than 10,000 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!

Virginia Department of Health Professions

David E. Brown, D.C.
Director

Jaime H. Hoyle, J.D.
Chief Deputy Director

Healthcare Workforce Data Center Staff:

Dr. Elizabeth Carter, Ph.D.	Justin Crow, MPA	Laura Jackson	Christopher Coyle
Executive Director	*Research Analyst*	*Operations Manager*	*Research Assistant*

The Board of Pharmacy

Chair

Ellen B. Shinaberry
Harrisonburg

Vice-Chair

Empsy Munden
Virginia Beach

Members

Sheila K. W. Elliott
Hampton

Melvin L. Boone, Sr.
Chesapeake

Ryan K. Logan
Fairfax

Rebecca Thornbury
Grundy

Jody H. Allen
Midlothian

Michael I. Elliott
Forest

Dinny Li
Lorton

Cynthia Warriner
Chester

Executive Director

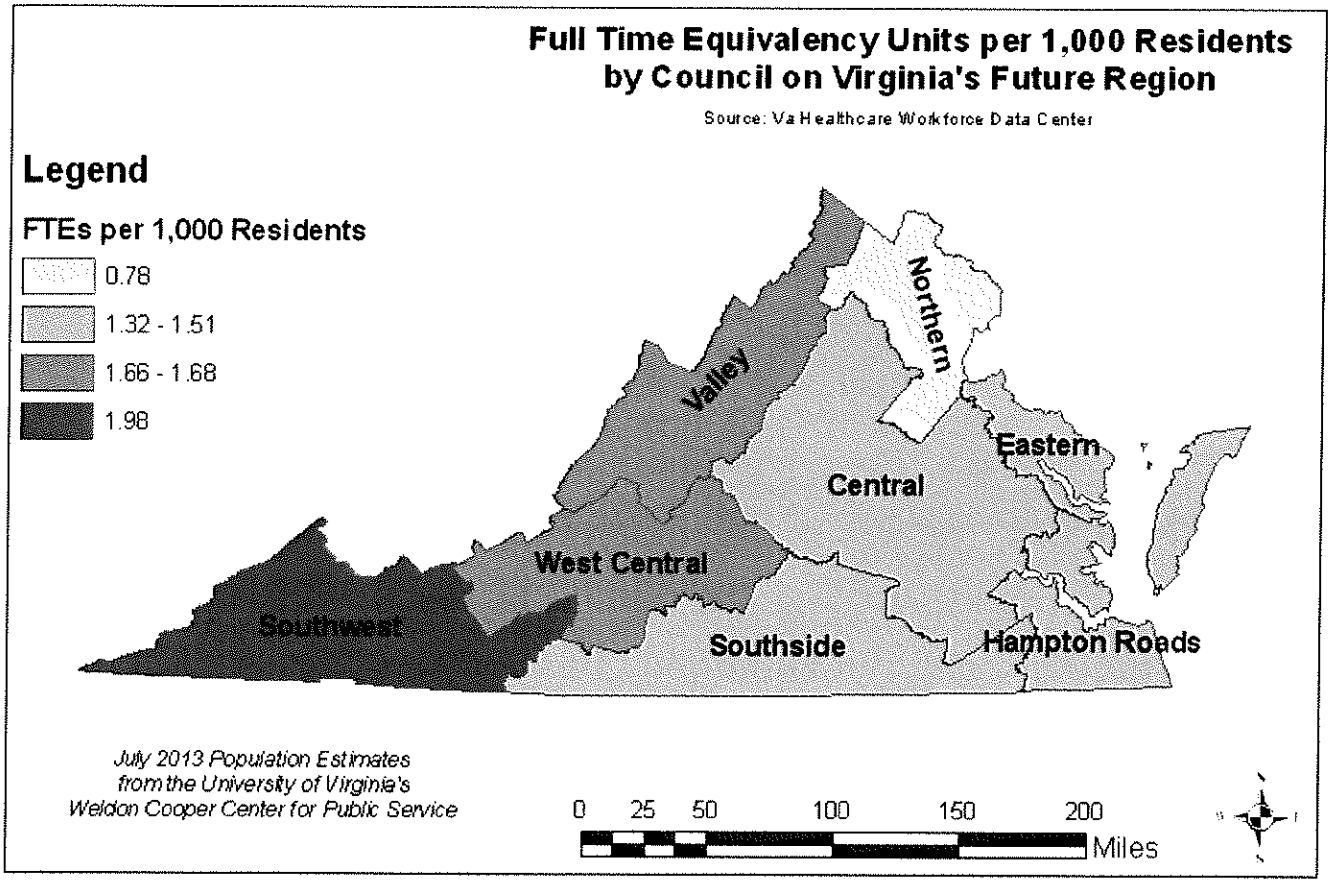
Caroline D. Juran
Richmond

Contents

The Pharmacy Technician Workforce: At a Glance:

The Workforce		Background		Current Employment	
Licensees:	14,686	Rural Childhood:	41%	Employed in Prof.:	78%
Virginia's Workforce:	13,783	HS Degree in VA:	75%	Hold 1 Full-time Job:	62%
FTEs:	10,487	% Work Rural:	14%	Satisfied?:	89%
Survey Response Rate		**Education**		**Job Turnover**	
All Licensees:	71%	High School/GED:	59%	Switched Jobs in 2014:	4%
Renewing Practitioners:	95%	Associate Degree:	20%	Employed over 2 yrs:	54%
Demographics		**Finances**		**Primary Roles**	
Female:	84%	Median Inc.:	$20k-$25k	Medication Disp.:	64%
Diversity Index:	58%	Health Benefits:	52%	Administration:	4%
Median Age:	34	Under 40 w/ Ed debt:	51%	Supervision:	2%

Source: Va Healthcare Workforce Data Center



10,498 pharmacy technicians voluntarily took part in the 2014 Pharmacy Technician Workforce Survey. The Virginia Department of Health Professions' Healthcare Workforce Data Center (HWDC) administers the survey during the license renewal process, which takes place every December for pharmacy technicians. These survey respondents represent 71% of the 14,686 pharmacy technicians who are licensed in the state and 95% of renewing practitioners.

The HWDC estimates that 13,783 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 10,487 "full-time equivalency units" during the survey time period, which the HWDC defines simply as working 2,000 hours a year (or 40 hours per week for 50 weeks with 2 weeks off).

The pharmacy technician workforce tends to be young, female, and diverse. 84% of pharmacy technicians are female and the median age of the workforce is 34. In addition, more than one-third of Virginia's pharmacy technicians are under the age of 30. Meanwhile, in a random encounter between two pharmacy technicians, there is a 58% chance that they would be of a different race or ethnicity, a measure known as the diversity index. For the Virginia population as a whole, this same probability is 54%.

41% of all pharmacy technicians grew up in a rural area, and 28% of these professionals currently work in non-Metro areas of the state. Overall, 14% of pharmacy technicians work in non-Metro areas of the state. Three-quarters of Virginia's pharmacy technicians graduated from high school in Virginia.

Nearly three out of five pharmacy technicians earned a high school degree or GED as their highest professional degree, while 20% have earned an Associate degree. More than half of pharmacy technicians who are under the age of 40 currently carry educational debt. The median debt burden for those with educational debt is between $12,000 and $14,000.

78% of pharmacy technicians are currently employed in the profession, while only 2% are involuntarily unemployed. 62% of Virginia's pharmacy technician workforce holds one full-time position, while 9% have multiple positions. 54% of pharmacy technicians have been at their primary work location for at least two years, while nearly one-quarter of all professionals began work at a new location in 2014.

Most pharmacy technicians receive an hourly wage at their primary work location. In total, the median annual income for pharmacy technicians is between $20,000 and $25,000. Among professional who receive an hourly wage or salary at their primary work location, two-thirds receive at least one employer-sponsored benefit, including 52% who receive employer-sponsored health insurance. 89% of pharmacy technicians indicate they are satisfied with their current employment situation, including 46% who indicate they are "very satisfied".

Nearly 90% of all pharmacy technicians work in the private sector, including 76% who work at a for-profit establishment. Large Chain Community Pharmacies (i.e. pharmacies with more than 10 locations) employ more than one-third of Virginia's pharmacy technician workforce, the most of any establishment type in the state.

A typical pharmacy technician spends approximately three-quarters of her time dispensing medication. In fact, 64% of all pharmacy technicians serve a medication dispensing role, meaning that at least 60% of their time is spent in such activities. A small number of pharmacy technicians fill other roles related to administration, supervision, or education.

53% of pharmacy technicians expect to retire by the age of 65. Although only 4% of the current workforce expects to retire in the next two years, half of the current workforce expects to retire by 2044. Over the next two years, 9% of all pharmacy technicians expect to leave the profession, while 5% expect to leave the state entirely. However, nearly one quarter of Virginia's pharmacy technician workforce expect to pursue additional educational opportunities within the next two years.

A Closer Look:

Licensee Counts		
License Status	#	%
Renewing Practitioners	10,194	69%
New Licensees	2,107	14%
Non-Renewals	2,385	16%
All Licensees	14,686	100%

Source: Va. Healthcare Workforce Data Center

HWDC surveys tend to achieve very high response rates. 95% of renewing pharmacy technicians submitted a survey. These represent 71% of pharmacy technicians who held a license at some point in 2014.

Response Rates			
Statistic	Non Respondents	Respondent	Response Rate
By Age			
Under 30	1,869	3,395	65%
30 to 34	644	1,690	72%
35 to 39	420	1,217	74%
40 to 44	287	973	77%
45 to 49	266	938	78%
50 to 54	205	810	80%
55 to 59	220	725	77%
60 and Over	277	750	73%
Total	4,188	10,498	72%
New Licenses			
Issued in 2014	1,270	837	40%
Metro Status			
Non-Metro	531	1,583	75%
Metro	3,316	8,502	72%
Not in Virginia	339	406	54%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Licensed Pharmacy Tech.

Number:	14,686
New:	14%
Not Renewed:	16%

Survey Response Rates

All Licensees:	71%
Renewing Practitioners:	95%

Source: Va. Healthcare Workforce Data Center

Response Rates	
Completed Surveys	10,498
Response Rate, all licensees	71%
Response Rate, Renewals	95%

Source: Va. Healthcare Workforce Data Center

Definitions

1. **The Survey Period:** The survey was conducted in December 2014.
2. **Target Population:** All professionals who held a Virginia license at some point in 2014.
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 2014.

At a Glance:

Workforce

2014 Pharm. Tech. Workforce:	13,783
FTEs:	10,487

Utilization Ratios

Licensees in VA Workforce:	94%
Licensees per FTE:	1.40
Workers per FTE:	1.31

Source: Va. Healthcare Workforce Data Center

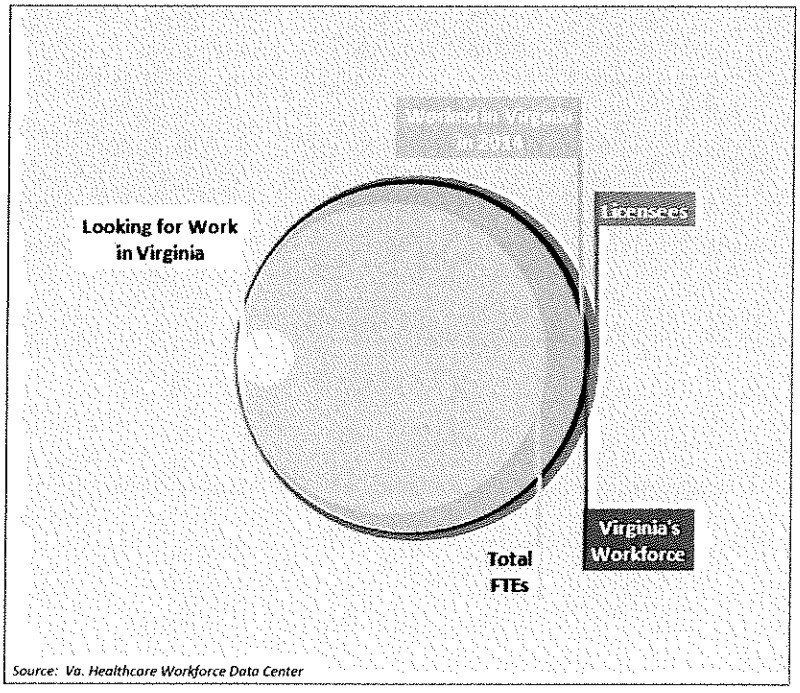
Definitions

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.

Virginia's Pharm. Tech. Workforce		
Status	**#**	**%**
Worked in Virginia in Past Year	13,436	97%
Looking for Work in Virginia	347	3%
Virginia's Workforce	13,783	100%
Total FTEs	10,487	
Licensees	14,686	

Source: Va. Healthcare Workforce Data Center

This report uses weighting to estimate the figures in this report. Unless otherwise noted, figures refer to the Virginia Workforce only. For more information on HWDC's methodology visit: www.dhp.virginia.gov/hwdc



Source: Va. Healthcare Workforce Data Center

A Closer Look:

Age & Gender						
Age	Male		Female		Total	
	#	% Male	#	% Female	#	% in Age Group
Under 30	919	19%	3,808	81%	4,727	37%
30 to 34	336	16%	1,721	84%	2,057	16%
35 to 39	212	15%	1,208	85%	1,420	11%
40 to 44	153	14%	920	86%	1,073	8%
45 to 49	142	14%	908	87%	1,051	8%
50 to 54	97	11%	776	89%	873	7%
55 to 59	96	12%	702	88%	798	6%
60 +	124	15%	712	85%	836	7%
Total	2,080	16%	10,754	84%	12,834	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Gender

% Female:	84%
% Under 40 Female:	82%

Age

Median Age:	34
% Under 40:	64%
% 55+:	13%

Diversity

Diversity Index:	58%
Under 40 Div. Index:	62%

Source: Va. Healthcare Workforce Data Center

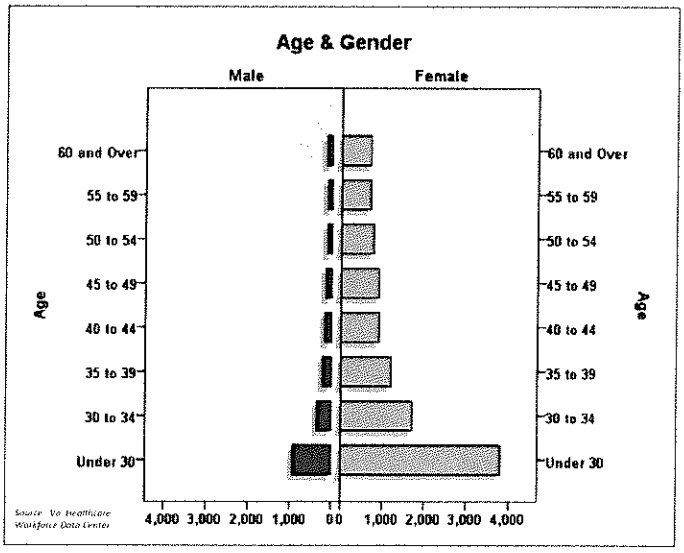
Race & Ethnicity					
Race/ Ethnicity	Virginia*	Pharmacy Tech.		Pharm. Tech. Under 40	
	%	#	%	#	%
White	64%	7,815	60%	4,641	56%
Black	19%	2,781	22%	1,881	23%
Asian	6%	1,211	9%	834	10%
Other Race	0%	180	1%	129	2%
Two or more races	2%	364	3%	303	4%
Hispanic	8%	579	4%	456	6%
Total	100%	12,930	100%	8,244	100%

*Population data in this chart is from the US Census, ACS 1-yr estimates, 2011 vintage.

Source: Va. Healthcare Workforce Data Center

In a chance encounter between two professionals, there is a 58% chance that they would be of a different race/ethnicity (a measure known as the Diversity Index). For Virginia's population as a whole, the comparable number is 54%.

Nearly two-thirds of all pharmacy technicians are under the age of 40, and 82% of these professionals are female. In addition, pharmacy technicians who are under the age of 40 are more diverse than the overall pharmacy technician workforce.



131

At a Glance:

Childhood

Urban Childhood:	20%
Rural Childhood:	41%

Virginia Background

HS in Virginia:	75%

Location Choice

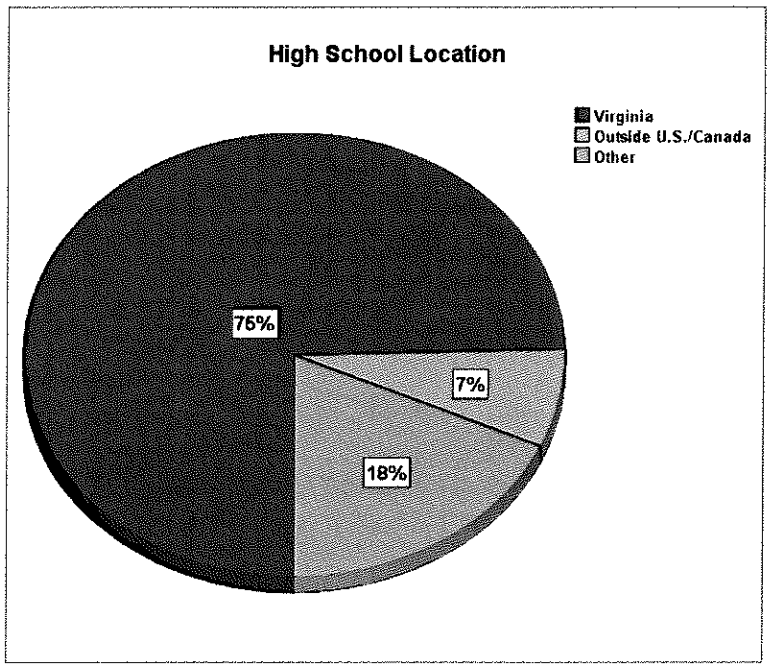
% Work Rural:	14%
% Rural to Non-Metro:	28%
% Urban/Suburban to Non-Metro:	5%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Primary Location: USDA Rural Urban Continuum		Rural Status of Childhood Location		
Code	Description	Rural	Suburban	Urban
	Metro Counties			
1	Metro, 1 million+	25%	50%	26%
2	Metro, 250,000 to 1 million	58%	29%	13%
3	Metro, 250,000 or less	64%	26%	10%
	Non-Metro Counties			
4	Urban pop 20,000+, Metro adj	65%	22%	13%
6	Urban pop, 2,500-19,999, Metro adj	80%	14%	7%
7	Urban pop, 2,500-19,999, nonadj	89%	6%	5%
8	Rural, Metro adj	86%	11%	3%
9	Rural, nonadj	73%	18%	9%
	Overall	41%	40%	20%

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

41% of pharmacy technicians grew up in self-described rural areas, and 28% of these professionals currently work in non-Metro counties. Overall, 14% of Virginia's pharmacy technician workforce is employed in non-Metro areas of the state.

Top Ten States for Pharmacy Technician Recruitment

Rank	High School Location			
	All Pharmacy Technicians		Licensed in Past 5 Years	
	State	#	State	#
1	Virginia	9,566	Virginia	4,588
2	Outside U.S./Canada	920	Outside U.S./Canada	429
3	New York	230	North Carolina	103
4	North Carolina	199	Maryland	95
5	Maryland	169	New York	88
6	Pennsylvania	164	Florida	71
7	West Virginia	161	West Virginia	69
8	Florida	142	Pennsylvania	64
9	California	112	California	52
10	New Jersey	111	Illinois	50

Source: Va. Healthcare Workforce Data Center

Three-quarters of Virginia's pharmacy technician workforce received their high school diploma in Virginia. Among those pharmacy technicians who received their initial license in the past five years, 74% received their high school degree in the state.

Just 6% of Virginia's licensed pharmacy technicians did not participate in Virginia's workforce in 2014. 81% 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

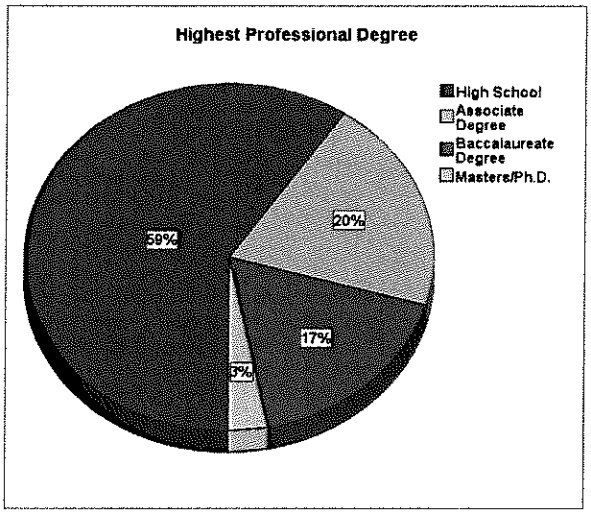
Total:	903
% of Licensees:	6%
Federal/Military:	5%
Va Border State/DC:	39%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Highest Professional Degree		
Degree	#	%
High School/GED	7,547	59%
Associate	2,539	20%
Baccalaureate	2,211	17%
Masters	372	3%
Ph.D.	27	0%
Total	12,697	100%

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

39% of pharmacy technicians currently carry educational debt, including more than half of those under the age of 40. For those with educational debt, the median amount is between $12,000 and $14,000.

At a Glance:

Education

High School/GED: 59%
Associate Degree: 20%

Educational Debt

Carry debt: 39%
Under age 40 w/ debt: 51%
Median debt: $12k-$14k

Source: Va. Healthcare Workforce Data Center

Nearly 40% of all pharmacy technicians have at least some college education.

Educational Debt				
Amount Carried	All Pharm. Tech.		Pharm. Tech. Under 40	
	#	%	#	%
None	6,262	61%	3,217	49%
Less than $10,000	1,583	15%	1,310	20%
$10,000-$19,999	902	9%	759	12%
$20,000-$29,999	646	6%	539	8%
$30,000 or more	882	9%	746	11%
Total	10,275	100%	6,571	100%

Source: Va. Healthcare Workforce Data Center

At a Glance:

Top Certifications

PTCB:	68%
ExCPT:	8%
Total w/ Cert.:	76%

Nat'l Certifications

Required:	41%
Pay Raise w/ Cert.:	35%

Source: Va. Healthcare Workforce Data Center

Professional Certifications		
Certification	#	% of Workforce
Pharmacy Technician Certification	9,373	68%
Exam for Certification of Pharmacy Technicians	1,119	8%
Total	**10,492**	**76%**

More than three-quarters of all pharmacy technicians in Virginia's workforce hold a professional certification.

More than 40% of pharmacy technicians work for an employer that requires a national certification as a condition of employment. Meanwhile, 35% of employers offer a pay raise for those pharmacy technicians that have earned a national certification.

National Certifications		
Required for Employment?	#	%
Yes	5,129	41%
No	7,353	59%
Pay Raise with Certification?	#	%
Yes	3,760	35%
No	5,410	51%
No Certification Held	1,508	14%

At a Glance:

Employment

Employed in Profession: 78%
Involuntarily Unemployed: 2%

Positions Held

1 Full-time: 62%
2 or More Positions: 9%

Weekly Hours:

40 to 49: 40%
60 or more: 3%
Less than 30: 19%

Source: Va. Healthcare Workforce Data Center

A Closer Look:

Current Work Status		
Status	#	%
Employed, capacity unknown	19	0%
Employed in a pharmacy technician-related capacity	9,889	78%
Employed, NOT in a pharmacy technician-related capacity	2,102	17%
Not working, reason unknown	0	0%
Involuntarily unemployed	276	2%
Voluntarily unemployed	367	3%
Retired	57	1%
Total	**12,711**	**100%**

Source: Va. Healthcare Workforce Data Center

78% of Virginia's pharmacy technicians were employed in the profession, and only 2% were involuntarily unemployed at the time the survey was completed. 62% of all pharmacy technicians hold one full-time job, and 40% work between 40 and 49 hours per week.

Current Positions		
Positions	#	%
No Positions	700	6%
One Part-Time Position	2,905	23%
Two Part-Time Positions	311	2%
One Full-Time Position	7,792	62%
One Full-Time Position & One Part-Time Position	749	6%
Two Full-Time Positions	29	0%
More than Two Positions	56	0%
Total	**12,542**	**100%**

Source: Va. Healthcare Workforce Data Center

Current Weekly Hours		
Hours	#	%
0 hours	700	6%
1 to 9 hours	395	3%
10 to 19 hours	755	6%
20 to 29 hours	1,199	10%
30 to 39 hours	3,502	29%
40 to 49 hours	4,886	40%
50 to 59 hours	411	3%
60 to 69 hours	138	1%
70 to 79 hours	79	1%
80 or more hours	143	1%
Total	**12,208**	**100%**

Source: Va. Healthcare Workforce Data Center

136

A Closer Look:

Income		
Annual Income	#	%
Volunteer Work Only	188	3%
Less than $10,000	950	16%
$10,000-$14,999	624	10%
$15,000-$19,999	730	12%
$20,000-$24,999	955	16%
$25,000-$29,999	755	13%
$30,000-$34,999	748	13%
$35,000-$39,999	382	6%
$40,000-$44,999	296	5%
$45,000-$49,999	124	2%
$50,000 or more	219	4%
Total	**5,973**	**100%**

Source: Va. Healthcare Workforce Data Center

At a Glance:

Annual Income
Median Income: $20k-25k

Benefits
Employer Health Insrnce: 52%
Employer Retirement: 45%

Satisfaction
Satisfied: 89%
Very Satisfied: 46%

Source: Va. Healthcare Workforce Data Center

Job Satisfaction		
Level	#	%
Very Satisfied	5,744	46%
Somewhat Satisfied	5,270	43%
Somewhat Dissatisfied	964	8%
Very Dissatisfied	431	4%
Total	**12,409**	**100%**

Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician earned between $20,000 and $25,000 in 2014. Among pharmacy technicians who received either an hourly wage or a salary as compensation at the primary work location, 52% received health insurance and 45% also had access to a retirement plan.

Employer-Sponsored Benefits		
Benefit	#	%
Health Insurance	5,819	59%
Paid Leave	5,722	58%
Dental Insurance	5,387	54%
Retirement	5,051	51%
Group Life Insurance	3,233	33%
Signing/Retention Bonus	291	3%
At Least One Benefit	**7,521**	**76%**

*From any employer at time of survey.

Source: Va. Healthcare Workforce Data Center

137

A Closer Look:

Underemployment in Past Year		
In the past year did you . . .?	#	%
Experience Involuntary Unemployment?	270	2%
Experience Voluntary Unemployment?	459	3%
Work Part-time or temporary positions, but would have preferred a full-time/permanent position?	685	5%
Work two or more positions at the same time?	1,591	12%
Switch employers or practices?	561	4%
Experienced at least 1	3,002	22%

Source: Va. Healthcare Workforce Data Center

Only 2% of Virginia's pharmacy technicians were involuntary unemployed at some point in 2014. For comparison, Virginia's average monthly unemployment rate was 5.1%.[1]

At a Glance:

Unemployment Experience 2014

Involuntarily Unemployed: 2%
Underemployed: 5%

Stability

Switched: 4%
New Location: 24%
Over 2 years: 54%
Over 2 yrs, 2nd location: 41%

Employment Type

Hourly Wage: 91%

Source: Va. Healthcare Workforce Data Center

Location Tenure				
Tenure	Primary		Secondary	
	#	%	#	%
Not Currently Working at this Location	440	4%	329	14%
Less than 6 Months	1,004	9%	335	14%
6 Months to 1 Year	1,131	10%	286	12%
1 to 2 Years	2,806	24%	489	20%
3 to 5 Years	2,554	22%	457	19%
6 to 10 Years	1,835	16%	285	12%
More than 10 Years	1,888	16%	238	10%
Subtotal	11,657	100%	2,419	100%
Did not have location	787		11,004	
Item Missing	1,339		360	
Total	13,783		13,783	

Source: Va. Healthcare Workforce Data Center

54% of pharmacy technicians have worked at their primary location for more than 2 years—the job tenure normally required to get a conventional mortgage loan.

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

Employment Type		
Primary Work Site	#	%
Salary/ Commission	833	8%
Hourly Wage	10,091	91%
By Contract	54	0%
Business/ Practice Income	16	0%
Unpaid	89	1%
Subtotal	11,084	100%

Source: Va. Healthcore Workforce Data Center

[1] As reported by the US Bureau of Labor Statistics. The non-seasonally adjusted monthly unemployment rate ranged from 5.7% in August to 4.5% in November and December. At the time of publication, December's unemployment rate was still preliminary.

138

At a Glance:

Concentration

Top Region:	23%
Top 3 Regions:	66%
Lowest Region:	2%

Locations

2 or more (Past Year):	20%
2 or more (Now*):	18%

Source: Va. Healthcare Workforce Data Center

More pharmacy technicians work in Central Virginia than in any other COVF region in the state.

A Closer Look:

Regional Distribution of Work Locations

COVF Region	Primary Location #	Primary Location %	Secondary Location #	Secondary Location %
Central	2,670	23%	602	23%
Eastern	248	2%	56	2%
Hampton Roads	2,503	22%	577	22%
Northern	2,522	22%	600	23%
Southside	525	5%	95	4%
Southwest	846	7%	154	6%
Valley	889	8%	166	6%
West Central	1,316	11%	268	10%
Virginia Border State/DC	38	0%	27	1%
Other US State	19	0%	40	2%
Outside of the US	3	0%	10	0%
Total	11,579	100%	2,595	100%
Item Missing	1,418		182	

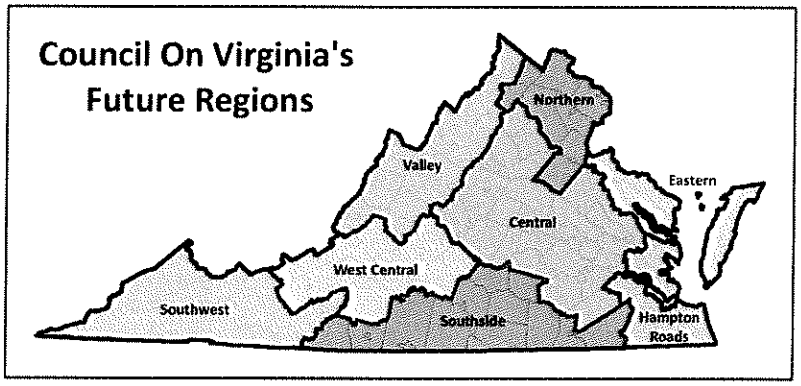
Source: Va. Healthcare Workforce Data Center

Number of Work Locations

Locations	Work Locations in Past Year #	Work Locations in Past Year %	Work Locations Now* #	Work Locations Now* %
0	783	6%	687	6%
1	10,224	74%	9,054	76%
2	1,628	12%	1,320	11%
3	1,013	7%	793	7%
4	61	0%	35	0%
5	26	0%	15	0%
6 or More	47	0%	32	0%
Total	13,783	100%	11,936	100%

*At the time of survey completion, December 2014.

Source: Va. Healthcare Workforce Data Center



Over the past year, 20% of Virginia's pharmacy technician workforce has worked at multiple locations.

139

A Closer Look:

Location Sector				
Sector	Primary Location		Secondary Location	
	#	%	#	%
For-Profit	8,365	76%	1,606	71%
Non-Profit	1,411	13%	324	14%
State/Local Government	809	7%	221	10%
Veterans Administration	56	1%	5	0%
U.S. Military	183	2%	51	2%
Other Federal Gov't	154	1%	47	2%
Total	**10,978**	**100%**	**2,254**	**100%**
Did not have location	787		11,004	
Item Missing	2,017		525	

At a Glance:
(Primary Locations)

Sector

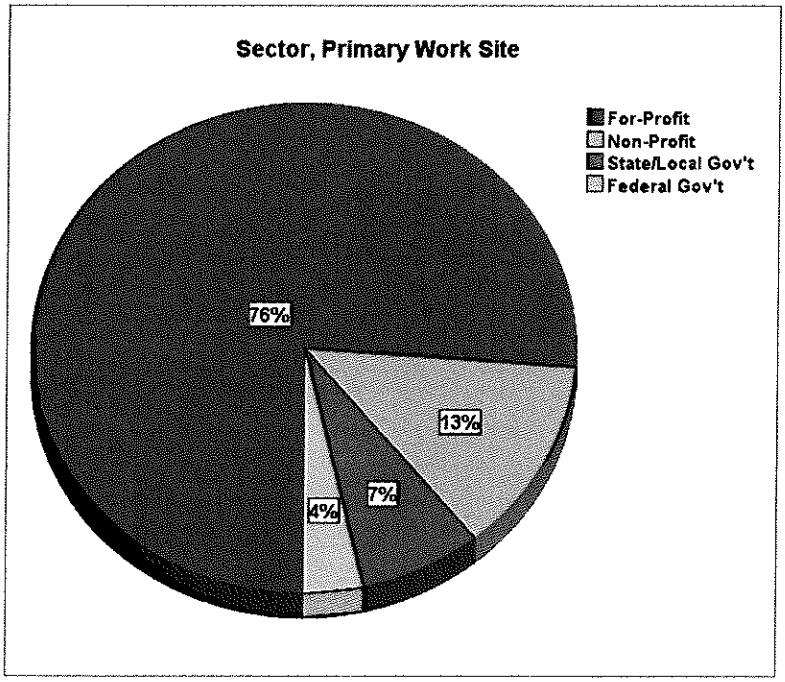
For Profit: 76%
Federal: 4%

Top Establishments

Large Chain Pharmacy (11+ Stores): 36%
Hospital/Health System (Inpatient): 13%
Independent Pharmacy (1-4 Stores): 11%

Source: Va. Healthcare Workforce Data Center

Nearly 90% of Virginia's pharmacy technicians work in the private sector, including 76% who work in a for-profit establishment. Another 7% of pharmacy technicians work for either the state or local government.



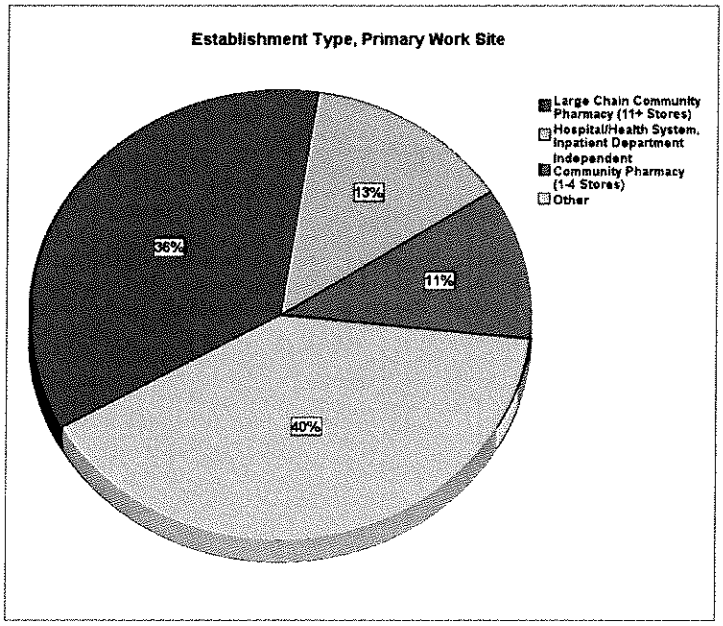
Source: Va. Healthcare Workforce Data Center

140

Top 10 Location Type				
Establishment Type	Primary Location		Secondary Location	
	#	%	#	%
Large Chain Community Pharmacy (11+ Stores)	3,910	36%	735	33%
Hospital/Health System, Inpatient Department	1,477	13%	255	11%
Independent Community Pharmacy (1-4 Stores)	1,200	11%	198	9%
Supermarket Pharmacy	980	9%	151	7%
Nursing Home/Long-Term Care	529	5%	104	5%
Mass Merchandiser (i.e. Big Box Store)	519	5%	86	4%
Hospital/Health System, Outpatient Department	488	4%	95	4%
Clinic-Based Pharmacy	237	2%	61	3%
Home Health/Infusion	152	1%	28	1%
Benefit Administration	150	1%	33	1%
Academic Institution	118	1%	71	3%
Small Chain Community Pharmacy (5-10 Stores)	113	1%	37	2%
Wholesale Distributor	66	1%	14	1%
Mail Service Pharmacy	54	0%	8	0%
Manufacturer	39	0%	10	0%
Other	944	9%	372	16%
Total	**10,976**	**100%**	**2,258**	**100%**
Did Not Have a Location	787		11004	

Large Chain Community Pharmacies (i.e. pharmacies with more than 10 stores) employ more than one-third of Virginia's pharmacy technician workforce, the most of any establishment type.

For pharmacy technicians who also have a secondary work location, large chain community pharmacies are still the most common establishment type.



Source: Va. Healthcare Workforce Data Center

141

At a Glance:
(Primary Locations)

Typical Time Allocation

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

Roles

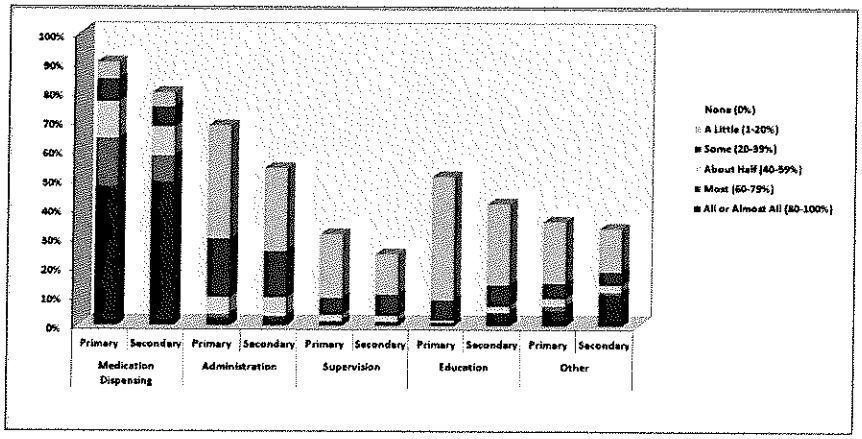
Medication Disp.:	64%
Administration:	4%
Supervision:	2%
Education:	1%

Patient Care Pharm. Techs.

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

64% of 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	
	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site	Prim Site	Sec. Site
All or Almost All (80-100%)	47%	49%	3%	3%	1%	1%	1%	4%	5%	11%
Most (60-79%)	17%	9%	1%	1%	1%	1%	0%	1%	2%	1%
About Half (40-59%)	13%	10%	6%	6%	2%	2%	1%	2%	3%	2%
Some (20-39%)	7%	7%	20%	16%	6%	7%	7%	7%	5%	4%
A Little (1-20%)	6%	5%	39%	29%	22%	14%	42%	28%	21%	15%
None (0%)	10%	20%	32%	46%	69%	75%	49%	58%	64%	67%

Source: Va. Healthcare Workforce Data Center

142

A Closer Look:

Retirement Expectations				
Expected Retirement Age	All		Over 50	
	#	%	#	%
Under age 50	2,528	25%	-	-
50 to 54	465	5%	41	2%
55 to 59	594	6%	123	6%
60 to 64	1,664	17%	528	27%
65 to 69	2,064	21%	751	38%
70 to 74	633	6%	218	11%
75 to 79	176	2%	49	3%
80 or over	118	1%	27	1%
I do not intend to retire	1,679	17%	218	11%
Total	9,923	100%	1,955	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: 35%
- Under 60: 8%

Time until Retirement
- Within 2 years: 4%
- Within 10 years: 13%
- Half the workforce: by 2044

Source: Va. Healthcare Workforce Data Center

53% of all pharmacy technicians expect to retire by the age of 65, including 36% who expect to retire no later than the age of 60. Among pharmacy technicians who are age 50 and over, more than one-third still expect to retire by the age of 65.

Within the next two years, 9% of Virginia's pharmacy technician workforce expects to leave the profession and 5% expect to leave the state. Meanwhile, 24% of all pharmacy technicians also expect to pursue additional educational opportunities.

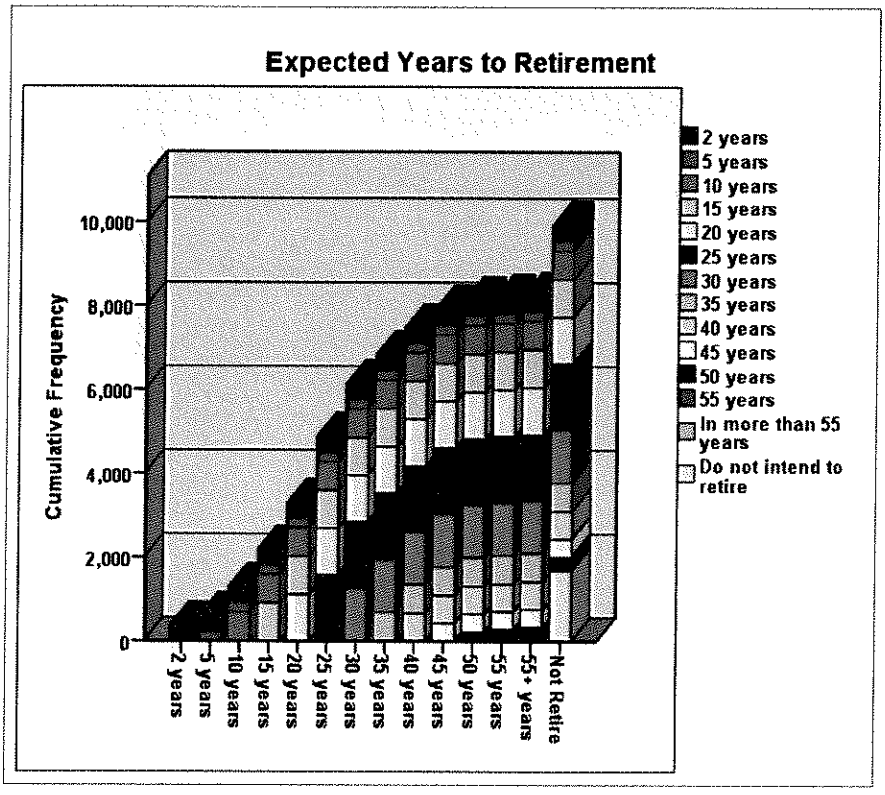
Future Plans		
2 Year Plans:	#	%
Decrease Participation		
Leave Profession	1,192	9%
Leave Virginia	626	5%
Decrease Patient Care Hours	191	1%
Decrease Teaching Hours	112	1%
Increase Participation		
Increase Patient Care Hours	987	7%
Increase Teaching Hours	707	5%
Pursue Additional Education	3,257	24%
Return to Virginia's Workforce	190	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 4% of pharmacy technicians plan on retiring in the next two years, while 13% plan on retiring in the next ten years. Half of the current workforce expects to be retired by 2044.

Time to Retirement			
Expect to retire within. . .	#	%	Cumulative %
2 years	377	4%	4%
5 years	234	2%	6%
10 years	685	7%	13%
15 years	904	9%	22%
20 years	1,109	11%	33%
25 years	1,581	16%	49%
30 years	1,259	13%	62%
35 years	684	7%	69%
40 years	660	7%	76%
45 years	423	4%	80%
50 years	218	2%	82%
55 years	55	1%	83%
In more than 55 years	54	1%	83%
Do not intend to retire	1,679	17%	100%
Total	9,923	100%	

Source: Va. Healthcare Workforce Data Center



Source: Va. Healthcare Workforce Data Center

Using these estimates, retirements will begin to reach 10% of the current workforce starting in 2034. Retirements will peak at 16% of the current workforce around 2039 before declining to below 10% of the current workforce again around 2049.

At a Glance:

FTEs

Total:	10,487
FTEs/1,000 Residents:	1.270
Average:	0.81

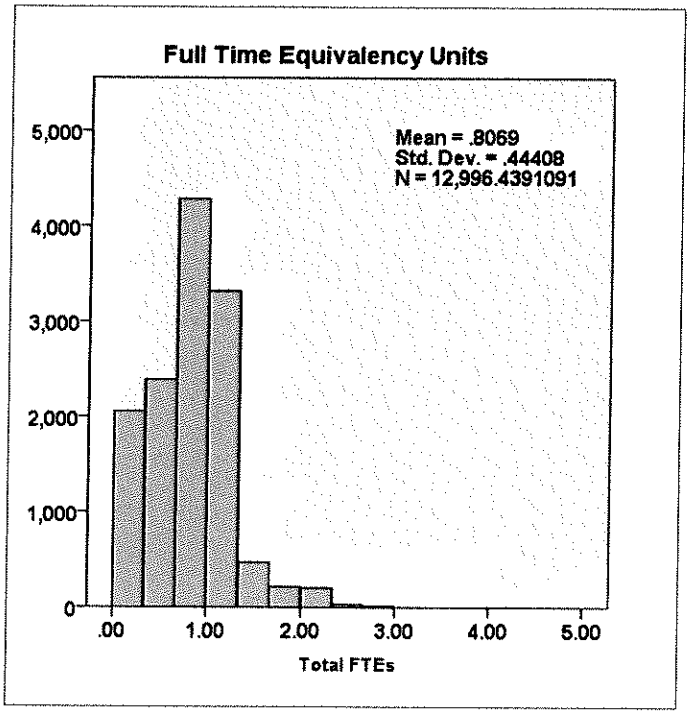
Age & Gender Effect

Age, Partial Eta^2:	Medium
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:

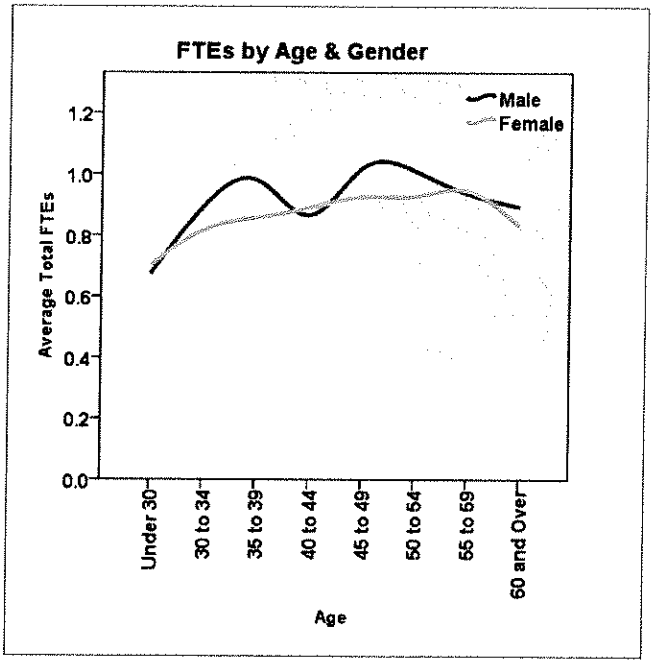


Source: Va. Healthcare Workforce Data Center

The typical pharmacy technician provided 0.84 FTEs in 2014, or approximately 32 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.[2]

Full-Time Equivalency Units	Average	Median
Age		
Under 30	0.69	0.67
30 to 34	0.83	0.88
35 to 39	0.87	0.93
40 to 44	0.88	0.93
45 to 49	0.92	0.96
50 to 54	0.92	0.96
55 to 59	0.94	0.96
60 and Over	0.84	0.83
Gender		
Male	0.82	0.86
Female	0.81	0.89

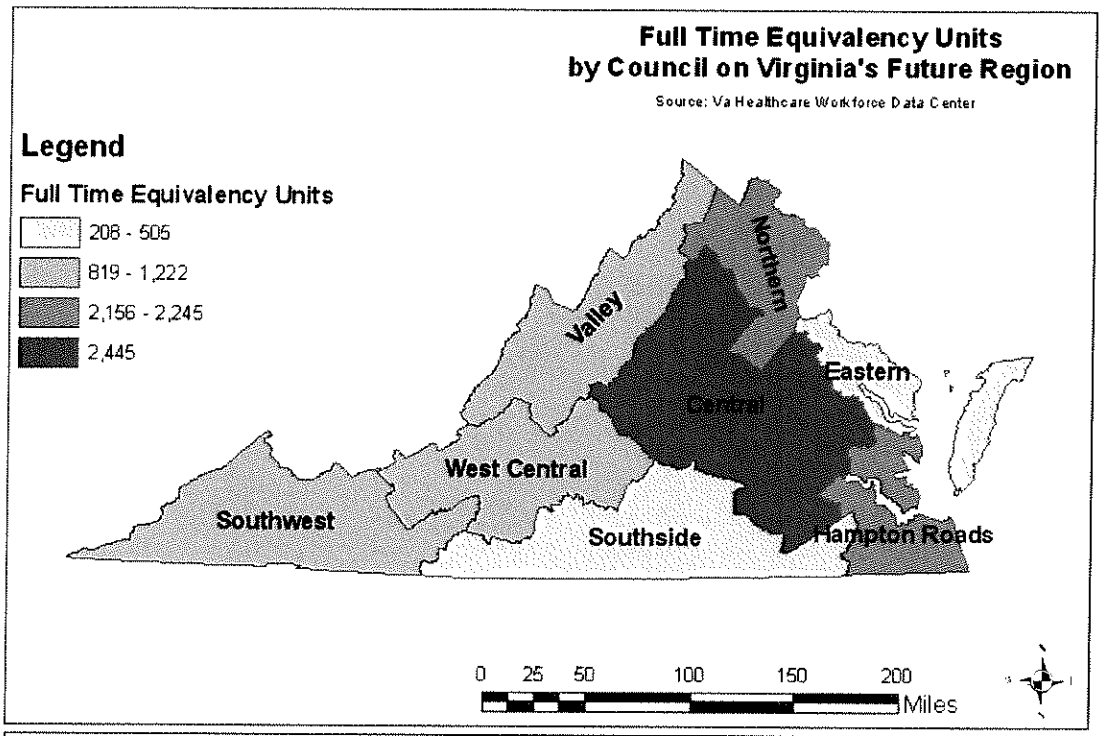
Source: Va. Healthcare Workforce Data Center

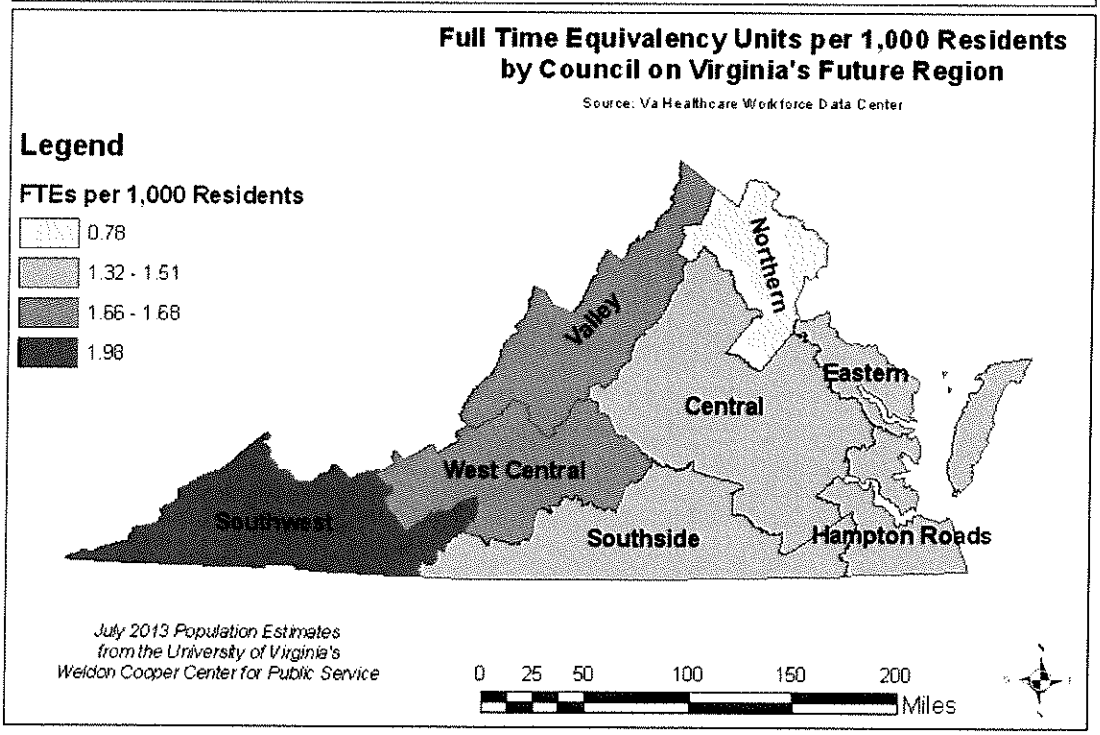


Source: Va. Healthcare Workforce Data Center

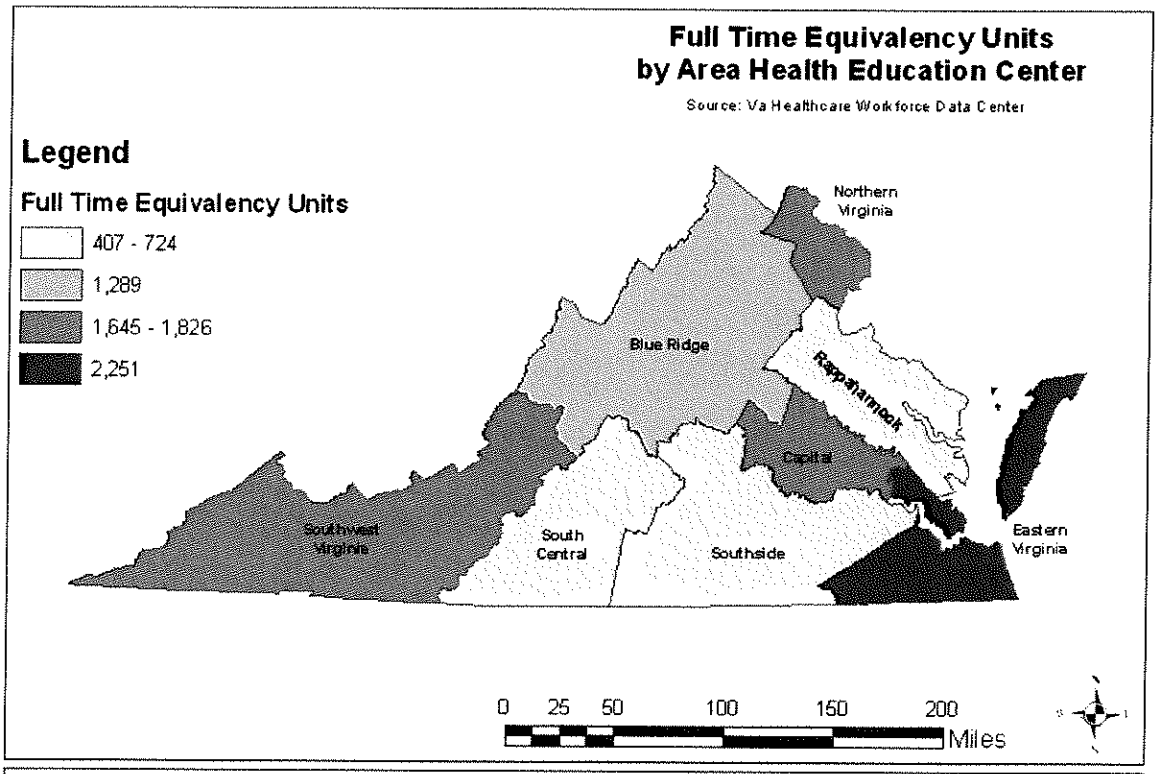
[2] Due to assumption violations in Mixed between-within ANOVA (Levene's Test & Interaction effect are significant).

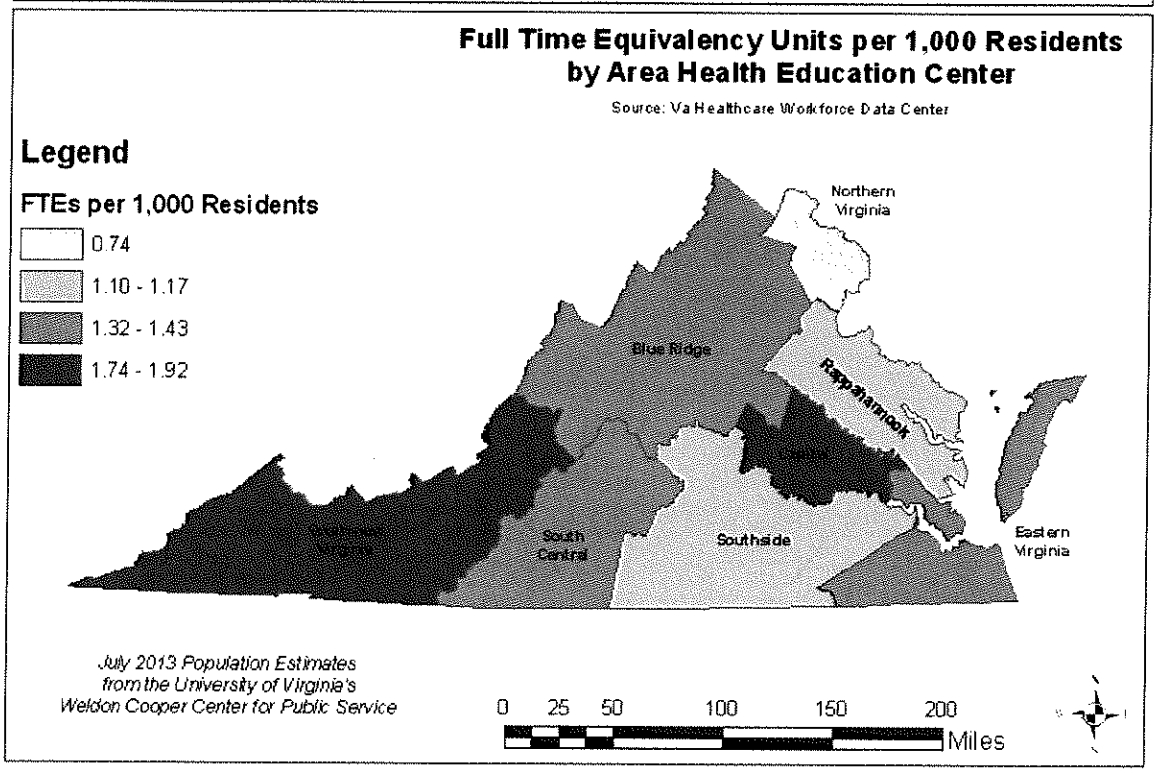
Council on Virginia's Future Regions

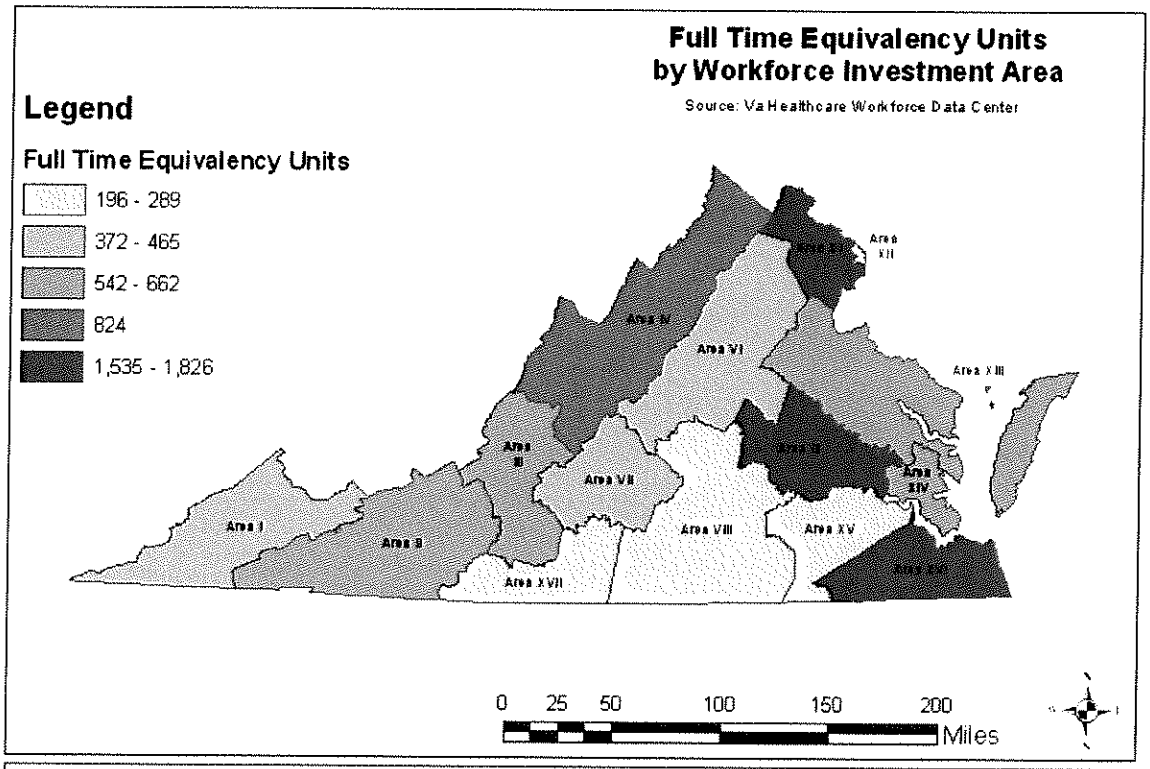


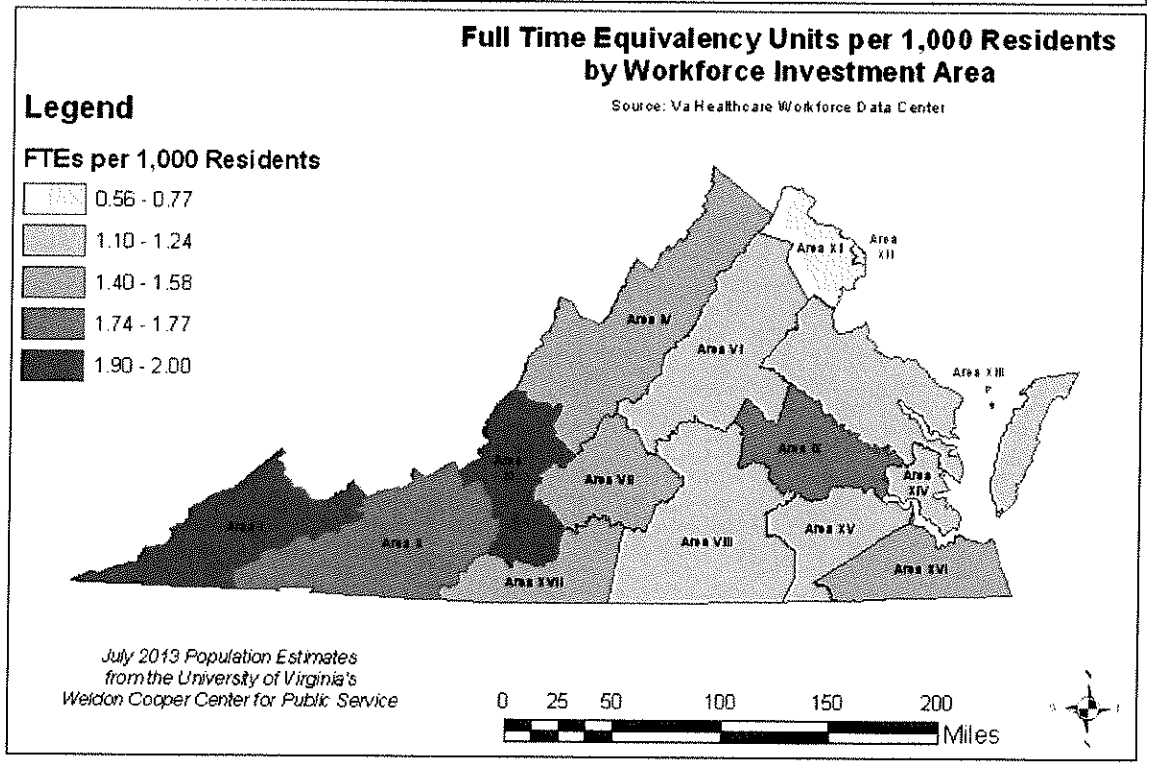


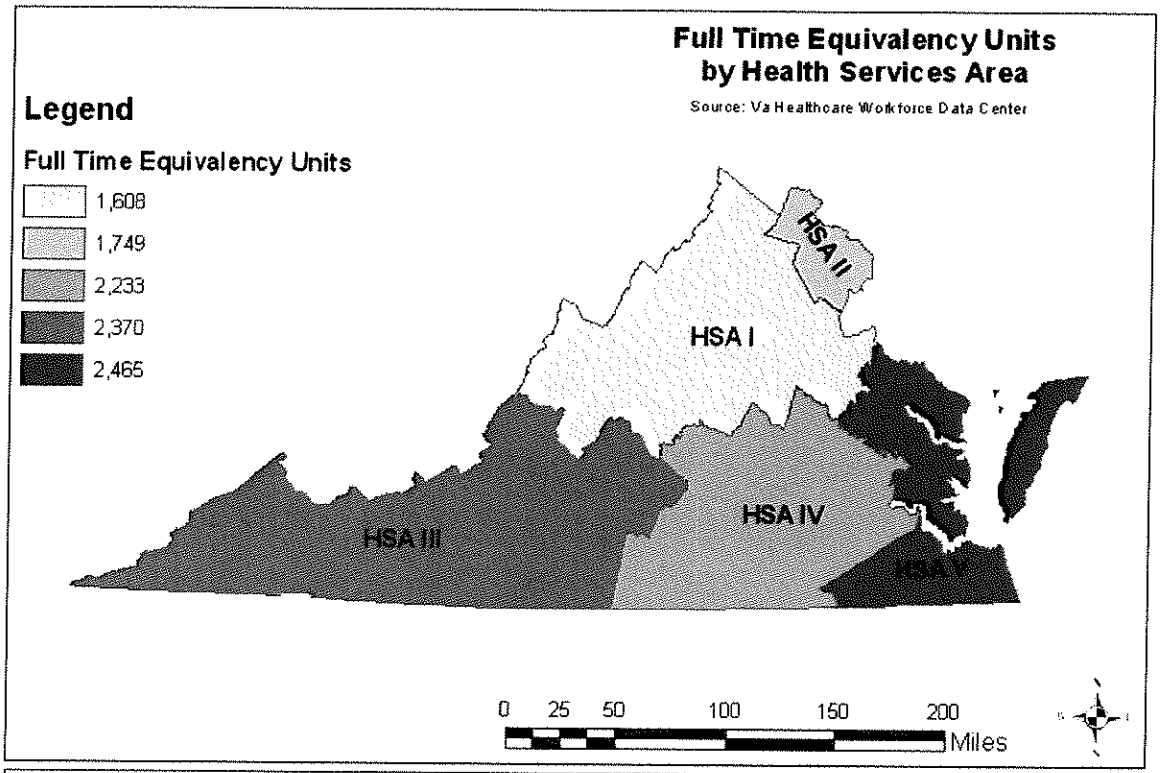
146

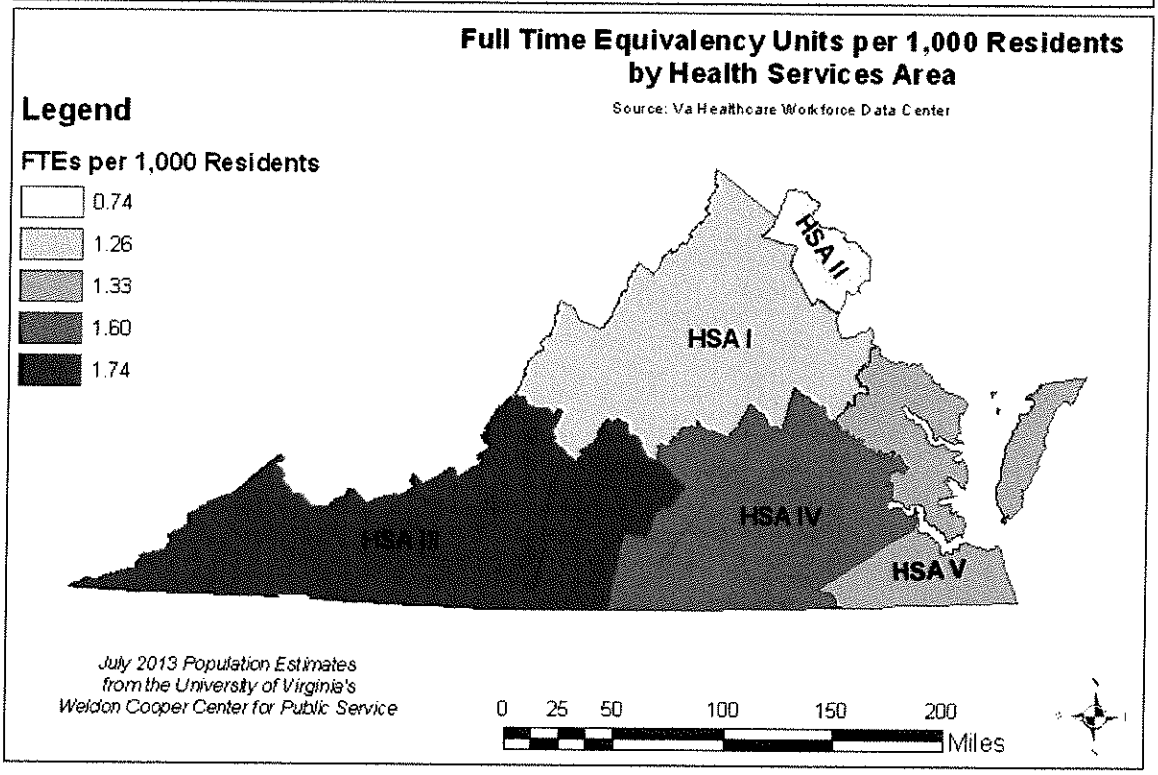

Full Time Equivalency Units
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
407 - 724
1,289
1,645 - 1,826
2,251
Northern Virginia
Blue Ridge
Rappahannock
Capital
Southwest Virginia
South Central
Southside
Eastern Virginia
0 25 50 100 150 200
Miles

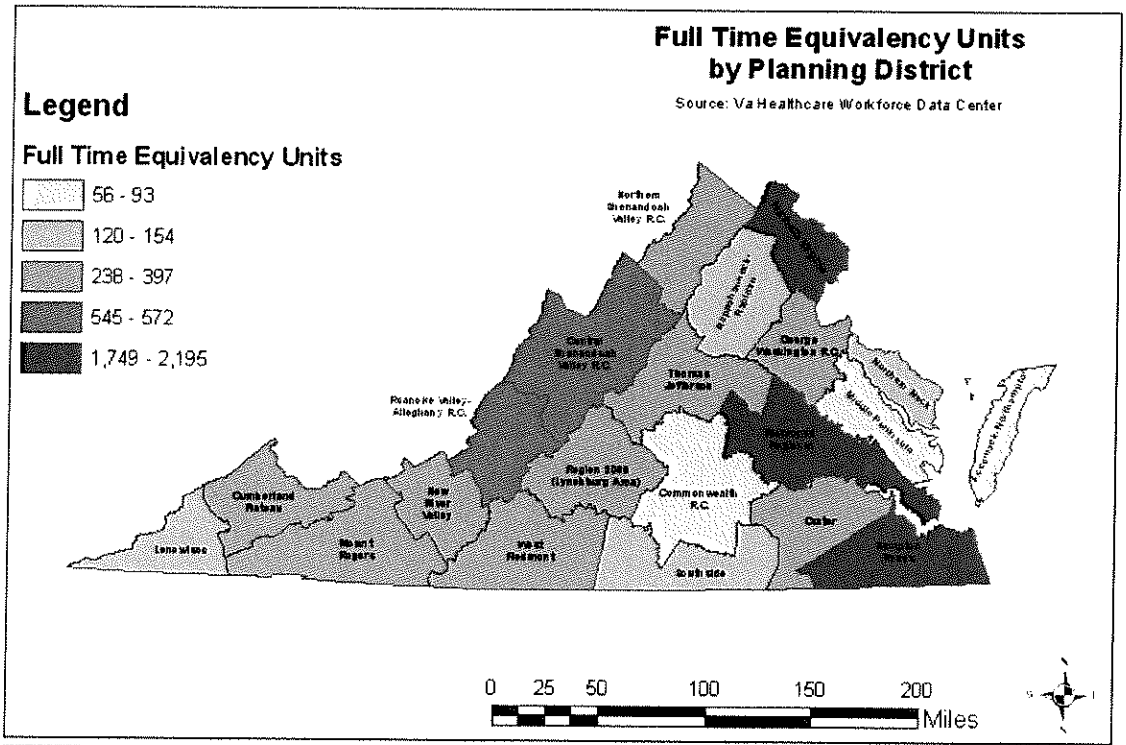

Full Time Equivalency Units per 1,000 Residents
by Area Health Education Center
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.74
1.10 - 1.17
1.32 - 1.43
1.74 - 1.92
Northern Virginia
Blue Ridge
Rappahannock
Southwest Virginia
South Central
Southside
Eastern Virginia
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles

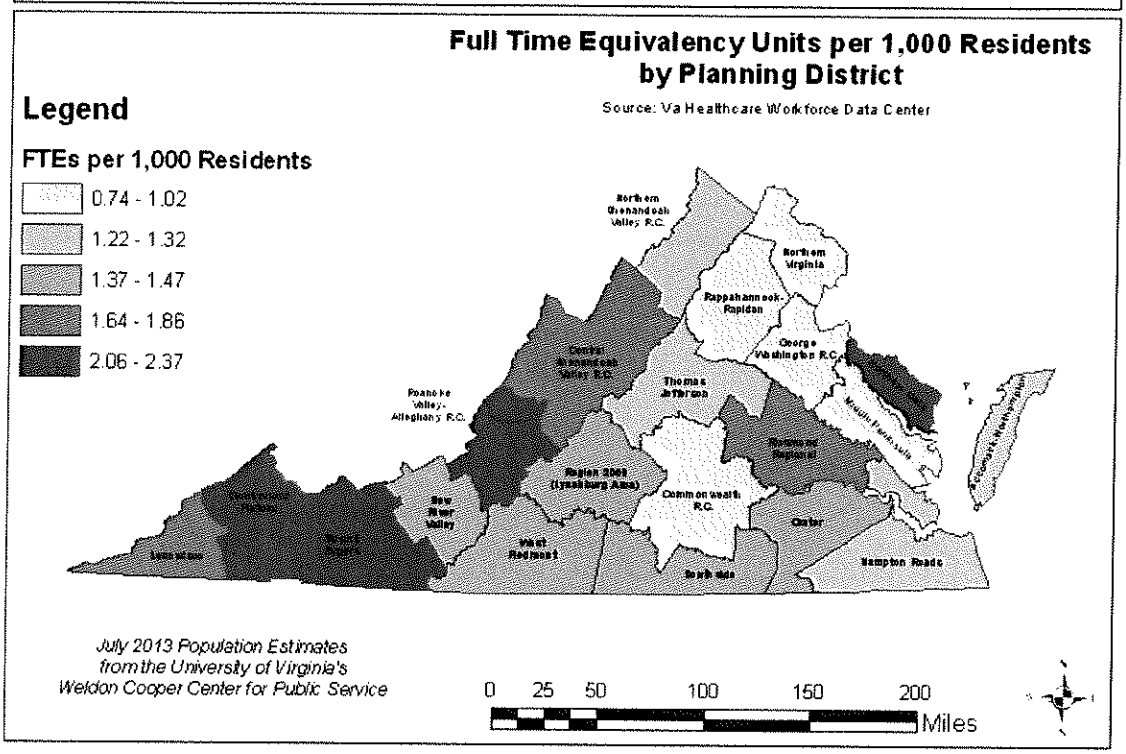

Full Time Equivalency Units
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
196 - 289
372 - 465
542 - 662
824
1,535 - 1,826
Area I
Area II
Area III
Area IV
Area V
Area VI
Area VII
Area VIII
Area IX
Area X
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Workforce Investment Area
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.56 - 0.77
1.10 - 1.24
1.40 - 1.58
1.74 - 1.77
1.90 - 2.00
Area I
Area II
Area III
Area IV
Area V
Area VI
Area VII
Area VIII
Area IX
Area X
Area XI
Area XII
Area XIII
Area XIV
Area XV
Area XVI
Area XVII
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles


Full Time Equivalency Units
by Health Services Area
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
1,608
1,749
2,233
2,370
2,465
HSA II
HSA I
HSA III
HSA IV
HSA V
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Health Services Area
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.74
1.26
1.33
1.60
1.74
HSA II
HSA I
HSA III
HSA IV
HSA V
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles


Full Time Equivalency Units
by Planning District
Source: Va Healthcare Workforce Data Center
Legend
Full Time Equivalency Units
56 - 93
120 - 154
238 - 397
545 - 572
1,749 - 2,195
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Thomas Jefferson
Roanoke Valley-Alleghany R.C.
New River Valley
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Hampton Roads
Cumberland Plateau
Mount Rogers
West Piedmont
Southside
Lenowisco
0 25 50 100 150 200
Miles


Full Time Equivalency Units per 1,000 Residents
by Planning District
Source: Va Healthcare Workforce Data Center
Legend
FTEs per 1,000 Residents
0.74 - 1.02
1.22 - 1.32
1.37 - 1.47
1.64 - 1.86
2.06 - 2.37
Northern Shenandoah Valley R.C.
Northern Virginia
Rappahannock-Rapidan
George Washington R.C.
Thomas Jefferson
Roanoke Valley-Alleghany R.C.
New River Valley
Region 2000 (Lynchburg Area)
Commonwealth R.C.
Crater
Hampton Roads
Cumberland Plateau
Mount Rogers
West Piedmont
Southside
Lenowisco
July 2013 Population Estimates
from the University of Virginia's
Weldon Cooper Center for Public Service
0 25 50 100 150 200
Miles

150

Weights

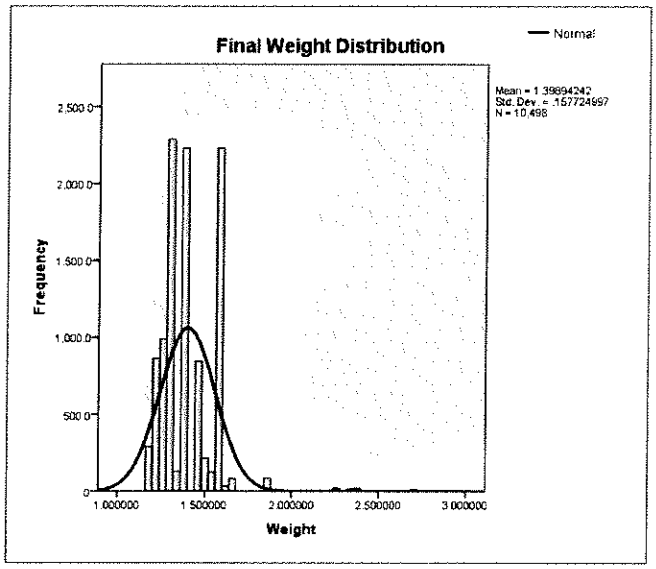
Rural Status	Location Weight			Total Weight	
	#	Rate	Weight	Min	Max
Metro, 1 million+	9,021	70.62%	1.415947	1.268327	1.569373
Metro, 250,000 to 1 million	1,397	76.45%	1.308052	1.171681	1.449787
Metro, 250,000 or less	1,400	75.93%	1.317027	1.17972	1.459735
Urban pop 20,000+, Metro adj	345	76.81%	1.301887	1.166158	1.442954
Urban pop 20,000+, nonadj	0	NA	NA	NA	NA
Urban pop, 2,500-19,999, Metro adj	687	75.55%	1.323699	1.185696	1.46713
Urban pop, 2,500-19,999, nonadj	544	73.90%	1.353234	1.212152	1.499864
Rural, Metro adj	294	74.83%	1.336364	1.19704	1.481166
Rural, nonadj	244	72.54%	1.378531	1.234811	1.527903
Virginia border state/DC	546	59.34%	1.685185	1.509495	1.867785
Other US State	199	41.21%	2.426829	2.173819	2.68979

Age	Age Weight			Total Weight	
	#	Rate	Weight	Min	Max
Under 30	5,264	64.49%	1.550515	1.442954	2.68979
30 to 34	2,334	72.41%	1.381065	1.285258	2.395832
35 to 39	1,637	74.34%	1.345111	1.251798	2.33346
40 to 44	1,260	77.22%	1.294964	1.20513	2.246467
45 to 49	1,204	77.91%	1.283582	1.194538	2.226722
50 to 54	1,015	79.80%	1.253086	1.166158	2.173819
55 to 59	945	76.72%	1.303448	1.213026	2.261185
60 and Over	1,027	73.03%	1.369333	1.27434	2.37548

See the Methods section on the HWDC website for details on HWDC Methods:
www.dhp.virginia.gov/hwdc/

Final weights are calculated by multiplying the two weights and the overall response rate:

Age Weight x Rural Weight x Response Rate = Final Weight.



Overall Response Rate: 0.714830