COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

(804) 367-4456 (Tel)
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Tentative Agenda of Public Hearing and Full Board Meeting

December 1, 2015

9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Addressing Hours of Continuous Work by Pharmacists: Cynthia Warriner, Chairman • Welcome & Introductions • Reading of Emergency Evacuation Script	
Call for Public Comment: • Proposed amendments to Regulation 18VAC110-20-110	1-2
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Cynthia Warriner, Chairman • Approval of Agenda • Approval of Previous Board Meeting Minutes:	
o September 29, 2015, Public Hearing for Scheduling Certain Chemicals	3-4
o September 29, 2015, Full Board Meeting	5-12
o September 29, 2015, Panel Formal Hearings	13-14
o September 30, 2015, Inspection Special Conference Committee	15-21
o November 3, 2015, Regulation Committee	22-27
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: David Brown, DC	
Report on Appalachian College of Pharmacy: Dean Susan Mayhew	
Report on Howard University College of Pharmacy: Dean Wayne Harris	
Regulatory Actions: • Regulatory Update - Elaine Yeatts	Handout
• Regulation Committee Report regarding Guidance for Issuance of Controlled Substances Registrations to Medical Office Buildings – Ellen Shinaberry	
• Request for Rulemaking to Allow "Back-up" Pharmacy to Dispense First Fill of Prescription without Necessitating Transfer of Prescription –Yeatts/Juran	28-29

New Business: Caroline D. Juran/Elaine Yeatts

- Need Guidance for Nurses Pumping Methadone Take Home Bottles 30-36
- Amend Guidance Document 110-8, Prescriptive Authority in Virginia 37-40
- Amend Guidance Document 110-4, Continuing Pharmacy Education Guide Handout
- Amend Guidance Document 110-27, Pharmacist-in-Charge Responsibilities 41-45
- Presentation on the Health Practitioners' Monitoring Program (HPMP) – Janet Knisely, Ph.D. and Sherman Master, M.D.
- Reconsider Date for March 2016 Full Board Meeting
- Set Dates for January and March Regulation Committee Meetings

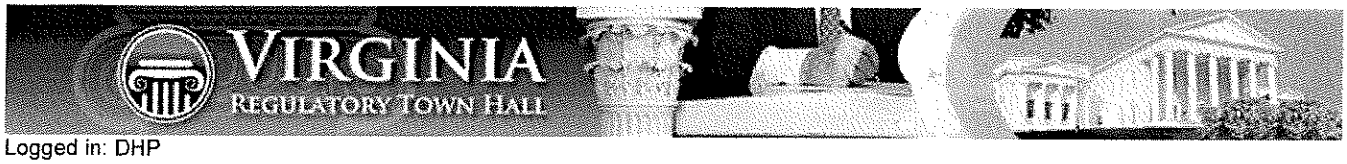
Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on ACPE Visit to Appalachian College of Pharmacy – Rebecca Thornbury
- Report on Licensure Program – J. Samuel Johnson, Jr. Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report –Caroline D. Juran
  - 2015 BOP Report, Possession and Administration of Controlled Substances by Wildlife Rehabilitators Handout 46-52
  - 2015 VDH/DHP Study of the Expansion of Access to Epinephrine Auto-Injectors in the Commonwealth of Virginia 53-74

Consideration of consent orders and possible summary restrictions/suspensions, if any

Adjourn

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



Proposed Text

Action: Addressing hours of continuous work by pharmacists

Stage: Proposed 3/4/13 3:08 PM

Part IV
Pharmacies

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

~~B.~~ C. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

~~C.~~ D. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

~~D.~~ E. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

~~E.~~ F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

~~F.~~ G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

~~G.~~ H. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

~~H.~~ I. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be

issued to any person to operate from a private dwelling or residence after September 2, 2009.

(Draft)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

September 29, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:05 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael Elliott
Sheila Elliott
Ryan K. Logan
Rafael Saenz
Ellen B. Shinaberry
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

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

CALL FOR COMMENT: Ms. Warriner called for comment to consider placement of the following chemical substances, identified by the Department of Forensic Science, into Schedule I:

- acetyl fentanyl (other name: desmethylfentanyl);
- Etizolam;
- 4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 251-NBOH);
- alpha-Pyrrolidinohexiophenone (other name: alpha-PHP), a substituted cathinone;
- alpha-Pyrrolidinoheptiophenone (other name: PV8), a substituted cathinone; and,
- 1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201), a cannabimimetic agent.

Mr. John Prysbylski with the Department of Forensic Science stated that these six chemicals have been identified in forensic labs within Virginia and nationally. No additional public comment was provided.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

ADJOURN: The public hearing adjourned at 9:15 a.m.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 29, 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 9:15 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Michael Elliott
Freeda Cathcart
Ryan Logan
Rafael Saenz
Rebecca Thornbury
Ellen Shinaberry
Jody Allen
Sheila Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David Brown, Director, Department of Health Professionals
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Beth O'Halloran, Individual Licensing Manager
Sharon Davenport, Administrative Assistant

QUORUM: With ten board members present, a quorum was established.

APPROVAL OF AGENDA: The agenda was approved as presented.

APPROVAL OF MINUTES: Staff provided as a handout an amended version of the draft minutes for the June 16, 2015 Special Conference Committee which replaced the version in the agenda packet. The board reviewed draft minutes in the agenda packet for June 15, 2015 (Public Hearing for Scheduling Certain Chemicals); June 15, 2015 (Full Board Meeting); July 9, 2015 (Telephone Conference Call); July 23, 2015 (Special Conference Committee); August 4, 2015 (Panel Formal Hearings); August 11, 2015 (Special Conference Committee); and the handout for the June 16, 2015 (Special Conference Committee).

MOTION: **The Board voted unanimously to approve the minutes as presented for the meetings held between June 15, 2015 and August 11, 2015. (motion by Ryan, second by Boone)**

PUBLIC COMMENTS:

The following individuals addressed the Board during public comment:

Cynthia Williams from Riverside PACE provided comment in support of HB1733 and the emergency regulations that provide PACE facilities with similar allowances as CSB and BHA for repackaging dispensed prescriptions for their clients. She requested the board allow a reasonable amount of time for the PACE facilities to meet requirements for obtaining the associated controlled substances registrations.

Gill Abernathy, pharmacist with INOVA Fairfax Hospital, provided comment in support of the board's consideration of issuing a single controlled substance registration to a sole ownership of a building with multiple practices within as may be allowed by the DEA.

Matthew Jenkins, pharmacist with University of Virginia Health System, provided comment also in support of the board's consideration for issuing a single controlled substance registration to a building with multiple outpatient clinics located within the building.

DHP DIRECTOR'S REPORT:

Dr. Brown welcomed the two new board members, Freeda Cathcart and Rafael Saenz to the Board of Pharmacy. Dr. Brown provided comment that the board member development day went very well. Dr. Brown provided an update on the pharmacy benefit manager workgroup (PBM) that DHP will host. Invitations to 18 stakeholders have been sent. The workgroup will tentatively discuss the role of a PBM, how PBMs work with insurance companies, the credentialing process, drug coverage, and if additional oversight of PBMs is warranted. Cynthia Warriner and Jody Allen both thanked Dr. Brown for the board member development session.

REPORT ON SHENANDOAH UNIVERSITY, BERNARD J. DUNN SCHOOL OF PHARMACY

Dr. Penny S. Shelton, Associate Dean for Academic Affairs from Shenandoah University School of Pharmacy, provided a report to the board. Dean McKay is presently on sabbatical and will retire at the end of the academic year; there is an active search for a new dean. Due to changes in the ACPE standards for 2016, the university has made some changes to the pharmacy program. Some of these changes include adding labs in physical assessment so that the students may better understand the importance of direct patient care, moving basic science to a prerequisite for entry into the program, changes to the health information technology, an additional APPE in May 2017, a focus on problem solving, a three component capstone including outcomes assessment, top 200 exam and multi-station clinical exam, and additional training for preceptors. Dr. Shelton also commented that Shenandoah was awarded a SAMHSA grant to address interprofessional development and the provision of training for screening for substance abuse.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the chart of regulatory actions in the agenda packet as of September 11, 2015. Ms. Yeatts stated the NOIRAs for prohibition against incentives to transfer prescriptions and continuous hours worked by pharmacists have been moved to the Governor's office.

- CONSIDERATION OF ANY SCHEDULING FROM PUBLIC HEARING:

Ms. Yeatts requested that the Board consider whether the chemicals discussed during the public hearing should be placed into Schedule I.

MOTION:

Pursuant to subsection D of 54.1-3443, the Board voted unanimously to adopt amendments to 18VAC110-20-322 to place the following six chemicals identified by the Department of Forensic Science into Schedule I:

- **Acetyl fentanyl (other name: desmethylfentanyl);**
- **Etizolam;**
- **4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 251-NBOH);**
- **Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP), a substituted cathinone;**
- **Alpha-Pyrrolidinoheptiophenone (other name: PV8), a substituted cathinone; and,**
- **1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201), a cannabimimetic agent. (motion by Allen, second by Saenz)**

- ADOPTION OF PROPOSED REGULATIONS FOR AUTHORIZED COLLECTORS OF DRUGS

Ms.Yeatts reviewed the NOIRA for collection sites for disposal of unused drugs, a fact sheet from Drug Enforcement Administration on the Secure and Responsible Drug Disposal Act of 2010 that allows ultimate users to deliver unused controlled substances to authorized entities for disposal, and draft proposed regulations to be considered by the Board. A definition for "collector" will be added to Chapter 50 as requested. Ms. Warriner suggested a guidance document be created to provide information to a licensee who wishes to become a collector. Ms. Thornberry suggested adding a definition of "ultimate user" to both regulations, Chapter 20 and Chapter 50.

MOTION:

The Board voted unanimously to amend the proposed regulations authorizing the collection of drugs as permitted in the Secure and Responsible Drug Disposal Act of 2010 by adding the definition for "collector" in Chapter 50 and adding the definition of "ultimate user" as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household" to Chapters 20 and 50, and adopt the proposed regulations as amended. (motion by Thornberry, second by Allen).

REPORT FROM THE REGULATION COMMITTEE

- Adoption of Emergency Regulations for Outsourcing Facilities and Compounding

Ms. Yeatts reviewed the 2015 legislation mandating issuance of permits to resident and non-resident outsourcing facilities and the emergency regulations as recommended by the regulation committee. It was recognized that no mention of expiration date was included in the records for compounding and therefore verbiage was added to that effect.

MOTION:

The board voted unanimously to amend proposed subsection C, 2, b of Regulation 18VAC110-20-215 as recommended by the Regulation Committee to read, "Compounding records shall include identification and strength of the drugs and shall provide the ingredient with expiration dates; and the source of such ingredients, including the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individual units produced; the national drug code number of the final product, if assigned, or lot number and appropriately assigned expiration date or beyond use date." (motion by S. Elliott, second by Boone)

MOTION:

The board voted unanimously to adopt the proposed emergency regulations for outsourcing facilities as previously amended. (motion by S. Elliott, second by M. Elliott)

- Adoption of Emergency Regulations for Permitting Facilities in which Practitioners of the Healing Arts Sell Controlled Substances

Ms. Yeatts reviewed the 2015 legislation mandating the issuance of permits to facilities in which practitioners of the healing arts dispense drugs. She also reviewed the emergency regulations as recommended by the Regulation Committee.

MOTION:

The board voted unanimously to adopt the proposed emergency regulations for permitting facilities in which practitioners of the healing arts sell controlled substances as recommended by the Regulation Committee.

- Adoption of Fast-Track Regulations for Repackaging Drugs at PACE Facilities

Ms. Yeatts reviewed 2015 legislation mandating promulgation of regulations relating to training, packaging, labeling, and recordkeeping for drug repackaging for individual patients receiving services at programs for all-inclusive care for the elderly (PACE). Ms. Yeatts also reviewed proposed regulations as recommended by the Regulation Committee.

MOTION:

The board voted unanimously to adopt the proposed fast-track regulations for repackaging drugs at PACE programs as recommended by the Regulation Committee.

OLD BUSINESS:

- Request to Amend Guidance Document 110-36

Ms. Juran reviewed with the board a letter from VPhA requesting an amendment to Guidance Document 110-36 to allow for alternative sterility testing methods. Mr. Logan requested staff to research if other states allow for alternative methods of testing. There was discussion of whether USP allows for alternative testing under USP Chapter <71>. There was also discussion of how the inspector would determine its validity. Several members of the board stated more information is needed

before amending the guidance document albeit they were supportive of utilizing new technology.

ACTION ITEM:

The board requested that staff survey other states to determine if they are allowing alternative methods of sterility testing, contact USP experts for their opinions on the subject, and consult with board counsel to determine if USP chapters <71> and <797> presently allow alternative methods of sterility testing. The matter will be discussed further at the December full board meeting.

NEW BUSINESS:

- Request to Amend Guidance Document 110-18

Ms. Juran reviewed a request by the Department of Education (DOE) to re-insert into Guidance Document 110-18 a paragraph relating to advance preparation of drugs for school field trips. The paragraph had been removed in 2013 when the board believed guidance was no longer needed based on changes in law. The DOE recently indicated to board staff that continued guidance on the subject would benefit schools.

MOTION:

The Board voted unanimously to amend Guidance Document 110-18 as presented by adding guidance related to the advance preparation of drugs for school field trips. (motion by M. Elliott, second by Allen)

- Consider Amending Guidance Document 110-34

Ms. Juran explained that Title II of the Drug Quality and Security Act prohibits boards from licensing manufacturers as wholesale distributors. Therefore reference in Guidance Document 110-34, *Wholesale Distributor Licensure Guidance*, advising certain manufacturers to obtain licensure as a wholesale distributor should be amended to conform with federal law.

MOTION

The Board voted unanimously to amend Guidance Document 110-34 as presented (motion by S. Allen, second by Boone)

- Consider Adopting Guidance for Re-dispensing Drugs Previously Dispensed in Compliance Packaging

Ms. Juran reviewed the allowance in subsection A (2) of 54.1-3411.1 for certain drugs to be accepted for return for the purpose of re-dispensing by the pharmacist. She stated that after speaking with the FDA it appears that "sealed individual dose" as used in the statute could be interpreted to mean compliance packaging, e.g., bingo cards, and that drugs in these compliance packages that "meet official compendium class A or B container requirements, or better" could potentially be accepted and re-dispensed under specific conditions. She then reviewed with the board the draft guidance document prepared by staff to address the re-dispensing of drugs previously dispensed in compliance packaging. Mr. Logan questioned who would be liable if patient harm were to occur from re-dispensing drug from this type of returned product. Mr. Rutkowski mentioned there is an exemption in law to release the manufacturer from this liability. The board discussed different types of compliance packaging and concerns over possible adulteration. It was stated that the pharmacist must exercise professional judgement to determine if official compendium storage requirements are assured prior to re-dispensing any qualifying drug. Ms. Juran noted that there should be verbiage added

with respect to recalled product.

MOTION:

The board voted unanimously to amend the draft guidance document by adding at the end "If the lot number for the drugs removed from the sealed individual doses is not known, then the drug shall be removed from stock upon any recall of that drug product and returned to the manufacturer or otherwise disposed of in accordance with Regulation 18VAC110-20-210." and adopt the guidance document as amended. (motion by S. Elliott, second by M. Elliott).

- Request for Guidance on Issuance of Controlled Substance Registrations to Multiple Medical Clinics Located within a Medical Office Building with Same Ownership

Mr. Saenz recused himself from the discussion on this subject as the issue directly relates to his employer.

Ms. Juran explained that historically the board has issued a controlled substances registration (CSR) to each office practice or department since the drugs stored within that practice or department are typically used exclusively by that office or department. Additionally, while not directly prohibited in law or regulation, the board has informally advised against a supervising practitioner and responsible party serving on multiple CSRs or providing oversight for a stock of drugs that they are not directly accessing or overseeing.

DEA recently indicated it will consider issuing a single DEA registration to a medical office building when the medical practices have the same owner. Therefore, staff requested guidance for how CSRs should be issued.

ACTION ITEM:

The board requested that staff survey other states to determine if they are issuing a single controlled substances registration to a medical office building with multiple practices located within the building operating under the same ownership and referred the issue to the Regulation Committee for further consideration. (motion by Shinaberry, second by Allen)

ELECTION OF VICE-CHAIRMAN:

Because Ms. Munden was not reappointed for a second term to the board, Ms. Warriner, who was elected vice-chairman at the June full board meeting, recently assumed the role as chairman and therefore, the board was required to elect a new vice-chairman.

MOTION:

The board voted unanimously to elect Ms. Thornberry as vice-chairman for the term of September 29, 2015 through June 30, 2016. (motion by Shinaberry, second by Logan)

- Dates for 2016 Full Board Meetings and Tentative Regulation Committee Meetings

The following dates were chosen for full board meetings in 2016: March 29, June 14, September 7, and December 12. The following dates were chosen for tentative Regulation Committee Meetings in 2016: May 26 and November 29.

REPORTS:

- Chairman's Report

Ms. Warriner announced her appointments to the standing committees on

the board. Ms. Warriner commended the new board member training held by DHP and provided an update from the NABP/AACP District 1 and 2 meeting recently held in New Hampshire. She, Mr. Boone, Ms. Juran and former board member, Leo Ross, attended the meeting. Ms. Warriner reported that Ms. Juran was elected the nominee for District 2 to serve on the NABP executive committee. She also reported on the resolutions passed at the meeting and encouraged all to consider attending the NABP 112th Annual Meeting in San Diego, California, May 14-17, 2016.

- Report on Board of Health Professions

Ms. Shinaberry provided an update on the Board of Health Professions recent discussion for the need of a multi-level funeral director license. Ms. Shinaberry also stated that they are planning a spring retreat.

- Report on Wildlife Rehabilitator Workgroup

Ms. Shinaberry provided the board with an overview of the two-meeting wildlife rehabilitator workgroup and the information in the report to be sent to the Senate Committee on Education and Health and the Senate Committee on Agriculture, Conservation and Natural Resources as requested.

- Report on PMP

Ralph Orr, Director, Prescription Monitoring Program, provided an update on statistics regarding number of records maintained in the database, number of requests processed annually, and the impact of interoperability with other states and pilots involving the integration of PMP data into prescriber/pharmacist workflow. He also stated pharmacists who have provided the board with a current email address will receive an email on October 5th regarding automatic registration as a user of the PMP.

- Report on Licensure Program

Mr. Johnson reported the Board currently licenses 35,106 individuals and facilities. The Board issued 1,338 licenses and registrations for the period of June 1, 2015 through August 31, 2015. Inspectors conducted 437 facility inspections including 171 routine inspections of pharmacies: 45 (26%) resulted in no deficiency, 63 (37%) with deficiencies and 63 (37%) 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.

- Report on Disciplinary Program

Ms. Reiniers-Day was pleased to introduce Loni Dickerson to the Board. Ms. Dickerson has been with the Board since August 25, 2015, and is employed as the Disciplinary Program Specialist.

Ms. Reiniers-Day then provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of December 8, 2014; March 24, 2015; June 12, 2015; and September 28, 2015. For the final date, the number of open cases were none at the entry stage; 62 at the investigation stage; 182 at the probable cause stage; two at the administrative proceedings division stage; four at the informal stage; three at the

formal stage; and 108 at the pending closure stage.

- Executive Director's Report

Ms. Juran reported that two reports for legislative committees, as requested by the legislators, were about to be sent to the Secretary for his review – one involved consideration for expanded use of epinephrine and the other possession and administration of drugs by wildlife rehabilitators. Ms. Juran will provide a copy of the final reports to the board. She also provided an update on the Governor's Task Force on Heroin and Prescription Drug Abuse. Ms. Juran will provide a copy of the implementation plan when finalized. She indicated she served as a panelist at the Appalachian Opioid Summit recently held in Wise, VA. Ms. Juran acknowledged Ms. Warriner for her good work running the business sessions as district 2 chairman at the NABP District 2 meeting. She stated she will attend the upcoming Tri-Regulator meeting and ACPE Stakeholder Invitational Conference. Ms. Juran reported that Ms. Thornbury will represent the board during the ACPE accreditation meetings of Appalachian College of Pharmacy in mid-November. She indicated that she also recently participated in the cut score development process of the MPJE. Ms. Juran also indicated that USP has published a notice of intent to revise Chapter <797>. The comment period opens November 2, 2015 and closes January 31, 2016.

CONSIDERATION OF CONSENT ORDERS OR POSSIBLE SUMMARY SUSPENSIONS:

None were presented or considered.

ADJOURN:

With all business concluded, the meeting concluded at approximately 12:36 pm.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, September 29, 2015
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 3:20 p.m.
PRESIDING:	Cindy Warriner, Chair
MEMBERS PRESENT:	Melvin Boone Freeda Cathcart Michael Elliott Ryan Logan Rebecca Thornbury
STAFF PRESENT:	Caroline D. Juran, Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Sharon Davenport, Administrative Assistant Loni Dickerson, Disciplinary Program Specialist James Rutkowski, Assistant Attorney General Wayne Halbleib, Senior Assistant Attorney General Mykl D. Egan, DHP Adjudication Specialist
QUORUM:	With six (6) members of the Board present, a panel was established.
JACKIE MCCALL, JR. License No. 0202-212502	A formal hearing was held in the matter of Jackie McCall, Jr. to discuss the reinstatement of his license and allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia. Wayne Halbleib, Senior Assistant Attorney General, presented the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. McCall testified on his own behalf.
Closed Meeting:	Upon a motion by Ms. Thornbury, and duly seconded by Mr. Boone, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Jackie McCall, Jr.

Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Loni Dickerson, Sharon Davenport, and James Rutkowski attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Boone, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the Board, and read by Mr. Rutkowski.

Upon a motion by Mr. Elliott and duly seconded by Mr. Logan, the panel voted 5-1, with Mr. Logan voting nay, to grant the application of Jackie McCall, Jr., for the reinstatement of his pharmacist license and that his pharmacist license shall be placed on terms and conditions.

Adjourn:

With all business concluded, the meeting adjourned at 5:05 p.m.

Cindy Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, September 30, 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 9:11 a.m.
PRESIDING:	Rebecca Thornbury, Committee Chair
MEMBERS PRESENT:	Ryan K. Logan, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist Beth L. O'Halloran, Individual Licensing Manager
TEMARA TURNER Pharmacy Technician Registration #0230016468	Temara Turner, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 28, 2015 Notice.
Closed Meeting:	Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 Temara Turner. 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. Logan, and duly seconded by Ms. Thornbury, the Committee found no violation and unanimously voted to dismiss this matter.

STEPHANIE WILEY Pharmacy Technician Registration #0230016334	Stephanie Wiley, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 28, 2015 Notice, however, sent in documentation for review by the Committee. The Chair of the Committee chose to proceed with the informal conference.
Closed Meeting:	Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 Stephanie Wiley. 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. Logan, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Stephanie Wiley in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $50 monetary penalty. As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Stephanie Wiley, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Stephanie Wiley 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.

ALESIA WINES
Pharmacy Technician Registration
#0230004228

Alesia Wines, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 28, 2015 Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 Alesia Wines. 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. Logan, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Alesia Wines in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $100 monetary penalty and requires the submission of ten (10) hours of continuing education.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Alesia Wines, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Alesia Wines 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.

NAI SATURN EASTERN, LLC D/B/A SAFEWAY PHARMACY Permit Number 0201003806	J. Richard Lee, Pharmacist-In-Charge, did not appear to discuss allegations that NAI Saturn Eastern, LLC d/b/a Safeway Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 28, 2015 Notice.
Closed Meeting	Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 NAI Saturn Eastern, LLC d/b/a Safeway 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. Logan, and duly seconded by Ms. Thornbury, the Committee accepts allegation #2a, #2b and #2c as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $500 monetary penalty. Additional documentation of evidence of corrective action for all violations must be submitted to the Board. As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on NAI Saturn Eastern, LLC d/b/a Safeway Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from NAI Saturn Eastern, LLC d/b/a Safeway 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.

EXPRESS PHARMACY
Permit #0201004491

Joel Sarasah, Pharmacist-In-Charge and James Walker, attorney, appeared to discuss allegations that Express Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 28, 2015 Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 Express 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. Logan, and duly seconded by Ms. Thornbury, the Committee accepts allegation #2a through #2i as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $2000 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Express Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Express 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.

SOUTHERN VIRGINIA MEDICAL CENTER
Permit #0201000977

Keith Johnson, Pharmacist-In-Charge and Anita Ivey, Chief Quality Officer appeared to discuss allegations that Southern Virginia Medical Center may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 28, 2015 Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, 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 Southern Virginia 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. Logan, and duly seconded by Ms. Thornbury, the Committee accepts allegation #2a through #2d as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $5500 monetary penalty. Additionally documentation from the monitoring company that both the land line and cellular line are operation shall be provided to the Board within thirty (30) days.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Southern Virginia Medical Center, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Southern Virginia 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.

ADJOURN: With all business concluded, the meeting adjourned at 1:10pm

Rebecca Thornbury, Chair

J. Samuel Johnson
Deputy Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

November 3, 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 1:09pm
PRESIDING:	Ellen B. Shinaberry, Chairman
MEMBERS PRESENT:	Ryan Logan Cynthia Warriner Melvin Boone
MEMBER ABSENT:	Rebecca Thornbury
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Deputy Executive Director Cathy M. Reiniers-Day, Deputy Executive Director Beth O'Halloran, Individual Licensing Manager Elaine J. Yeatts, Senior Policy Analyst
APPROVAL OF AGENDA:	The agenda was approved as presented.
PUBLIC COMMENT:	There was no public comment offered.
ISSUANCE OF CONTROLLED SUBSTANCES REGISTRATIONS TO MULTIPLE MEDICAL CLINICS LOCATED WITHIN A MEDICAL OFFICE BUILDING WITH SAME OWNERSHIP:	Ms. Juran provided background on previous discussion at the September 2015 full board meeting and the previous historical discussions surrounding the requests for the issuance of a single Controlled Substance Registration (CSR) to multiple clinics that are located within a medical office building with the same owner. She stated she surveyed several states and that most do not issue CSRs for the purpose of stocking drugs. They issue the CSRs for prescriber purposes. Delaware, however, issues CSRs in a manner similar to Virginia and it currently does not issue a single CSR to a building of multiple clinics. It issues CSRs to individual clinics within the building.
RECOMMENDATION:	**The Committee voted unanimously to recommend to the full board that it not issue a single controlled substances registration (CSR) to multiple medical clinics that are located within the same medical**

22

office building with shared ownership.

- Review of Parts I-IV and XIII-XVII of *Regulations Governing the Practice of Pharmacy, Chapter 20*

Ms. Yeatts reviewed the procedure with the Committee for the periodic regulatory review process. She stated a notice of periodic regulatory review has been posted on Town Hall and shared with the public participation guidelines list maintained by board staff. The public comment period is from November 30, 2015 until December 30, 2015. She indicated the Committee must first identify regulations that it will consider amending and that these regulations will be listed in the Notice of Intended Regulatory Action (NOIRA) once the board completes its review of the regulations in chapters 20 and 50. Because chapter 20 has become quite lengthy, she also recommended the board consider breaking chapter 20 into 3 separate chapters: one chapter for addressing individuals such as pharmacists, pharmacy technicians, and interns; one for addressing pharmacies; and one for addressing facilities other than pharmacies. The Committee then began identifying such regulations in chapter 20 (Attachment 1) and will continue this work at subsequent Regulatory Committee meetings until this first step is completed.

ADJOURN:

Next meeting will take place on January 6, 2016.

With all business concluded, the meeting concluded at approximately 5:00 pm.

_____ _____

Ellen B. Shinaberry, Chairman Caroline D. Juran, Executive Director

_____ _____

DATE: DATE:

Attachment 1

Below are regulations in Chapter 20, Parts I-IV and XIII-XVII identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

Part I. General Provisions

18VAC110-20-10 Definitions.

18VAC110-20-15 Criteria for delegation of informal fact-finding proceedings to an agency subordinate

- Should be moved to its own separate chapter

18VAC110-20-20 Fees

- Consider staggering renewals for pharmacist licenses and pharmacy technician registrations. Committee recommended no change to facility renewals. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-25 Unprofessional conduct

- Ms. Reiniers-Day to research other boards' language.

Part II. Licensure Requirements For Pharmacists

18VAC110-20-50 Curriculum and approved schools of pharmacy

- Consider striking subsection B to eliminate language for "first" professional degree. Staff to do further research on implications of this recommendation and will discuss at future meeting.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Discussed limiting validity of law exam score to 2 years, but recommended limiting to 3 years based on record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Recommended clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee as staff is currently requiring and not the current active renewal fee.
- Staff will review to ensure the terms "reactivate" and "reinstate" are being used correctly.

18VAC110-20-90 Requirements for continuing education

- Consider ability to accept inter-professional continuing education; staff to research how it is currently being awarded and by whom.
- Suggested wording in (B) (2) be changed from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of CE

Attachment 1

- Consider striking ability for board to approve and accept board-approved CE programs
- Committee discussed recommendations for requiring live CE and having ability to carry over hours into subsequent year, but concluded a statutory amendment would be necessary. Staff will research what other state boards of pharmacy may require live CE.
- Committee discussed recommendation for requiring CE annually in the subject of opioids. Statutory ability to specify topic for CE annually also discussed. No final recommendation was made.

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove ability for board to approve CE programs.

PART III Requirements For Pharmacy Technician Registration

18VAC110-20-102 Criteria for approval of training programs

- Consider including training program approval number to be printed on certificate awarded by training program.
- Consider requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Consider changing "certificates" to "documentation" in both sentences of subsection D.

PART IV Pharmacies

18VAC110-20-110 Pharmacy permits generally

- Consider specifying minimum number of hours PIC must practice at the location listed on the pharmacy permit application
- Consider requiring minimum number of years of experience for PIC eligibility. There was discussion for a possible ability for exceptions, but no final recommendation made.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider requirement for inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider amending to allow Board to rescind pharmacy permit if not opened within 60 days of issuing permit. Concern raised that board counsel may recommend criteria if the term "may" is used as proposed in the agenda packet.

18VAC110-20-150 Physical standards for all pharmacies

- Consider specifying acceptable refrigeration facilities based on CDC guidance for vaccine storage, require calibrated thermometer, weekly temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Consider requiring security system to have at least one hard wired communication method for transmitting breach as is required for wholesale distributors.
- Consider clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient. Committee discussed whether pharmacist must practice at the pharmacy or if acceptable to notify district supervisor pharmacist who does not necessarily practice at location. No final recommendation made.
- Discussed whether regulation should clarify how long security system auxiliary source of power must last, but concluded that it may be problematic to address this issue.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Add language from Guidance Document 110-40 regarding dispersion of Schedule II drugs
- Discussed clarifying subsection D to include old chemicals used for compounding, but concluded that the board should consider adopting guidance indicating subsection D includes old chemicals and that it will be a violation of this regulation to use old chemicals that exceed the expiration date that is assigned based on USP standards.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amend regulation based on recent amendments to §54.1-3423 changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Add language to regulation that applications must include name of responsible party
- Requirement to notify the Board within 14 days of a change in the responsible party

18VAC110-20-680 Medical equipment suppliers

- Consider adding language from Guidance Document 110-19 for MES to transfer prescriptions based on amended handout.
- Consider adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

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

- Amend schedules to include Schedule I

Attachment 1

Additional subjects recommended for inclusion in board regulations:

18VAC110-20-22 (as proposed by staff in 11/3/15 agenda packet) – Submission of corrective action related to inspections

- Consider adding requirement in the General Provisions for PIC, responsible party, or owner to respond to inspection deficiencies within 14 days. This would be added to all relevant facility chapters.

18VAC110-20-10

- Review definition for "robotic pharmacy system"; appears to encompass more than traditional robot addressed in 18VAC110-20-425.

General ability for pharmacist to delegate to someone else to enter pharmacist's initials when required for recordkeeping purposes

Regulations discussed but <u>not</u> recommended for inclusion in the NOIRA:

18VAC110-20-40 Procedure for gaining practical experience

- Discussed adding requirement for licensees to submit certain documents when individual's name changes. However, decided not to require licensee change name in regulation, but to continue addressing in policy the documents needed to change a licensee's name.

Request for Rulemaking to Allow "Back-up" Pharmacy to Dispense First Fill of Prescription without Necessitating Transfer of Prescription

Background: CVS Health (Omnicare) has requested the board consider rulemaking to authorize a pharmacy providing services to a long term care facility to provide prescription information for Schedule VI drugs to a "back-up" pharmacy located near the facility enabling the "back-up" pharmacy to provide the first dispensing of the prescription without the act constituting a transfer of the prescription.

Possible Actions:

- Refer matter to Regulation Committee for further consideration or
- Adopt Notice of Intended Regulatory Action or
- Deny request

From: Irvin, William [mailto:William.Irvin@omnicare.com]
Sent: Wednesday, October 14, 2015 2:51 PM
To: Juran, Caroline (DHP)
Cc: mark.johnston@cvscaremark.com
Subject: Follow Up Omnicare Meeting - First Fill Discussion

Good Afternoon Caroline,

During our recent meeting, we discussed Omnicare's protocol for handling "first fill" doses for patients residing in long term care facilities. In consultation with Mark Johnston, we respectfully share the language used by the Idaho Board of Pharmacy that governs this issue. We believe it is most representative of Omnicare's current process as well as those conducted in other pharmacies engaged in providing long term care pharmacy services. The specific language is noted below along with a link to the full suite of Idaho Rules. Please let me know if I can provide any additional information that may further assist with the regulation review. Last, would it be possible to participate in the regulation review meeting as a key stakeholder?

Thank you gain for your time and consideration.

All the best,

Bill

http://adminrules.idaho.gov/rules/current/27/0101.pdf

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY. A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13) 01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13) 02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13) 03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13) 04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required.

Bill Irvin, R.Ph.
Director, Pharmacy Regulatory Affairs
13 Commerce Avenue
Londonderry, NH 03053
603-339-7846 Mobile
513-719-0433 E-fax
William.irvin@omnicare.com

CVSHealth

Need Guidance for Nurses Pumping Methadone Take Home Bottles

Background: Narcotic Treatment Programs have historically possessed few drugs, primarily limited to methadone for administration and dispensing of take-home doses. They do not typically employ a full-time pharmacist. Many years ago, they were issued a controlled substances registration, but the board concluded that a limited-use pharmacy permit may be more appropriate. The limited-use pharmacy permit allows nurses to access the pharmacy during the absence of a pharmacist for the sole purpose of retrieving methadone take-home doses that have been previously verified for accuracy by a pharmacist. The current request is for nurses to also have the ability to assist the pharmacist by preparing the methadone take-home doses in the presence of the pharmacist.

Associated regulations:

from **Regulations Governing the Practice of Pharmacy**

18VAC110-20-120. Special or limited-use pharmacy permits.

A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.

2. The PIC shall be notified prior to each entry and give permission for the designated, specific individuals to enter.

3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.

4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The PIC shall ensure that the alarm access code is changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for one year.

from **Regulations Governing the Practitioners of the Healing Arts to Sell Controlled Substances**

18VAC110-30-40. Acts to be performed by the licensee.

A. The selection of the controlled substance from the stock, any preparation or packaging of a controlled substance or the preparation of a label for a controlled substance to be transferred to a patient shall be the personal responsibility of the licensee.

1. Any compounding of a controlled substance shall be personally performed by the licensee or a registered pharmacy technician under the supervision of the licensee.

2. A licensee may supervise one person who may be present in the storage and selling area to assist in performance of pharmacy technician tasks, as set forth § 54.1-3321 of the Code of Virginia, provided such person is either:

a. A pharmacy technician registered with the board; or

b. A licensed nurse or physician assistant who has received training in technician tasks consistent with training required for pharmacy technicians.

3. Unless using one of the board-approved training courses for pharmacy technicians, a licensee who uses a nurse or physician assistant to perform pharmacy technician tasks shall develop and

maintain a training manual and shall document that such licensee has successfully completed general training in the following areas:

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

b. The preparation of prescription labels or patient information;

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

d. The counting or measuring of the drug to be dispensed to include pharmacy calculations;

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

f. The stocking or loading of automated dispensing devices or other devices used in the dispensing process, if applicable; and

g. Applicable laws and regulations related to dispensing.

4. A licensee who employs or uses pharmacy technicians, licensed nurses or physician assistants to assist in the storage and selling area shall develop and maintain a site-specific training program and manual for training to work in that practice. The program shall include training consistent with that specific practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used in the practice in performing technician duties, and pharmacy calculations consistent with the duties in that practice.

5. A licensee shall maintain documentation of successful completion of the site-specific training program for each pharmacy technician, nurse or physician assistant for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed persons shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

B. Prior to the dispensing, the licensee shall:

1. Conduct a prospective drug review and offer to counsel a patient in accordance with provisions of § 54.1-3319 of the Code of Virginia; and

2. Inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction.

C. If the record of sale is maintained in an automated data processing system as provided in 18VAC110-30-200, the licensee shall personally place his initials with each entry of a sale as a certification of the accuracy of, and the responsibility for, the entire transaction.

Possible Actions:

- Approve request and capture in a newly created guidance document or
- Deny request

Juran, Caroline (DHP)

From: Michael Whipple <michael.whipple@cmglp.com>
Sent: Friday, October 23, 2015 12:06 PM
To: Juran, Caroline (DHP); James Harrison; Jessica Matthews
Cc: Oehl, Diane (DBHDS); Virginia Maclelland; robin.sayles@hcahealthcare.com; Robin Sayles
Subject: Re: Pumping Methadone Take Home Bottles

Follow Up Flag: Follow up
Flag Status: Flagged

Certainly. Anything that would assist us in the preparation of take home medication would be helpful.

Michael Whipple, Program Director

On Fri, Oct 23, 2015 at 11:39 AM, Juran, Caroline (DHP) <Caroline.Juran@dhp.virginia.gov> wrote:

Mr. Whipple,

The Board could possibly consider allowing the nurse to assist the pharmacist with preparing the take-home doses, but each dose must still be verified by the pharmacist. Is that a model that you are interested in pursuing?

Caroline D. Juran, RPh

Executive Director, Virginia Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Ste 300

Henrico, VA 23233

O: (804) 367-4456 | F: (804) 527-4472

http://www.dhp.virginia.gov/pharmacy | caroline.juran@dhp.virginia.gov

From: Michael Whipple [mailto:michael.whipple@cmglp.com]
Sent: Thursday, August 27, 2015 8:56 AM
To: Juran, Caroline (DHP)
Cc: Oehl, Diane (DBHDS); Virginia Maclelland; robin.sayles@hcahealthcare.com; Robin Sayles
Subject: Pumping Methadone Take Home Bottles

34

Good morning,

After discussing this with Diane Oehl, SMA; it was suggested by her to seek definitive clarification with respect to Nurses pumping methadone for patient take home medication.

We recently converted to a pump system from unit dosing and were advised that our consulting Pharmacists were the only persons authorized to pump methadone for our patients receiving take home medication.

This process has not been the most efficient as our Pharmacists have had to come in on multiple days to pump take home medication. Our Nurses currently label the bottles only and the Pharmacist pumps.

Is there any means or conditions upon which the Nurses can pump take home bottles in the presence of our Pharmacist?

Thank you for your assistance relative to this matter and any feedback is appreciated.

Michael

--

Michael Whipple | Program Director

Richmond Treatment Center | 2217 E. Franklin St. - Richmond VA 23223

Bus: (804) 213-0249 | Fax: (804) 213-0589 | Email: michael.whipple@cmglp.com

CMG Colonial Management Group, LP

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Michael Whipple | Program Director
Richmond Treatment Center | 2217 E. Franklin St. - Richmond VA 23223
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CMG Colonial Management Group, LP

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Agenda Item: Adoption of Revised Guidance Document

Included in your agenda package are:

A Draft of Guidance Document 110-8, Prescriptive Authority in Virginia

Staff Note:

Modifications are made to conform to changes in law and regulation for physician assistants and optometrists. Code section 54.1-3303 was revised in accordance with amendments effective July 1, 2015.

Board action:

Adoption of Guidance Document 110-8 as presented in the agenda package.

Virginia Board of Pharmacy
Prescriptive Authority in Virginia

Reference: § 54.1-3400 *et seq.* of the Code of Virginia commonly known as the Drug Control Act and § 54.1-3303 of the Code of Virginia, and respective Board regulations.

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

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

Nurse practitioners who meet certain criteria may be issued a license to prescribe Schedule II-VI drugs by the Boards of Nursing and Medicine. Authorization to prescribe schedules or categories of drugs will be set out in a practice agreement with a collaborating physician. Nurse practitioners with prescriptive authority may dispense samples of those drugs they are authorized to prescribe and may also sign for the receipt of those samples.

Physician assistants (PA's) who meet criteria and have been approved by the Board of Medicine for prescriptive authority may prescribe Schedule II-VI drugs that have been approved by the supervising medical practitioner or podiatrist. A Schedule II through V prescription written by a physician assistant should include the name of the supervising physician. Physician assistants may dispense samples of those drugs they are authorized to prescribe and may sign for receipt of samples.

Nurse practitioners or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For nurse practitioners, there is a 10-digit license number beginning with 0017, which should be on the prescription and can be verified through the web site www.dhp.virginia.gov under "on-line license lookup" and checking the occupation "Authorization to Prescribe." For physician assistants, there is a 10-digit license number beginning with 011, which can be verified through the web site www.dhp.virginia.gov under "on-line license lookup" and checking the occupation "Physician Assistant."

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

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

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV and VI narcotic and non-narcotic agents.

2. Topically administered Schedule VI agents:
    a. Alpha-adrenergic blocking agents;
    b. Anesthetic (including esters and amides);
    c. Anti-allergy (including antihistamines and mast cell stabilizers);
    d. Anti-fungal;

e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
f. Anti-infective (including antibiotics and antivirals);
g. Anti-inflammatory;
h. Cycloplegics and mydriatics;
i. Decongestants; and
j. Immunosuppressive agents.

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

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

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

from the Code of Virginia:

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by 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. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship.

For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects.

For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices

appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.

Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.

B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.
No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability.

D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).

E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.

G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain, (ii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa, (iii) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act, and (iv) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.

H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.

Virginia Board of Pharmacy

PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be

issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

Upon taking over responsibility as PIC:

- ~~You are not a PIC until the Board approves your signed application~~. A pharmacy permit application must be submitted to the Board indicating the effective date you intend to assume the role as PIC. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. ~~Once you are approved as PIC, the~~ Assuming you are eligible to assume the role of PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on ~~4/30~~ April 30th annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of **all** Schedule II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, prior to opening for business on the date you first ~~engage in business as the~~ assume the role as PIC, i.e., the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business, ~~that day~~ if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy, calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification.

- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -4° and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Safeguards against Diversion of All Controlled Substances:

- The PIC "shall provide safeguards against diversion of all controlled substances". This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.

- It is the policy of the Board to include the name of the PIC (s) in the findings of fact in any disciplinary proceeding involving diversion of drugs.

- The PIC shall:

    - Ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;

- Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

- Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

- Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.

- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:

  - Perform state and federal criminal background checks on all personnel with access to controlled substances;

  - Require periodic urine drug screening of all personnel with access to controlled substances;

  - Prohibit personnel from bringing smocks or bags into the prescription department;

  - Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;

  - Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;

  - In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconcile all discrepancies;

  - Do not delegate the management of drug inventory to solely one individual;

  - Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;

- Install surveillance cameras to prevent and/or identify theft or loss of controlled substances; and

- Have full and timely access to all reports relating to inventories, invoices, and audits

- In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

Upon leaving as PIC:

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.

- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.

45

2015 Report of the Virginia Board of Pharmacy

Possession and Administration of Controlled Substances by Wildlife Rehabilitators

Preface

In a letter from the Senate Committee on Education and Health and the Senate Committee on Agriculture, Conservation and Natural Resources, the Board of Pharmacy was requested to convene a working group to review current laws and regulations related to the possession and use of certain Schedule VI controlled substances by individuals engaged in the practice of wildlife rehabilitation. The Board was asked to report to the committees on options and recommendations on the issue of whether wildlife rehabilitators should be allowed to possess and administer a stock of controlled substances to care for sick and injured wildlife.

As requested, membership on the workgroup included representatives from the Boards of Pharmacy and Veterinary Medicine, the Department of Game and Inland Fisheries (DGIF), the Virginia Veterinary Medical Association, the Virginia State Police, the Virginia Department of Health, and the Wildlife Center of Virginia.

Meetings of the Workgroup

At its first meeting, the Workgroup heard the following presentations:

- From Jim Husband with the Department of Game and Inland Fisheries, a review of the permitting and training of wildlife rehabilitators and the changes made to permit conditions in November 2014. To obtain a permit as a wildlife rehabilitator, a person must document an apprenticeship, have an initial inspection of his facility (typically a residence), and document six hours of continuing education. The permits are issued to both individuals and facilities. There is no requirement for training associated with administration of drugs because the assumption is that they are administered under the direction of veterinarian's valid order. There are 347 total wildlife rehabilitators.
  Category I (Apprentice, sponsored by a Category II or III) – 67
  Category IIA – Individuals (May care for all wildlife except threatened or endangered species; work in cooperation with a veterinarian) – 145
  Category IIB – Organizations (same as above) – 13
  Category III (Professionally operated facility with on-sight veterinary staff) – 26
  Category IV (Care provider to work with wildlife at facility of permittee) - 96

- From Caroline Juran with the Board of Pharmacy, an overview of the Drug Control Act statutes that relate to this topic and the Board's involvement in the issue. A brief review of the Guidance Document 110-30 that addresses the allowances to purchase, possess and administer drugs within a public or private animal shelter was also given.

- From Leslie Knachel with the Board of Veterinary Medicine, a brief review of Chapter 38 of Title 54.1 on the practice of veterinary medicine. In addition, the Board's Guidance Documents 150-22, titled *Veterinarians and Wildlife Rehabilitators and Prescription Drugs*, and Document 150-13, titled *Controlled Substances (Schedule II-VI) in Veterinary Practice*, were reviewed.

Current law does not authorize a person who holds a wildlife rehabilitator permit to possess a stock of drugs that have not been prescribed to an animal by a veterinarian. Advocates for a change in the law assert that wildlife rehabilitators need immediate access to certain Schedule VI medications to stabilize and provide emergency care for the animal. Drugs specifically mentioned are meloxicam, broad spectrum antibiotics, rehydration fluids, and antiparasitic drugs. It was suggested that the law could be amended to allow such drugs to be possessed as general stock by wildlife rehabilitators and administered to injured wildlife via a written protocol by the supervising veterinarian.

The Workgroup discussed wildlife rehabilitation in other states to determine if there were models for the availability of a stock of drugs. It does not appear that any state allows wildlife rehabilitators to have a general stock of drugs, but Wisconsin does allow a consulting veterinarian to have a protocol for the possession of certain drugs with a rehabilitator.

Concerns about a proposal to allow wildlife rehabilitators to possess a stock of drugs as expressed by members included the following:

- A decision about whether to administer a specific drug and the appropriate dose would appear to require a diagnosis of the animal by a wildlife rehabilitator, an act currently restricted to a licensed veterinarian. Currently, Category I and Category II permitted wildlife rehabilitators are authorized to only provide "basic care" and a decision on which drug and whether to administer a drug is a "prescribing" decision requiring a diagnosis of a disease or condition.

- There appears to be a wide variance in the level of education and training of wildlife rehabilitators. While the permit application requires six hours of continuing education, there is no verification of the hours, content or instruction listed. Indeed, it is possible for permits to be renewed annually without completing that portion of the application. Wildlife rehabilitators have no requirement for formal education and training, and there are no standards for the two years of apprenticeship in Category I. As stated by DGIF, there is no requirement for training associated with the administration of drugs because the assumption is that drugs are administered under the direction of a veterinarian's valid order.

- Some members of the workgroup expressed concern about the oversight of wildlife rehabilitators and their practice locations. All are required to have a working relationship with a veterinarian. Reportedly, some work closely with veterinarians and others are operating virtually independently with little or no oversight for their practice. While applicants have a site inspection performed by DGIF prior to issuance of a permit, DGIF

does not have the resources to routinely inspect the location of each permit holder. DGIF relies on permit fees, which are currently set in Code at $10, to fund activities associated with wildlife rehabilitators.

- In general, the Board of Pharmacy is authorized in the Drug Control Act to inspect facilities in which a stock of drugs is maintained. Private and public shelters may possess a stock of drugs by obtaining a controlled substance registration from the Board and receiving proper training from the State Veterinarian. Such a permit requires an initial and a regular inspection to ensure drugs are being stored and administered safely. If drugs are stocked in a private residence (the location for most wildlife rehabilitators), it would be problematic for the Department of Health Professions to inspect. If there is no license or permit with the Board of Pharmacy, it may be necessary to obtain a search warrant for an inspection of a private residence. First Sgt. John Welch of the Virginia State Police, while not providing binding legal comment, suggested that this was true.

- Finally, concern about the proliferation of antibiotics and increased risk of antibiotic resistance and creation of "superbugs" was expressed. While controlled substances such as oxygen, lidocaine, sterile saline, and epinephrine are allowed by the Drug Control Act to be in possession of certain persons who are not licensed prescribers outside of licensed or permitted facilities, the persons so named are either licensed health care professionals or have very specific training for administration of those drugs. None have been authorized to possess and administer antibiotics.

Options and Recommendations

Options discussed by the Workgroup but <u>not</u> recommended were:

- Amend § 54.1-3423 to authorize wildlife rehabilitators to obtain a controlled substance registration (CSR) from the Board of Pharmacy with provisions similar to subsection E for public and private animal shelters. For shelters, the Code provides: "*The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the shelter shall be determined by the supervising veterinarian of the shelter and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter.*" Shelters that apply for and maintain a CSR for possession and administration of drugs are inspected by the Board of Pharmacy. The primary issue relating to the option of allowing wildlife rehabilitators to obtain a CSR was to strengthen the authorization for the Board to inspect private residencies where most of the wildlife rehabilitators do their work. If the responsibility for inspection of drug stock was given to DGIF, it would not have the manpower or the expertise to conduct such an inspection.

- Amend the Drug Control Act and § 54.1-3303 to redefine the veterinarian-client-patient relationship to allow the veterinarian to prescribe to a group of animals similar to

allowances for prescribing to a herd. This option would allow a veterinarian to "prescribe" for a group of deer, rabbits, raccoons, etc. The Workgroup agreed that prescribing for a herd was not applicable to the work of wildlife rehabilitators in Virginia because prescriptions for a herd are given when all animals in the herd are being treated for the same problem at the same time with the same medication. Wildlife is treated on an individual or case by case basis.

Following extensive discussion of the options at a meeting of the Workgroup on August 27, 2015, **there is no consensus on a single recommendation**. However, the following options are presented:

Option 1: Make no changes to the Drug Control Act to authorize wildlife rehabilitators to possess a stock of drugs. The Drug Control Act allows a veterinarian to prescribe, label and dispense a drug to a wildlife rehabilitator for the treatment of a specific animal after establishing a bona fide practitioner-patent relationship.

Option 2: Amend the Drug Control Act to authorize wildlife rehabilitators to possess certain Schedule VI drugs, including anti-inflammatories to treat pain, sterile fluids for rehydration, and antiparasitics for deworming, *but excluding antibiotics*.
Such authorization would be:

- Pursuant to an oral or written order or standing protocol issued by a veterinarian for use in emergency cases for stabilization of the animal and safety of the humans coming in contact; and
- Granted to a wildlife rehabilitator who has obtained a special permit from DGIF for possession of drugs requiring specified education and training and oversight by the veterinarian writing the order.

Option 3: Amend the Drug Control Act to authorize wildlife rehabilitators to possess certain Schedule VI drugs, including anti-inflammatories to treat pain, sterile fluids for rehydration, and antiparasitics for deworming, but the order or standing protocol could be *inclusive of broad spectrum antibiotics*.

- Support for Option 3 largely came one member of the Workgroup who contended that antibiotics are necessary to treat specific conditions rehabilitators encounter and could be narrowly specified in the protocol.
- Objections to Option 3 included:
  1) Prescribing of antibiotics necessitates making a medical diagnosis for which rehabilitators are currently not authorized. Veterinarians agree that wildlife rehabilitators may need access to antibiotics and that veterinary care is available to treat and prescribe. However, it may be somewhat limited based on the availability of veterinarians to care for wildlife.
  2) As noted above, concern was expressed by some members about the proliferation of antibiotics and increased risk of antibiotic resistance and creation of "superbugs".
  3) The Drug Control Act does allow possession of controlled substances such as oxygen, lidocaine, sterile saline, and epinephrine by persons who are not licensed prescribers, but those persons so named are either licensed health care professionals or have very

specific training for administration of those drugs. Currently, no other non-health care practitioners have been authorized to possess and administer antibiotics.

Finally, the Workgroup was in agreement that adoption of Options 2 or 3 would require the following:

1) Specific education and training for wildlife rehabilitators on the proper storage and administration of drugs would have to be a prerequisite for authority to possess any scheduled drug.
2) Additional authority for possession and administration of drugs would necessitate a new permit category for wildlife rehabilitators issued by the Department of Game and Inland Fisheries.
3) A standing protocol or order for the supervising veterinarian to authorize possession and administration of controlled substances by wildlife rehabilitators would have to be developed in accordance with regulations promulgated by the Department of Game and Inland Fisheries in consultation with the Boards of Pharmacy and Veterinary Medicine.
4) The Department of Game and Inland Fisheries would need additional funding and resources to provide adequate training and oversight for wildlife rehabilitators that may be permitted to possess a stock of drugs.

Commonwealth of Virginia

GENERAL ASSEMBLY
RICHMOND

February 26, 2015

Ms. Caroline Juran, Executive Director
Virginia Board of Pharmacy
Department of Health Professions
Richmond, VA

Dear Ms. Juran,

On behalf of the Senate Committee on Education and Health which has jurisdiction over matters related to the Department of Health Professions, and the Senate Committee on Agriculture, Conservation and Natural Resources, which has jurisdiction over the Department of Game and Inland Fisheries, we would like to request the Board of Pharmacy to convene a working group to review current laws and regulations related the possession and use of certain Schedule VI Controlled Substances required by individuals and organizations engaged in the practice of wildlife rehabilitation, as authorized and regulated by the Department of Game and Inland Fisheries.

Because wildlife is a public trust resource, individual wild animals are not privately owned. Therefore, when they are sick or injured, unlike pets or livestock, traditional veterinary care is not generally available; a traditional doctor/patient relationship may not be practical. To accommodate the public's interest in providing care for sick and injured wildlife, the Department of Game and Inland Fisheries authorizes certain individuals and organizations who meet regulatory requirements to provide emergency and rehabilitative care, under the supervision of a licensed veterinarian.

Because of the special circumstances surrounding the needs of injured and orphaned wildlife, certain laws and regulations related to more typical veterinary practice simply may not accommodate the special circumstances associated with wildlife rehabilitation. As you may know, in the 2014 session of the General Assembly, legislation was passed exempting wildlife rehabilitators who are hold permits from the Department of Game and Inland Fisheries from the requirement to be licensed by the Board of Veterinary Medicine in order to provide care to native wildlife.

As currently written, the Virginia Drug Control Act does not authorize wildlife rehabilitators to possess controlled substances, which is problematic for their care of sick and injured animals. While we clearly recognize the need restrict and regulate prescription

medications and other controlled substances, there needs to be a practical balance between these competing public interests.

On behalf of the aforementioned Committees of the Senate, we are requesting the Board of Pharmacy to convene a workgroup for the purpose of examining the current language of the Code to recommend options for licensed veterinarians who supervise and work with wildlife rehabilitators to dispense and supervise the use of certain Schedule VI drugs and other controlled items, outside the traditional doctor/patient relationship. We further request that you include in the workgroup the Board of Veterinary Medicine, the Department of Game and Inland Fisheries, the Virginia Veterinary Medical Association, and the Wildlife Center of Virginia.

We would like to request that a report to our respective committees be generated by November 1, 2105, and that this report contain options and recommendations to resolve the issues outlined herein. During the course of the deliberations of this workgroup, we would request that input from the regulated community, at large, as well as the public be solicited.

Thank you for your consideration. We look forward to hearing from you.

Sincerely,

Senator Stephen H. Martin
Chair, Senate Committee on Education and Health

Senator Emmett W. Hanger, Jr.
Chair, Senate Committee on Agriculture,
Conservation and Natural Resources

Cc: Department of Health Professions, Board of Veterinary Medicine, Department of Game and Inland Fisheries, Virginia Veterinary Medical Association, Wildlife Center of Virginia

THE VIRGINIA DEPARTMENT OF HEALTH
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

Study of the Expansion of Access to Epinephrine Auto-Injectors in the Commonwealth of Virginia

November 2015

53

Workgroup Participants

Virginia Pharmacists Association (James Pickral)
Virginia Academy of Family Physicians (Hunter Jamerson)
Virginia Chapter – American Academy of Pediatricians (Aimee Seibert)
Virginia College of Emergency Physicians (Aimee Seibert)
Medical Society of Virginia (Tyler Cox and Ann Hughes)
Virginia EMS Council (Ed Rhodes)
Virginia School Nurses Association (Becky Bowers-Lanier)
Virginia Academy of Nutrition and Dietetics (Andrew Lamar)
Food Allergy Support Groups of Virginia (Tiffany Glass Ferreira)
No Nuts Moms (Stephanie Gatewood)
Mylan (Michele Satterlund)
Kaleo (Myles Louria)
Sanofi (Kathryn Lavriha & Eric Jones)
Virginia Hospitality and Travel Association (Kristian Havard)
YMCA (Tyler Bishop)
Virginia Campground Association (Lauren Schmitt)
Virginia Child Care Association (Kim Hutcher)

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Study of the Expansion of Access to Epinephrine Auto-Injectors in the Commonwealth of Virginia

Introduction

During the 2015 Session of the General Assembly, Senate Bill 1167 (Hanger) was passed by indefinitely in the Senate Education and Health Committee with the understanding that a letter would be sent requesting the Virginia Department of Health and the Virginia Department of Health Professions to convene a workgroup "aimed at identifying opportunities to expand the number of sites that may choose to voluntarily stock epinephrine auto-injectors for administration by trained individuals in the event of an anaphylactic reaction." Subsequently, the committee chairman sent a letter (Appendix A) with a request for a study in which the following questions were posed:

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?
2. What liability protections are needed for administration by lay-persons?
3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?
4. What states currently allow administration of epinephrine auto-injectors by trained lay-people?
5. What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?
6. What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?

Accordingly, the Workgroup consisting of representatives from health care provider associations, pharmaceutical companies, business and trade associations, and other organizations was convened to review issues pertaining to the potential expansion of use of epinephrine auto-injectors at sites other than medical facilities and public and private schools in Virginia. The Workgroup met on May 27, 2015 and July 30, 2015.

Workgroup Activities

At the meeting on May 27th, the workgroup reviewed SB1167 and the study mandate as well as the Virginia Drug Control Act and the "Good Samaritan" liability protection provisions in Virginia law. The workgroup received a presentation from the Virginia Department of Health (VDH) concerning anaphylaxis and epinephrine. Information about other states in which epinephrine auto-injectors have been authorized for use in non-health care settings by trained lay-persons was reviewed, including information obtained through interviews with health department staff in states that have enacted such legislation. Particular attention was given to Rhode Island and Florida which were among the first states to enact legislation similar to SB1167 The Workgroup then engaged in a discussion of the study questions posed in the letter

from Senate Education and Health Committee and was requested by staff to submit written responses to the questions prior to the July meeting.

At the meeting on July 30th, the workgroup discussed the responses to the study questions that were received and observed that there was a wide discrepancy among workgroup members concerning the level of support for expansion of access to auto-injectors for authorized entities, i.e., sites other than medical facilities and public and private schools, to be administered by lay-persons. The workgroup examined additional, updated information about other state laws and regulations. The workgroup also received a presentation from VDH about emergency medical services (EMS) calls in response to anaphylaxis, training requirements for EMS personnel, and the type of EMS personnel allowed to administer epinephrine. Several workgroup members raised questions concerning how epinephrine auto-injectors are dispensed and stored in other states where the expansion legislation has been passed, such as whether the auto-injectors are dispensed to the entity or the person who has received the training and which party is responsible for storage.

Medical Overview of Epinephrine for Rapid Treatment of Anaphylaxis

Anaphylaxis is a sudden and severe allergic reaction that typically occurs within minutes of exposure to the allergen and almost always within two hours. The anaphylactic reaction results in a release of chemicals in the blood and body tissue encouraging the dilation of blood vessels, leading to a decrease in blood pressure and fluid leaks (often resulting in hives and swelling). Anaphylaxis can occur as an allergic response to peanuts, tree nuts, shellfish, dairy products, eggs, insect stings, latex, and medications.

Anaphylaxis can present in different ways. Anaphylactic symptoms may be pronounced or they may be subtle and difficult to recognize. A person in anaphylaxis may note swelling of tissues; hives; itching; nausea, vomiting, or diarrhea; dizziness or fainting; coughing or difficulty breathing. A person in anaphylaxis may be found to have rapid, weak pulse; flushed or pale skin; abnormal lung sounds; or loss of consciousness. Untreated anaphylaxis can result in death from asphyxiation due to upper or lower airway obstruction or from cardiovascular collapse. Untreated anaphylaxis itself can lead to chest pain, myocardial infarction, and cardiac arrhythmias. The goal is early recognition of anaphylaxis and treatment with epinephrine to prevent progression to life-threatening respiratory and cardiovascular effects.

Epinephrine is the drug of choice for the emergency treatment of anaphylaxis and other severe allergic reactions. It helps maintain blood pressure by lessening the dilation of blood vessels and fluid leakage from blood vessels that occurs during anaphylaxis. Epinephrine relaxes the smooth muscles in the airways and helps reduce bronchospasm, wheezing and shortness of breath. It reduces itching, hives and generalized swelling. Epinephrine may also relieve gastrointestinal and genitourinary symptoms by relaxing the smooth muscles of the stomach, intestine, uterus, and urinary bladder. Epinephrine can quickly improve a person's symptoms, but the effects are not long lasting. If symptoms recur, referred to as a biphasic reaction, additional doses of epinephrine are needed.

There are no absolute contraindications to the use of epinephrine in a life-threatening situation. The risk of death or serious complications from the loss of oxygen to the brain from inadequately treated anaphylaxis usually outweighs other concerns. Epinephrine is not contraindicated for persons who have heart disease, including cardiac arrhythmias, coronary artery or organic heart disease, or hypertension, if they are having an acute, life-threatening anaphylactic reaction. However, some patients may be at greater risk for developing adverse reactions after epinephrine administration. Persons who might be in a position to administer epinephrine to an elderly individual, pregnant woman, or persons with certain health conditions should be carefully instructed in regard to the circumstances under which epinephrine should be used. Epinephrine should be administered with caution to patients who have heart disease, including patients with cardiac arrhythmias, coronary artery or organic heart disease, or hypertension. In such patients, or in patients who are on drugs that may sensitize the heart to arrhythmias, epinephrine may precipitate or aggravate angina pectoris as well as produce ventricular arrhythmias. Epinephrine should be administered with caution to patients with hyperthyroidism, diabetes, elderly individuals, and pregnant women. Patients with Parkinson's disease may notice a temporary worsening of symptoms. (Source: Full Prescribing Information for Auvi-Q)

Epinephrine administered by any route can cause anxiety, restlessness, headache, dizziness, palpitations, pallor, nausea and vomiting, headache, respiratory difficulties, and/or tremor. The natural epinephrine released in a sudden frightening or life-threatening situation causes similar symptoms. These symptoms occur in some persons receiving therapeutic doses of epinephrine, but are more likely to occur in patients with hypertension or hyperthyroidism. Arrhythmias, including fatal ventricular fibrillation, have been reported, particularly in patients with underlying cardiac disease or those receiving certain drugs. Rapid rises in blood pressure have produced cerebral hemorrhage, particularly in elderly patients with cardiovascular disease. Angina may occur in patients with coronary artery disease. (Source: Full Prescribing Information for Auvi-Q)

The most common adverse event reported to the U. S. Food and Drug Administration associated with epinephrine auto-injectors is unintentional injections. From October 2011 to September 2012, the U.S. Food and Drug Administration received 256 reports of adverse events and the use of epinephrine auto-injectors. The most common reports were: accidental exposure (131); drug ineffective (51); injury associated with device (44); and expired drug administered (40). However, these reports are not verified clinical evidence of an adverse effect. The rate of unintentional injections of epinephrine from auto-injectors is increasing: more than 15,000 events were reported voluntarily to the American Association of Poison Control Centers from 1994 to 2007.

Emergency Medical Services Response to Anaphylaxis

Emergency Medical Technicians (EMT) are to provide basic emergency medical care and transportation for critical and emergent patients who access the emergency medical system. This individual possesses the basic knowledge and skills necessary to provide patient care and transportation. EMTs function as part of a comprehensive EMS response, under medical oversight, and perform interventions with the basic equipment typically found on an ambulance. The EMT is a link from the scene to the emergency health care system.

During 2014, a total of 1,174,253 emergency calls were made to 911 that subsequently involved treatment by EMS. Among those calls, 10,285 (0.88%) were for a person having an allergic/anaphylactic reaction. Among those calls involving anaphylaxis, epinephrine was administered by EMS in 1,070 (10.4%) of the cases. Appendix B contains additional data from the Virginia Department of Health's Office of Emergency Medical Services.

Certification as an EMT in Virginia requires between 150 and 190 hours of training including the four integrated phases of education (didactic, laboratory, clinical and field.) Specific education for the EMT includes but is not limited to:

1. Anatomy and physiology of the immune system
2. Causes of an immune response causing an allergic and anaphylactic reaction
3. Obtaining a history for a current event
4. Signs and symptoms of an allergic and anaphylactic reaction
5. Treatment interventions for such a reaction to include but not limited to:
    a. Airway management
    b. Assuring adequate breathing
    c. Assuring adequate circulation
    d. Assisting / administering appropriate medications:
        i. Oxygen
        ii. Epinephrine

The Virginia EMS Scope of Practice - Procedures allow for the administration of medication by the various types of EMS responders. The Virginia EMS Scope of Practice – Formulary allows for the EMT to administer various drugs, including epinephrine.

By contrast, certification as an Emergency Medical Responder (EMR), formerly known as a First Responder, requires between 48 and 60 hours of training. EMRs are not allowed to administer medication, including epinephrine, with the exception of certain drugs to be administered during an incident involving weapons of mass destruction.

Responses to Study Questions

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?

There was no consensus among the participants in the Workgroup in response to the question about where such administration would be appropriate. Responses included the following:

Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians

- Administration of epinephrine auto-injectors by lay-persons should occur in "controlled" locations, with an emphasis on those sites at which large groups of children are typically

present, such as private schools, camps, and daycares. These are locations where staff can be appropriately trained and where training can be documented and updated as the technology changes. There is also a higher likelihood that a trained healthcare provider will be present in these "controlled" settings.

- If lay-persons are permitted to administer a prescription medication such as an epinephrine auto-injector, proper training will be critical, particularly in distinguishing anaphylaxis from other conditions. While classic anaphylaxis is quite distinctive, the list of symptoms associated with anaphylaxis is broad and a lay-person could misinterpret symptoms of another medical condition as being caused by anaphylaxis – in which case administration of epinephrine may exacerbate that medical condition or other underlying conditions of the individual. The risk of adverse events resulting from unnecessary administration of epinephrine is higher in elderly individuals than in children and adults.

Virginia Pharmacists Association

- The most appropriate environments for the administration of epinephrine auto-injectors by lay-persons would be those frequented by, or catering specifically to, children. These would include schools, daycare, summer camps and similar environments. These environments should have a responsible party that takes possession of the auto-injector and ensures that all handling and storage requirements are met.

Mylan Pharmaceutical Company

- Supports the position of the American Medical Association and the American Academy of Allergy and Immunology that lay-persons in occupations likely to involve contact with people who may experience an anaphylactic reaction should be allowed to receive training in the symptoms of anaphylaxis.
- Supports additional training specific to the administration of epinephrine by employees of entities that voluntarily choose to stock epinephrine pursuant to a prescription, standing order or protocol.
- Many entities already choose to stock and provide training to employees regarding the use of first-aid supplies, including automated external defibrillators, to individuals who may be injured, ill or experiencing cardiac arrest on the premises of the entity. Allowing epinephrine auto-injectors to be stocked will enable entities to come to the aid of individuals who experience anaphylaxis in a public setting.

Virginia Campground Association

- Opposes expanding the law to allow "any entity" to be allowed to have standing orders for epinephrine auto-injectors. Even if it is optional, they do not believe this is an appropriate function for campgrounds and campground employees to perform because it would be: 1) overly burdensome to stock the necessary amounts of epinephrine auto-injectors for adults and children that visit Virginia campgrounds; 2) cost-prohibitive; and 3) time-consuming to train seasonal workers. It would also create a false sense of security for campground guests if private businesses were allowed the option. Consumers would be confused as to whether a business has auto-injectors and trained staff.

No Nuts Moms

- Supports expanded access to epinephrine auto-injectors in all settings. It will save lives of food-allergic individuals. Even if a food-allergic individual carries his own injector, it could misfire or not inject correctly or a second or third dose might be needed. Food allergies are increasing in children and there are more late-onset allergies occurring.

2. What liability protections are needed for administration by lay-persons?

Section 8.01-225 of the Code of Virginia provides an exemption from liability for:
A. Any person who:
3. In good faith and without compensation, including any emergency medical services provider who holds a valid certificate issued by the Commissioner of Health, administers epinephrine in an emergency to an individual shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment if such person has reason to believe that the individual receiving the injection is suffering or is about to suffer a life-threatening anaphylactic reaction.

The Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians:

- Good Samaritan laws are in place in Virginia that protect individuals from liability when they are providing emergency care in good faith. However, the locations that stock the epinephrine auto-injectors for lay-person use might need additional liability protections.

Virginia Pharmacists Association:

- Virginia has a "Good Samaritan" law already in statute. However, it is unclear whether this would apply to situations beyond administration of the medication. For example, would it also cover a scenario where an auto-injector was improperly stored or had expired so that efficacy was decreased, therefore resulting in harm?

3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?

The Medical Society of Virginia, American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians:

- There seem to be a handful of nationally recognized programs available to train lay-persons. These organizations support training programs that are "hands-on." They do not believe that training via a webinar or telephone conference will give the lay-person the appropriate level of knowledge to administer an epinephrine auto-injector. These auto-injectors require a certain handling in order to be administered correctly. That is why "training" epi-pens are manufactured, in order provide a hands-on approach to training. These organizations also believe training in accurate identification of anaphylaxis is critical.

Virginia Pharmacists Association:

- They believe that hands-on training is most appropriate.

Mylan Pharmaceutical Company:

- There are several training programs that train lay persons to recognize the symptoms of allergic reaction/anaphylaxis and to assist in the administration, or to directly administer an epinephrine auto-injector. Nationally-recognized training programs include the Red Cross course entitled "Anaphylaxis and Epinephrine Auto-Injector Online Course;" Wilderness Medical Associates course entitled "Wilderness First Aid;" and American Heart Association course entitled "Heartsaver Pediatric First Aid CPR AED." The Red Cross course costs $20. Training programs can be conducted online or in person. Various free programs in administration of auto-injectors are also available online. Training programs are updated as needed, based on current information.
- Several staff from other state health departments, responsible for implementation of the training component of their state statute, noted that training for this authorization can be completed through programs offered by American Red Cross, American Heart Association, National Safety Council, or any other first aid program that covers epinephrine auto-injectors.

4. ***What states currently allow administration of epinephrine auto-injectors by trained lay-people?***
5. ***What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?***

Responses to these two questions have been combined for the purposes of this report, as all of the legislation enacted by other states contain provisions that authorize both the administration by lay-people and the stocking at certain sites.

Laws to allow administration of epinephrine auto-injectors by trained lay-people *in connection with an authorized entity* have recently been enacted in a number of states (Appendix C). Rhode Island and Florida passed legislation similar to SB1167 in 2014, which allowed the stocking of the injectors at certain facilities at which allergens capable of causing anaphylaxis may be present, and allowed trained employees of that entity to administer the epinephrine auto-injector to another person they believe to be in an emergency anaphylaxis situation. The two states' laws outline various authorizations, training requirements, liability protections and, in Rhode Island's case, incident reporting requirements.

Similar provisions have been adopted in 14 other states in 2015, including: Arkansas, Colorado, Georgia, Iowa, Indiana, Kentucky, Maine, Minnesota, Nevada, North Carolina, Oklahoma, Utah, West Virginia and Wisconsin. Additionally, similar provisions are currently pending in 5 more states, including: Massachusetts, Michigan, New Jersey, Ohio and Pennsylvania.

These statutes are all fairly similar, and all authorize certain entities to stock epinephrine auto-injectors and allow trained lay people in connection with the authorized entity to administer it to an individual believed to be experiencing anaphylaxis. Most of the statutes apply this authorization to any entity at which allergens capable of causing anaphylaxis may be present, however, a few limit this definition to several explicitly listed types of entities, such as campgrounds. Most of these statutes authorize the state's health commissioner, board of health, or other similar entity or individual to create and maintain a list of entities that will be authorized for these provisions.

The statutes differ slightly in their training requirements (for example, some do not include storage and follow-up emergency procedures as a minimum training requirement) or their reporting requirements (several do not require reporting at all). Additionally, the statutes differ in their requirements for or inclusion of an expanded availability provision: four states allow an untrained layperson at the authorized entity to access the epinephrine auto-injectors from a secure storage container and administer it under direction and authorization of a health practitioner via remote electronic communication,

Aside from these various discrepancies from state to state, as well as other minor differences in the language, these statutes all authorize the administration of epinephrine auto-injectors by trained lay-people in connection with an authorized entity that is authorized to stock and maintain epinephrine auto-injectors.

Among those states that have already enacted this type of legislation, implementation remains in the early stages. During interviews conducted by VDH, staff from health departments in those states were asked how the dispensing and prescribing processes would work, what practitioners would typically be writing these prescriptions, and what individual would be responsible for getting the entity's prescription filled and receiving the auto-injector supply. Given that implementation is still in the early stage, these processes and details had not yet been determined, though some states mentioned an assumption that these responsibilities would belong to the entity's employee who is already responsible for receiving training and for oversight and maintenance of the auto-injector supply. Wisconsin is the only state with epinephrine auto-injector legislation that includes dispensing details, lays out basic requirements as with typical prescription orders, and adds that prescriptions in the case of this type of legislation must include the name and address of the authorized entity receiving the prescription. It does not, however, address who would be the individual to fill and pick up an entity's prescribed epinephrine auto-injectors.

The Board of Pharmacy surveyed the following states to determine the process for authorized entities to obtain epinephrine: West Virginia; Kentucky; Maryland; Georgia; Rhode Island; Oklahoma; and, Florida. Responses were received from Oklahoma and Utah.

Oklahoma reported that the epinephrine law will be handled under a protocol or order from the physician. The physician will determine who he or she will authorize to have the epinephrine under the authority. The pharmacy will fill a prescription written by the physician using the entity name as the patient name on the prescription. The physician, e.g., a medical director

associated with the entity, will be responsible for assuring the entity he authorizes to have the medication is trained properly and has an appropriate policy and procedure.

Utah's legislation states that a qualified entity may obtain from a physician, pharmacist, or any other person or entity authorized to prescribe or dispense prescription drugs, a prescription for a supply of epinephrine auto-injectors. The epinephrine must be stored on the qualified entity's premises and used by a qualified adult. The entity must also designate an individual to complete an initial and annual refresher training program regarding the proper storage and emergency use of an epinephrine auto-injector and store the epinephrine auto-injectors in accordance with regulations to be promulgated by the department.

6. ***What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?***

The Medical Society of Virginia, Virginia Chapter - American Academy of Pediatricians, American College of Emergency Physicians and Virginia Association of Family Physicians posed a series of questions that they believe need to be addressed as a prerequisite to considering the types of changes that are needed to Virginia's laws and regulations:

- Would this be voluntary? How would immunity be handled? Where does the funding come from? Or would this be an unfunded mandate, if not voluntary? Are private physicians writing the standing orders or are VDH physicians? Who would create the regulations? How would the current standing order language need to be changed?

Virginia Pharmacists Association (VPhA)

- There must be clarity as to who possesses the auto-injector and who is responsible for safe handling and storage. Specific concerns of VPhA were:
  1) Possession and storage. The responsible party must be clearly defined. The responsibilities of that person as related to possession and storage must also be clearly delineated;
  2) Diagnosis of anaphylactic shock. When a child is diagnosed with food allergies and a prescription is written for an auto-injector the parents or guardians know to expect anaphylaxis and to use the auto-injector appropriately. A lay person has no such fore-knowledge when an unknown individual presents symptoms. VPhA would have serious concerns with the scenario of, for example, an 18 year old, part-time food service employee attempting to diagnose anaphylaxis. They also have concerns that underlying medical conditions may be exacerbated by the improper use of the auto-injector especially in older adults.
  3) VPhA is not sure that making auto-injectors administered by lay-persons more widely available would promote improved public health or reduce medical expenses. VPhA's understanding is that the main argument made by proponents for making auto-injectors more widely available in public settings is to be able to treat anaphylaxis in individuals who are unaware that they have food sensitivity. It is also their understanding that when a food sensitivity first presents the reaction is generally mild and not life threatening. The situation is often handled by EMS which then decides the course of initial treatment. When EMS does

treat with an auto-injector it is their understanding that the patient will most likely also be taken to an emergency department.

Mylan Pharmaceutical Company

- In 2012, Virginia laid the foundation for entity prescribing by allowing prescribers, pursuant to an order or standing protocol, to provide any individual who is an employee of a public school system, local governing body, or local health department who has received training, to possess and administer epinephrine to an individual experiencing anaphylaxis in a public school setting. The school guidelines provide a framework that can be used by entities other than public schools, for prescribing epinephrine to non-specific individuals.
- In 2015, Virginia passed legislation to expand the availability of epinephrine to employees of a school for students with disabilities, or of 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.
- Legislation passed in 2015 also allows a prescriber, pursuant to an order or standing protocol, to dispense naloxone to a person who may administer the drug to another person who is experiencing a life-threatening opiate overdose. However, the model used for prescribing naloxone is not being recommended by Mylan for prescribing epinephrine auto-injectors.
- Virginia laws provide a framework from which drug products may be dispensed to individuals or entities, other than the intended recipient of the medication, and most notably, demonstrate that medications may be prescribed and dispensed outside the requirements of §54.1-3303 of the Code.

In order to authorize the dispensing of epinephrine by oral or written order or standing protocol to an employee of an authorized entity, § 54.1-3408 of the Drug Control Act would need to be amended similar to authorization in subsection D for an employee of a local school board to possess and administer epinephrine. Currently, § 8.01-225 of the Code of Virginia provides an exemption from liability for any person who in good faith and without compensation administers epinephrine in an emergency to an individual 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. However, there may need to be additional protection from civil liability for the entity that stocks the auto-injectable epinephrine.

CONCLUSION

The Workgroup conducted a review of existing laws and regulations and responded to the six questions identified by the Chairman of the Senate Committee on Education and Health. Though the Workgroup actively engaged in the discussion of the study questions and received extensive information about epinephrine and legislative initiatives in other states, it was unable to reach consensus on a policy recommendation concerning the expansion of authorization for unlicensed persons in entities other than schools to possess and administer auto-injectable epinephrine. Members of the Workgroup representing health care provider organizations remain concerned about potential adverse events relating to recognition of anaphylaxis and unnecessary administration. Representatives of entities, such as restaurants and campgrounds, that would potentially be authorized to stock epinephrine and train employees in administration remain

concerned about costs, liability, and public expectations. Representatives of pharmaceutical companies with auto-injectable epinephrine products and allergy advocacy groups continue to support increased access in entities where allergens may be present. While legislation similar to SB1167 has been enacted in 16 other states, it appears that additional stakeholder engagement may be necessary in order to move forward with developing new state policy in this area.

Appendix A: Letter from Chairman of Senate Committee on Education & Health

COMMONWEALTH OF VIRGINIA

STEPHEN H. MARTIN
[illegible]

SENATE

COMMITTEE ASSIGNMENTS
EDUCATION AND HEALTH, CHAIR
GENERAL LAWS AND TECHNOLOGY
LOCAL GOVERNMENT
PRIVILEGES AND ELECTIONS
RULES

February 16, 2015

The Honorable Marissa Levine
Commissioner
Virginia Department of Health
109 Governor Street
Richmond, Virginia 23219

The Honorable David Brown
Director
Virginia Department of Health Professions
9960 Mayland Drive
Ste. 300
Richmond, VA 23233-1463

RE: Senate Bill 1167 (Hanger): Expansion of Access to Epinephrine Auto-Injectors Request that the Virginia Department of Health Professions and the Virginia Department of Health Convene an Epinephrine Auto-Injector Access Workgroup

Dear Dr. Brown and Dr. Levine,

On Thursday, February 4, 2015, the Virginia General Assembly voted unanimously to pass by Senate Bill 1167 with a letter requesting the Virginia Department of Health and the Virginia Department of Health Professions to convene a workgroup aimed at identifying opportunities to expand the number of sites that may choose to voluntarily stock epinephrine auto-injectors for administration by trained individuals in the event of an anaphylactic reaction.

In 2012, the Virginia General Assembly laid the foundation to save lives by mandating that public schools stock and train public school and local government employees to administer epinephrine auto-injectors to students experiencing anaphylaxis. The legislation authorized practitioners to prescribe, via a standing order or protocol, epinephrine auto-injectors to a public school rather than a particular individual.

Allergic reactions, however, don't just happen at a public schools setting, and as the number of individuals (of all ages) suffering from life-threatening anaphylaxis continues to grow, it is important that the Commonwealth find solutions for expanding access to epinephrine—which is the only first-line treatment for anaphylaxis.

The goal of the workgroup shall be to review existing laws and regulations and to provide a report by November 15, 2015 that considers, at a minimum, the following:

1. Where, and under what conditions, would it be appropriate for the administration of epinephrine auto-injectors by lay-persons?
2. What liability protections are needed for administration by law-persons?
3. What is the availability of nationally recognized programs that train lay-persons in the administration of epinephrine auto-injectors?
4. What states currently allow administration of epinephrine auto-injectors by trained lay-people?
5. What states allow stocking of epinephrine auto-injectors at sites other than medical facilities and public schools?
6. What changes must be made to Virginia's laws and regulations in order to expand the use of epinephrine auto-injectors in sites other than medical facilities and public schools?

A list of potential workgroup participants is attached.

If you have any questions, please do not hesitate to contact me.

Sincerely,

Stephen H. Martin
Senate of Virginia

cc: The Honorable Emmett Hanger

Enclosure

Epinephrine Auto-Injector Expansion Work Group: Suggested Participants

- Virginia Department of Health Professions (The Hon. Dr. David Brown/Elaine Yeatts)
- Virginia Department of Health (The Hon. Marissa Levine/Joe Hilbert)
- Virginia Department of Health Board of Pharmacy (Caroline Juran)
- Virginia Association of Pharmacists (James Pickral)
- Virginia Association of Plastic Surgeons (James Pickral)
- Food Allery Support Groups of Virginia (Tiffany Glass Ferreira)
- No Nuts Moms (Stephanie Gatewood)
- Mylan (Michele Satterlund)
- Kaleo (Myles Louria)
- Sanofi (Kathryn Lavriha)
- Association of Family Physicians (Hunter Jamerson)
- Association of Pediatric Physicians (Aimee Seibert)
- Virginia College of Emergency Physicians (Aimee Seibert)
- Virginia Association of Allergists (TBD)
- Virginia Hospitality Association (Kristian Havard)
- YMCA (Tyler Bishop)
- Campground Association (Lauren Schmitt)
- Afterschool Care Association (Tia Campbell)
- Daycare Association (Matt Benedetti)
- Virginia School Nurses (Becky Bowers Lanier)
- Virginia EMS Council (Ed Rhodes)
- Medical Society of Virginia (Tyler Cox)
- Virginia Academy of Nutrition and Dietetics (Andrew Lamar)

Appendix B: Anaphylaxis Data from the Virginia Department of Health's Office of Emergency Medical Services

Frequencies for FY14 (7/1/13 to 6/30/14)							
EMS Region	**Population Estimate for 2013**	**All 911 (Treated) Events**	**Anaphylactic Reaction**	**Any Epi Given**	***Epinephrine 1:1000***	***Epi-Pen Adult***	***Epi-Pen Junior***
Blue Ridge	256,455	45,542	485	22	*19*	*3*	*1*
Central Shenandoah	291,649	60,210	621	71	*42*	*30*	*3*
Lord Fairfax	228,087	33,827	218	25	*14*	*13*	*0*
Northern Virginia	2,388,316	206,517	2,438	361	*349*	*9*	*3*
Old Dominion	1,398,792	233,598	2,111	182	*148*	*30*	*5*
Peninsulas	623,676	75,401	709	57	*44*	*11*	*3*
Rappahannock	504,372	66,025	627	78	*72*	*4*	*2*
Southwest Virginia	395,939	81,468	418	34	*31*	*3*	*0*
Thomas Jefferson	254,064	42,381	542	65	*51*	*15*	*1*
Tidewater	1,214,817	206,709	1,129	113	*102*	*9*	*4*
Western Virginia	704,238	122,575	987	62	*42*	*17*	*4*
Total (Statewide)	*8,260,405*	*1,174,253*	*10,285*	*1,070*	*914*	*144*	*26*

Rates for FY14 (7/1/13 to 6/30/14)				
EMS Region	**911 (Treated) Events/100K**	**Anaphylaxis Events/100K**	**Anaphylaxis/100K Events**	**Epi Given/1K Anaphylaxis Events**
Blue Ridge	1,776	19	5	45
Central Shenandoah	2,064	21	12	114
Lord Fairfax	1,483	10	7	115
Northern Virginia	865	10	17	148
Old Dominion	1,670	15	8	86
Peninsulas	1,209	11	8	80
Rappahannock	1,309	12	12	124
Southwest Virginia	2,058	11	4	81
Thomas Jefferson	1,668	21	15	120
Tidewater	1,702	9	5	100
Western Virginia	1,741	14	5	63
Total (Statewide)	1,422	12	9	104

Epinephrine 1:1000 - This is a high concentration form of the drug often administered subcutaneously by EMTs for treating allergic reactions. It is not available as an auto-injector.

Epi-Pen Adult and Epi-Pen Jr. are auto-injectors that contain a pre-determined single dose of epinephrine that is administered intramuscularly or subcutaneously into the thigh.

Anaphylaxis Events/100K - Allergic reactions per 100,000 population.
Anaphylaxis /100K Events - Allergic reactions per 100,000 EMS events
Epi Given/1K Anaphylaxis Events - Epinephrine administration per 1,000 Anaphylaxis Events

This data does not include instances where an individual who was experiencing anaphylaxis may have been administered epinephrine, in any form, prior to EMS arrival.

Frequencies for FY14 (7/1/13 to 6/30/14) -- Anaphylaxis Events by Location Type

EMS Region	Total	Airport	Farm	Health Care Facility (clinic, urgent Care Ctr,hospital)	Home/ Residence	Industrial Place and Premises	Lake, River, Ocean	Other Location
Blue Ridge	485	0	0	35	331	5	0	12
Central Shenandoah	621	0	0	49	361	10	1	9
Lord Fairfax	218	0	1	36	112	5	0	8
Northern	2,438	49	1	312	1,060	15	2	68
Old Dominion	2,111	3	3	186	1,311	12	0	24
Peninsulas	709	0	0	48	446	8	1	15
Rappahannock	627	0	0	73	343	2	0	7
Southwest	418	0	0	30	278	3	0	5
Thomas Jefferson	542	0	1	29	336	2	1	11
Tidewater	1,129	7	2	131	639	17	6	24
Western	987		1	90	674	4		9
Total (Statewide)	*10,285*	*59*	*9*	*1,019*	*5,891*	*83*	*11*	*192*

Continued: Frequencies for FY14 (7/1/13 to 6/30/14) -- Anaphylaxis Events by Location Type

EMS Region	Place of Recreation or Sport	Public Building (schools, gov, offices)	Residential Institution (nursing home, jail/prison)	Street or Highway	Trade or Service (Business, bars, restaurants, etc.)	Unspecified place	Not Available
Blue Ridge	3	47	9	13	34	1	1
Central Shenandoah	1	85	23	20	62	1	0
Lord Fairfax	7	21	7	10	11	0	0

EMS Region	Place of Recreation or Sport	Public Building (schools, gov, offices)	Residential Institution (nursing home, jail/prison)	Street or Highway	Trade or Service (Business, bars, restaurants, etc.)	Unspecified place	Not Available
Northern	27	617	38	81	173	4	4
Old Dominion	25	256	65	85	145	3	0
Peninsulas	19	94	15	13	38	2	10
Rappahannock	9	103	22	23	45	0	2
Southwest	1	26	25	16	32	2	0
Thomas Jefferson	10	71	15	26	40	1	0
Tidewater	9	148	40	31	76	0	
Western	11	80	39	26	52		1
Total (Statewide)	*122*	*1,548*	*298*	*344*	*708*	*14*	*18*

Appendix C: Memorandum of Comparative Analysis of Epinephrine Auto-Injector Use Expansion Legislation in Other States

During the consideration of SB1167 in Virginia, proponents identified two states with similar existing laws – Rhode Island and Florida, both of which were enacted in 2014. These laws outline various authorizations, training requirements, liability protections and, in Rhode Island's case, incident reporting requirements. Oregon, North Dakota and Maryland utilize a different statutory framework for ensuring the availability of epinephrine in emergency situations in non-school settings, one that is focused on a trained individual rather than an authorized entity.

In 2015, 14 states joined Rhode Island and Florida in enacting legislation that authorizes trained laypersons, in connection with certain authorized entities, to administer epinephrine auto-injectors to persons believed to be experiencing an anaphylactic emergency. Those states were Arkansas, Colorado, Georgia, Iowa, Indiana, Kentucky, Maine, Minnesota, Nevada, North Carolina, Oklahoma, Utah, West Virginia and Wisconsin. An additional 5 states – Massachusetts, Michigan, New Jersey, Ohio and Pennsylvania – have similar legislation currently pending, and 13 states – Alabama, Arizona, California, Hawaii, Illinois, Missouri, New Hampshire, New York, Oregon, South Carolina, Vermont, Virginia and Washington – proposed this type of legislation in their 2015 legislative sessions, but did not enact it.

The basic provisions of each of these bills is the same – authorizing certain entities to obtain a prescription of and stock on their premises epinephrine auto-injectors, authorizing health practitioners to provide the prescription, and pharmacists to dispense the prescription. The entity must have a trained employee responsible for oversight of the auto-injectors, and who is authorized to administer it to an individual believed to be experiencing an anaphylactic emergency. The bills all note liability protections and set up the various provisions necessary to carry out the provisions of the bill. However, where these bills differ is in the specific definition of an authorized entity, the training requirements, reporting requirements, and expanded availability provision. Please see the table below for a comparative analysis of all of the passed bills of this nature.

The second column of the below table evaluates whether the term "authorized entity" is defined in the legislation as one in which allergens capable of causing anaphylaxis may be present. In the various states' bills, this definition will often include a few types of entities that would potentially fall under this definition, such as youth camps or sports arenas, but do not limit the definition to those. This list of authorized entities is also often subject to change and regular updating by the state's department of health or commissioner of health.

The last column evaluates whether the bill contains an expanded availability provision. This means that the legislation allows an authorized entity stocking a prescription of epinephrine auto-injectors to make them available for administration by non-trained laypersons if they are stored in a locked, secure container and made available to such individuals for use in a believed anaphylactic emergency upon remote authorization by a health care provider by electronic communication (audio, televideo, etc.).

	Authorized entity is defined as one in which allergens capable of causing anaphylaxis may be present	Training by nationally recognized organization or other entity approved by department, board or commissioner	Training - minimum requirements include recognition of anaphylaxis and administration of epinephrine auto-injector	Training - minimum requirements include storage requirements and follow-up emergency procedures	Authorized entities required to report to the department or board incidents of epinephrine auto-injector administration on their premises	Contains expanded availability provision
RI	✓	✓	✓	✓	✓	✓
FL	✓	✓	✓	X	X	✓
AR	✓	✓	✓	X	✓	X
CO	✓	✓	✓	✓	✓	✓
GA	✓	✓	✓	✓	✓	X
IA	X –"facility" means "a food establishment as defined in section 137F.1, a carnival as defined in section 88A.1, a recreational camp, a youth sports facility, or a sports area"	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X – no training requirements; left to be decided in the regulations that are to be adopted to implement this bill	X	X
IN	X – "entity" is any business, association, or governmental entity, including any branch location of the entity	X – training by a health care provider who is licensed or certified in Indiana, for whom the administration of auto-injectable epinephrine is within the health care provider's scope of practice, who has received training in the administration of auto-injectable epinephrine, and who is knowledgeable in recognizing the symptoms of anaphylaxis and the administration of auto-injectable epinephrine.	✓	X	X	X
KY	✓	✓	✓	X	X	X

	Authorized entity is defined as one in which allergens capable of causing anaphylaxis may be present	Training by nationally recognized organization or other entity approved by department, board or commissioner	Training - minimum requirements include recognition of anaphylaxis and administration of epinephrine auto-injector	Training - minimum requirements include storage requirements and follow-up emergency procedures	Authorized entities required to report to the department or board incidents of epinephrine auto-injector administration on their premises	Contains expanded availability provision
ME	✓	✓	✓	✓	X	X
MN	X	✓	✓	✓	X	X
NV	✓	✓	✓	✓	✓	X
NC	✓	✓	✓	✓	X	X
OK	✓	✓	✓	✓	X	✓
UT	X – "qualified entity" means a facility or organization that employs, contracts with, or has a similar relationship with a qualified adult who is likely to have contact with another person who may experience anaphylaxis	X – local health department or local EMS director designates what entities approved to provide this training	✓	✓	X	X
WV	✓	✓	✓	X	X	X
WI	✓	✓	✓	✓	X	X