COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Public Hearing and Full Board Meeting

September 29, 2015

9:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances:
Cynthia Warriner, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Possible scheduling of the following substances: 1-2
  - Acetyl fentanyl (other name: desmethylfentanyl)
  - Etizolam
  - 1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201)
  - 4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH)
  - Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP)
  - Alpha-Pyrrolidinoheptiophenone (other name: PV8)

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Cynthia Warriner, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - June 15, 2015, Public Hearing for Scheduling Certain Chemicals 3-4
  - June 15, 2015, Full Board Meeting 5-15
  - June 16, 2015, Special Conference Committee 16-23
  - July 9, 2015, Telephone Conference Call 24-25
  - July 23, 2015, Special Conference Committee 26-27
  - August 4, 2015, Panel Formal Hearings 28-30
  - August 11, 2015, Special Conference Committee 31-35

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 Shenandoah University, Bernard J. Dunn School of Pharmacy: Penny S. Shelton, PharmD, CGP, FASCP, Associate Dean for Academic Affairs

Regulatory Actions: Elaine Yeatts/Caroline Juran

- Regulatory Update 36
- Consideration of Any Scheduling Action from Public Hearing 37-43
- Adoption of Proposed Regulations for Authorized Collectors of Drugs 44-48B

- Report from Regulation Committee – Cynthia Warriner/Elaine Yeatts 49-55
  - Adoption of Emergency Regulations for Outsourcing Facilities 56-68
  - Adoption of Emergency Regulations for Permitting Facilities in which Practitioners of the Healing Arts Dispense Controlled Substances 69-76
  - Adoption of Emergency Regulations for PACE Facilities 77-84

Old Business: Caroline Juran

- Request to Amend Guidance Document 110-36 *Compliance with USP Standards for Compounding* 85-97

New Business: Caroline D. Juran/Elaine Yeatts

- Request to Amend Guidance Document 110-18 *Interpretation of "administer" to include preparation for administration* 98-99
- Consider Amending Guidance Document 110-34 *Wholesale Distributor Licensure Guidance* based on Pre-emption in Drug Supply Chain Security Act 100
- Consider Adoption of Guidance Document regarding Re-dispensing Drugs Previously Dispensed in Compliance Packaging 101-103
- Request for Guidance regarding Issuance of Controlled Substances Registrations to Medical Office Buildings 104-110
- Set Dates for 2016 Full Board and Tentative Regulation Committee Meetings 110A

Election of Vice-Chairman

Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions - Ellen B. Shinaberry
- Report on Wildlife Rehabilitator Workgroup – Ellen B. Shinaberry
- Report on PMP – Ralph Orr, PMP Director
- Report on Licensure Program – J. Samuel Johnson, Jr. 111-121
- Report on Disciplinary Program – Cathy M. Reiniers-Day handout
- Executive Director's Report –Caroline D. Juran

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

Adjourn

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

******A panel of the Board of Pharmacy will convene at 2pm or immediately following adjournment of the meeting, whichever is later.******

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on September 29, 2015** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 1, 2015 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

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

1. **Acetyl fentanyl (other name: desmethylfentanyl)**

   Acetyl fentanyl is a powerful synthetic opioid similar in structure to fentanyl and has been identified in DFS laboratories; however, acetyl fentanyl has not been approved for medical use in the United States. The Drug Enforcement Administration (DEA) issued a notice of intent on May 21, 2015 to temporarily place acetyl fentanyl into Schedule I. Upon finalization of this proposed action, DFS recommends placing acetyl fentanyl into Schedule I (§ 54.1-3446(1)).

2. **Etizolam**

   Etizolam is chemically related to the class of drugs referred to as benzodiazepines which are central nervous system depressants. Etizolam has been approved for medical use in some countries; however, Etizolam has not been approved for medical use in the United States and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. **4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH)**

   25I-NBOH is classified as a research chemical and is similar in structure to 25I-NBOMe – a schedule I compound. 25I-NBOH has been identified in DFS laboratories including post mortem toxicology cases. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

4. **alpha-Pyrrolidinohexiophenone (other name: alpha-PHP)**

   Alpha-PHP is classified as a research chemical and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

5. **alpha-Pyrrolidinoheptiophenone (other name: PV8)**

   PV-8 is classified as a research chemical and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

6. **1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201)**

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

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

June 15, 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 9:08a.m.

PRESIDING: Ellen Shinaberry, Chairman

MEMBERS PRESENT:
Melvin Boone
Michael Elliott
Dinny Li
Ryan K. Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
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 E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

CALL FOR COMMENT: Ms. Shinaberry called for comment to consider placement of the chemical substances N-(1-amino-3, 3-dimethyl-1-oxobutan-2yl)-1-(cyclohexylmethyl) indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA), methyl 2-(1-(5-fluropentyl)-1H-indazole-3-carboxamido)-3-methybutanoate (other name: 5-fluoro-AMB), 1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201), 1-4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144), 4-bromomethcathinone (other name: 4-BMC), and 4-chloromethcathinone (other name: 4-CMC) into Schedule I. 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 9:15am.

Ellen Shinaberry, Chairman

Caroline D. Juran, Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 15, 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 9:15am

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Michael Elliott
Dinny Li
Ryan Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
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
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: Ms. Shinaberry requested that an additional item be included on the agenda. She requested the Board consider whether it's an appropriate time to initiate a periodic review of regulations. Additionally, she stated that the Virginia Pharmacists Association requested that discussion regarding its letter to amend Guidance Document 110-36 be tabled until the September board meeting. Ms. Juran also asked the Board to disregard the minutes from the March 11, 2015 Special Conference Committee meeting that was included in the agenda packet since the minutes were previously approved at the March 24th full board meeting. The agenda was approved as amended.

APPROVAL OF MINUTES: Staff provided to the board amended handouts of the May 13, 2015

Telephone Conference Call draft minutes and the May 11, 2015 Regulation Committee Meeting draft minutes. Amendments of the Regulation Committee meeting draft minutes were suggested by several board members, including Ms. Warriner.

MOTION: **The Board voted unanimously to approve the minutes as amended for the meetings held between March 23, 2015 and May 13, 2015. (motion by Munden, second by Logan)**

PUBLIC COMMENTS: The Board reviewed written public comments from the following:

Janet Silvester, Pharm.D., M.B.A., FASHP, Vice President Accreditation Services, ASHP, wrote that she is in favor of the Pharmacy Technician Certification Board (PTCB) examination being a requirement for pharmacy technicians.

Amy Yarcich, MPA, Executive Director and Lisa Casler, MSW, CPhT, Director of Affiliate Services, of RxPartnership, expressed concerns with the Regulation Committee's proposed legislative proposal making the PTCB exam mandatory for pharmacy technicians especially in a free clinic setting.

Dominic A. Solimando, Jr., M.A., BCOP, FAPhA, FASHP, President, of Oncology Pharmacy Services, stated his concerns with the Board's consideration that closed system transfer devices not be recommended to extend the beyond use date (BUD) of single dose vials.

The following individuals addressed the Board during public comment:

Rafael Saenz, Administrator, Pharmacy Services, Assistant Dean, VCU School of Pharmacy-UVA Division, with University of Virginia Health System expressed his support for the Boards consideration in making the PTCB a requirement for pharmacy technician registration. He stated any consideration for the Board to potentially grant waivers for obtaining PTCB certification is premature as time is needed to develop educational and training resources. Mr. Saenz also commented that the University of Virginia Health System has been working with Piedmont Community College to implement a ACPE/ASHP-accredited pharmacy technician training program for individuals to obtain PTCB certification.

Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA) echoed comments made at the Regulation Committee concerning the Pharmacy Benefits Managers (PBMs) and stated that the VPhA was willing to assist the Board with the issue as it moves forward. He also gave an update regarding VPhA's meeting with Senator Warner in Washington, DC and reported that Sen. Warner's staff was pleased that the Board of Pharmacy was discussing the matter of PBMs. He stated the REVIVE! naloxone training will be offered at the VPhA's annual meeting in July and that meeting agenda will also address red flags for pharmacists to consider when dispensing controlled substances and armed

robberies of pharmacies.

William Shimmel, Associate Executive Director, with the Pharmacy Technician Certification Board (PTCB) offered comments regarding other states considering a requirement for PTCB. He stated that Louisiana decided to require the accreditation of pharmacy technician training programs in 2016 and to not wait until 2020. He reported that the development of accredited training programs has been positive; Louisiana went from having 5 training programs to 17.

H. Otto Wachsmann, Jr., pharmacist, Stoney Creek Pharmacy, expressed concerns that if the Board requires pharmacy technicians to become PTCB certified that he may not be able to find qualifying individuals to hire. He indicated he practices in a rural, low income area, and that some individuals may not be able to afford to obtain PTCB certification. He also questioned the need for all pharmacy technicians to receive training on sterile compounding since not all pharmacy technicians will practice in a pharmacy performing this activity. Additionally, regarding a possible review of PBMs, he recommended meeting with rural pharmacists to get an understanding of the concerns they have in regards to patients' ability to access drugs safely in a rural community.

Rafael Saenz, Administrator, Pharmacy Services, Assistant Dean, VCU School of Pharmacy-UVA Division, with University of Virginia Health Systems addressed concerns with the cost and affordability of obtaining PTCB certification. He stated that Texas which has a large rural population has made it affordable and accessible for pharmacy technicians in these areas to obtain PTCB certification.

DHP DIRECTOR'S REPORT:

Dr. Brown reminded the Board of the upcoming DHP board member training program to be held September 28, 2015 and encouraged attendance. The Governor's Task Force on Prescription and Heroin Abuse was well represented by both the Board of Pharmacy and DHP. He stated that DHP will be taking the lead on developing a resource website, one of the recommendations adopted by the Task Force. The Task Force will finalize the implementation plan on June 16th. A regional meeting of neighboring states is scheduled in Abingdon, VA in September to discuss prescription drug and heroin abuse issues. Additionally, a conference is scheduled this November in Roanoke to communicate the Task Force's activities. Dr. Brown stated he discussed with Secretary Hazel the oversight of PBMs. It was agreed that a broad-based workgroup needs to be organized and that it would be headed-up by DHP. The workgroup will likely consist of various agencies and key stakeholders. He stated that the workgroup could discuss issues and areas of concern; any recommendations would be relayed to Secretary Hazel. The meeting date for this workgroup has yet to be determined.

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REGULATORY ACTIONS:

- CONSIDERATION OF ANY SCHEDULING ACTION FROM PUBLIC HEARING:

Ms. Yeatts requested that the Board consider whether the chemicals discussed during the public hearing should be placed into Schedule I. The possible scheduling of the following substances are:

MOTION:

The Board voted unanimously to adopt an exempt regulatory action to strike the following three chemicals from regulation that were placed into law by the 2015 General Assembly:

- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA);**
- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB); and**
- **3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA)**

and to place the following six chemicals identified by the Department of Forensic Science into Schedule I:

- **N-(1-amino-3, 3-dimethyl-1-oxobutan-2yl)-1-(cyclohexylmethyl) indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);**
- **methyl 2-(1-(5-fluropentyl)-1H-indazole-3-carboxamido)-3-methybutanoate (other name: 5-fluoro-AMB);**
- **1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201);**
- **1-4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144);**
- **4-bromomethcathinone (other name: 4-BMC); and,**
- **4-chloromethcathinone (other name: 4-CMC). (motion by Warriner, second by Logan)**

- REGULATION UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions included in the agenda packet. A majority of the regulations have been approved and will go into effect in July 2015. Ms. Yeatts stated that the regulatory action for collection sites for the disposal of unused drugs was currently in comment period until July 1st.

- REVENUE AND EXPENDITURE ANALYSIS:

Ms. Yeatts reported that the required revenue and expenditure analysis has been performed as indicated in the letter from Dr. Brown included in the agenda packet. Dr. Brown recommended that no action to change license fees be taken at this time.

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- REPORT FROM REGULATION COMMITTEE:

The Board was provided an update on the 2016 Legislative Proposals discussed at the Regulation Committee meeting that was held on May 11, 2015.

2016 LEGISLATIVE PROPOSALS:

- THIRD PARTY LOGISTIC PROVIDERS, WHOLESALE DISTRIBUTORS, TRACK AND TRACE REQUIREMENTS:

Ms. Juran reminded the Board that Title II of the Drug Quality and Security Act preempts state boards from licensing third party logistic providers as wholesale distributors, a licensing model currently used by this Board. Additionally, the federal law preempts state pedigree requirements which do not comply with federal track and trace requirements for drug distribution. The Regulation Committee recommended the Board adopt the legislative proposal, with definitions for "co-licensed partner" and "track and trace", to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in §54.1-3410.2 F.

MOTION:

The Board voted unanimously to adopt the legislative proposal as recommended by the Regulation Committee and presented to require wholesale distributors to comply with federal track and trace requirements; create three new licensing categories to include in-state and nonresident third party logistics providers and non-resident manufacturers; clarify that manufacturers may distribute drug without an additional license as a wholesale distributor; and clarify the use of bulk drug substances in compounding as presented in §54.1-3410.2 F. (motion by Thornbury, second by Warriner)

- NON-RESIDENT MEDICAL EQUIPMENT SUPPLIERS:

The Regulation Committee recommended that the Board adopt a legislative proposal to create a new licensing category for non-resident medical equipment suppliers.

MOTION:

The Board voted unanimously to adopt the legislative proposal as recommended by the Regulation Committee and presented to create a new licensing category for non-resident medical equipment suppliers.

- PTCB CERTIFICATION

The Board discussed the Regulation Committee's recommendation for adoption of a legislative proposal to require Pharmacy Technician

REQUIREMENT: Certification Board (PTCB) certification for initial registration as a pharmacy technician and to include the word "initially" in section B of the draft proposal prior to the word "registered". The proposal has a suggested delayed implementation date of July 2017. The Board discussed various subjects such as the impact the legislative proposal could have on high school students obtaining registration as a pharmacy technician, cost of training programs obtaining accreditation, cost of persons completing an accredited training program, and the impact on free clinic pharmacies. Ms. Yeatts stated that the Board could not "waive" the initial PTCB exam cost to pharmacy technicians working as volunteers in free clinics since it was not a Board-issued exam but could consider "reimbursing" the fee. Additionally, she stated that this policy decision did not need to be addressed in statute. It was recommended that the phrase "and the first examination fee for the Board-approved examination" be stricken in section F of the proposed language, along with "If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination." William Shimmel from PTCB stated PTCB does not have a minimum age requirement, but does require a high school diploma or GED prior to obtaining PTCB certification. Additionally, he stated currently there are six states to include Texas, Louisiana, North Dakota, Wyoming and South Carolina that require pharmacy technicians to obtain PTCB certification. There are twenty-one states that currently accept either state-required training or PTCB certification. Ms. Shinaberry stated that she believes there is sufficient time for pharmacy technician training programs to obtain accreditation prior to 2020 and that a sufficient number of programs will do so.

MOTION: **The Board voted unanimously to adopt the legislative proposal as amended to require certification from the Pharmacy Technician Certification Board (PTCB) as a prerequisite for initial registration as a pharmacy technician, to waive the initial application fee for board registration and subsequent renewals fees for a limited-use pharmacy technician registration who works exclusively in a free clinic pharmacy, and to propose a delayed implementation date of July 1, 2017. (motion by Warriner, second by Munden)**

ADDITIONAL LEGISLATIVE ISSUES CONSIDERED BY REGULATION COMMITTEE:

- VAWD accreditation

Ms. Juran gave the Board some background information regarding the Verified-Accredited Wholesale Distributors (VAWD) which is an accreditation issued by the National Association of Boards of Pharmacy (NABP). It was reported that the Regulation Committee determined that it would not recommend to the full board at this time to require VAWD since federal regulations supporting the Drug Supply Chain Security Act have not been fully implemented, but that the Board may wish to revisit

this topic in the future.

- Separate license for pharmacies performing sterile compounding:

Ms. Juran reported that counsel advised that it could not authorize or prohibit a pharmacy from performing sterile compounding based on a licensing model using a subcategory of the pharmacy permit via regulation. The Board discussed the possible need to submit a legislative proposal to create an additional licensing category for those pharmacies performing sterile compounding. It was decided not to adopt such a legislative proposal at this time, but that the Board may revisit this issue later.

RECOMMENDED LEGISLATIVE PROPOSALS FROM PMP ADVISORY COMMITTEE:

- Expanded access and reporting requirements:

Ms. Yeatts stated that the Regulation Committee heard legislative proposals that were drafted by the Prescription Monitoring Program (PMP) Advisory Committee. The PMP Advisory Committee recommended a legislative proposal to amend §54.1-2523 to expand a pharmacist's ability to access PMP data when consulting on a specific patient and not simply dispensing a drug. A second legislative proposal recommends changing the reporting requirement from within 7 days of dispensing to within 24 hours of dispensing or the next business day whichever comes later.

MOTION:

The Board voted unanimously to support the recommended legislative proposals from the Prescription Monitoring Advisory Committee (motion by Warriner, second by Thornbury)

CLOSED SYSTEM TRANSFER DEVICES TO EXTEND BUD OF SINGLE DOSE VIALS:

Ms. Juran reported that the Regulation Committee had discussed whether closed system transfer devices (CSTD) should be allowed to extend beyond use dates (BUD) of single dose vials. It was suggested in the committee meeting that perhaps CSTDs should be allowed for this purpose if site-specific testing was maintained to demonstrate its successful use to safely extend the BUD without contamination. Ms. Juran reported that she contacted USP to ensure this recommendation would be consistent with USP allowances and determine what criteria should be included in any site-specific testing. USP indicated that the use of CSTDs for this purpose is not addressed. The Board further discussed the 2014 compounding workgroup's recommendation to amend Guidance Document 110-36 to not recommend the use of closed system transfer devices to extend the BUD of single dose vials. It was recommended to include the compounding workgroup's recommendation in Guidance Document 110-36 and to monitor USP addressing this issue in a future revision.

MOTION:

The Board voted to include the 2014 compounding workgroup's recommendation in Guidance Document 110-36 indicating that a closed system transfer device should not be used to extend the beyond use date (BUD) of a single dose vial to exceed the 1 hour assigned BUD when punctured outside of an ISO Class 5 environment or the 6 hour assigned BUD when punctured within and not removed from an ISO Class 5 environment. (motion by Munden, second by Logan) (Warriner abstained)

NEW BUSINESS:

- ADOPTION OF NALOXONE PROTOCOL:

Ms. Juran reviewed with the Board HB 1458 and the draft language for the naloxone protocol that would allow a pharmacist to dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opiate overdose. She indicated the draft language resulted from a meeting and collaboration with staff from the Virginia Department of Health, Board of Medicine, Department of Behavioral Health and Developmental Services, the Department of Criminal Justice Services, the Prescription Monitoring Program, the Department of Health Professions, and the Board of Pharmacy.

MOTION:

The Board voted unanimously to adopt the naloxone protocol as presented. (motion by Thornbury, second by Warriner)

- REQUEST FROM VPHA TO AMEND GUIDANCE DOCUMENT 110-36

At the request of VPhA, the Board tabled the request to amend Guidance Document 110-36 until the September Board meeting.

- 2014 VIRGINIA WORKFORCE REPORT:

- Pharmacist report and pharmacy technician reports:

Elizabeth Carter, PhD, Executive Director, Healthcare Workforce Data Center, provided the Board with a summary of the workforce survey information collected from pharmacists and pharmacy technicians during the 2015 licensure renewal cycle. Dr. Carter also showed the Board where it can view additional information collected and presented by the Healthcare Workforce Data Center at www.vahwdc.tumblr.com

REQUEST FOR PERIODIC REGULATORY REVIEW:

Ms. Shinaberry requested that a periodic regulatory review be initiated by the Regulation Committee this year. It was stated that such a review usually takes a year to complete.

MOTION: **The Board voted unanimously to have the Regulation Committee initiate a periodic regulatory review this Fall. (motion by Thornbury, second by Munden)**

REPORTS:

CHAIRMAN'S REPORT: Ms. Shinaberry gave a brief report on upcoming events. She stated that Ms. Munden, Ms. Thornbury, Ms. Warriner, Ms. Juran and herself attended the NABP 111th Annual Meeting that was held in New Orleans, May 16th-May 20th. She also stated that the Virginia Board of Pharmacy received the Fred T. Mahaffey award during the awards dinner on May 19th. NABP and AACP will be holding the districts 1 and 2 meeting this year in New Hampshire, September 24th –September 26th. She encouraged attendance, if possible.

BOARD OF HEALTH PROFESSIONS: Ms. Shinaberry gave an update on recent activities of the Board of Health Professions. Dental hygienists scope of practice is still under review and they are awaiting comment from the Board of Dentistry. There will be an upcoming public hearing for a proposed funeral licensing category.

LICENSURE PROGRAM: Mr. Johnson reported the Board currently licenses 35,105 individuals and facilities. The Board issued 967 licenses and registrations for the period of March 1, 2015 through May 31, 2015. Inspectors conducted 363 facility inspections including 161 routine inspections of pharmacies: 42 (26%) resulted in no deficiency, 48 (30%) with deficiencies and 71 (44%) with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

DISCIPLINARY PROGRAM: Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of September 9, 2014; December 8, 2014; March 24, 2015; and June 12, 2015. For the final date, open cases were none at the entry stage; 55 at the investigation stage; 138 at the probable cause stage; 6 at the administrative proceedings division stage; 5 at the informal stage; two at the formal stage; and 123 at the pending closure stage for a total of 329 cases.

EXECUTIVE DIRECTOR'S REPORT: Ms. Juran reported on the NABP 111th Annual Meeting that was held in New Orleans May 16th-May 20th. She provided a brief overview of resolutions passed and officers elected. The Virginia Board of Pharmacy received the Fred T. Mahaffey Award for its exceptional contributions to the protection and welfare of the public health, specifically in addressing concerns with compounding. Ms. Juran then provided an update on the DEA Pharmacy Diversion Awareness Conference that was held May 30th and 31st. She provided a presentation on board-related activities at the conference. She reported that an Epinephrine Workgroup met on May 27th as required pursuant to SB1167. VDH, DHP and other various

stakeholders met to discuss possibly expanding access to epinephrine. There is a second meeting scheduled for July 30th. She stated that the Governor's Task Force on Prescription Drug and Heroin Abuse met in May. A final implementation plan will be approved by the task force in June. The work will continue throughout the summer until its final meeting in September. Two new test forms for the Federal and State Drug Law Exam will be utilized in the near future. A workgroup will also begin the process for performing a job analysis for the pharmacy technician exam. The Drone and Space Law Continuing Education program will be held in Wise County, July 15th. Ms. Juran stated she will be highlighting an innovative (pilot) program wherein Mountain Care Pharmacy will use drones in an exhibition manner to deliver a small quantity of dispensed schedule VI drugs to the pharmacy on-site during the RAM clinic this July in Wise County. A Wildlife Rehabilitator Workgroup will meet upon request of the General Assembly. The meeting will be convened to examine the laws impacting veterinarians who supervise and work with wildlife rehabilitators. Currently, there is no authority for wildlife rehabilitators to possess drugs to administer to injured wildlife and this group will meet to discuss this aspect. A report will be provided to the legislators by November 1, 2015. Ms. Juran and Ms. Shinaberry will participate in this workgroup. The Board of Pharmacy will present a law update at the VPhA annual meeting being held in Williamsburg, July 26th-July 28th. There is a Virginia Substance Abuse Conference to be held in southwest Virginia September 24th-25th. Ms. Juran will be assisting in the planning of this event over the summer with Ralph Orr, Program Manager for the PMP and many others from various state agencies. She will also attend an NABP MPJE meeting in Chicago in August. The vacant disciplinary administrative assistant position was re-advertised and interviews are being scheduled. Lastly, she reported that pharmacy inspectors Vicki Garrison and Nan Dunaway announced that they were retiring May 1, 2016.

ELECTION OF OFFICERS:

MOTION: **The Board voted unanimously to elect Ms. Munden as chairman for the term July 1, 2015 through June 30, 2016. (motion by Shinaberry, second by Logan)**

MOTION: **The Board voted unanimously to elect Ms. Warriner as vice-chairman for the term July 1, 2015 through June 30, 2016. (motion by Munden, second by Shinaberry)**

CONSIDERATION OF CONSENT ORDERS

MOTION FOR CLOSED MEETING: **The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, James Rutkowski, and Heather Hurley attend the closed meeting**

because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Munden, second by Logan)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Munden, second by Warriner)

MOTION:

Upon a motion by Mr. Boone and duly seconded by Mr. Elliott, the Board voted 8-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Janet R. Underhill, a pharmacist.

ADJOURN:

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

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

15

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, June 16, 2015
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

PRESIDING: 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

CARDINAL HEALTH 414, LLC
Permit Number 0201001970

Richard L Green, Director of Radiopharmacy Practice, appeared with Michael A. Mone, V.P. Associate General Counsel, to discuss allegations that Cardinal Health 414, LLC may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 15, 2015 Notice.

Closed Meeting: Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Cardinal Health 414, LLC. 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 Ms. Thornbury, and duly seconded by Mr. Logan, the Committee accepts allegation #2a and #2b as a Findings of Fact and

Conclusions of Law, unanimously voted to enter an Order that imposed a $2,000 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Cardinal Health 414, LLC, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Cardinal Health 414, LLC 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.

WEGMANS FOOD MARKETS, INC.
Permit Number 0201004223

T.J. Yantsides, Pharmacy Operations Manager, appeared to discuss allegations that Wegmans Food Markets, Inc. may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 15, 2015 Notice.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Wegmans Food Markets Inc. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene

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

Decision

Upon a motion by Mr. Elliott, and duly seconded by Mr. Logan, the Committee accepts allegation #2a and #2b as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $250 monetary penalty.

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

SHAYNA W. COBB
Pharmacist license #0202207592

Shayna W. Cobb, Pharmacist, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 15, 2015 Notice.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Shayna W. Cobb. 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 Ms. Thornbury, and duly seconded by Mr. Logan, the Committee unanimously voted to dismiss this matter.

ALICIA H. IRBY
Pharmacy Technician Registration
#0230018973

Alicia H. Irby, 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 May 15, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Irby's legal address of record.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Alicia H. Irby. 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. Thornbury, and duly seconded by Mr. Logan, the Committee made certain Findings of Facts and Conclusions of Law found Alicia Irby 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 nine hours of additional continuing education.

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

MATTHEW R. THOMPSON
Pharmacy Technician
Registration Number 0230010690

Matthew R. Thompson, Pharmacy Technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 15, 2015 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Thompson's legal address of record.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Matthew R. Thompson. 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 Ms. Thornbury, and duly seconded by Mr. Logan, the Committee accepts all allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $100 monetary penalty and requires the submission of ten additional hours of continuing education.

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

FOOD LION PHARMACY #2620
Pharmacy Permit #0201004006

John Bednarz, Manager, Nicole Y Smith, Pharmacy Operations Manager, Mark Polli, Director, Pharmacy Government & Regulatory Affaris, and Jessica Carr, Pharmacist In Charge appeared to discuss allegations Food Lion Pharmacy #2620 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 15, 2015 Notice.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 Food Lion Pharmacy #2620. 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 Ms. Thornbury, and duly seconded by Mr. Logan, the Committee accepts allegation #2 as a Finding of Fact and Conclusion of Law and unanimously voted to enter an Order that imposes a $250 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Food Lion Pharmacy #2620, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Food Lion Pharmacy #2620 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 #1431
Pharmacy Permit #0201003218

Grubinder Saini, Pharmacist-In-Charge, did not appear to discuss allegations that NAI Saturn Eastern, LLC d/b/a/ Safeway Pharmacy #1431 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 15, 2015 Notice. Mr. Saini indicated that he would not appear at the informal conference and provided the Committee with additional documentation.

Closed Meeting

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, 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 #1431. 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 Ms. Thornbury, and duly seconded by Mr. Logan, the Committee accepts all allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $1,250 monetary penalty.

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 #1431, 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 #1431 within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

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

ADJOURN: With all business concluded, the meeting adjourned at 2:10pm

Rebecca Thornbury, Chair

J. Samuel Johnson
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, July 9, 2015

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

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

TIME & PURPOSE: Pursuant to § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on July 9, 2015, at 11:10 a.m., to consider two summary suspensions.

PRESIDING: Empsy Munden, Chair

MEMBERS PRESENT:
Jody H. Allen
Sheila Elliott
Dinny Li
Empsy Munden
Rebecca Thornbury
Cindy Warriner

MEMBERS ABSENT:
Melvin L. Boone, Sr.
Michael I. Elliott
Ryan Logan
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Corie Tillman Wolf, Assistant Attorney General
Jim E. Rutkowski, Assistant Attorney General

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

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

DOUGLAS F. COVENTRY
License No: 0202-009376

Corie Tillman Wolf presented a summary of the evidence in this case.

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Thornbury, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice of pharmacy by Douglas F. Coventry poses a substantial danger to the public; and therefore, the license of Mr. Coventry to practice pharmacy be summarily suspended. Further, a Consent Order shall be offered to Mr. Coventry for the indefinite suspension of his pharmacist license for not less than two years.

JULIAN R. KLUTZ
Registration No: 0230-018448

Corie Tillman Wolf presented a summary of the evidence in this case.

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Allen, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice of pharmacy technicians by Julian R. Klutz poses a substantial danger to the public; and therefore, the registration of Mr. Klutz to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Mr. Klutz for the indefinite suspension of his pharmacy technician registration for not less than two years.

ADJOURN:

With all business concluded, the telephone conference call adjourned at 11:40 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Empsy Munden, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, July 23, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

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

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

PRESIDING: Jody Allen, Committee Chair

MEMBERS PRESENT: Ryan Logan, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist
Corie E. Tillman Wolf, Assistant Attorney General

Brenda A. Epps
License Number 0202-005189

Brenda A. Epps appeared with Crystal Bailey, her attorney and daughter; and Viola Coleman, her mother to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 21, 2015, Notice.

Closed Meeting: Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, 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 Brenda A. Epps. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, the Committee voted to send this matter to a formal administrative hearing.

ADJOURN: With all business concluded, the meeting adjourned at 3:30 p.m.

Jody Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, August 4, 2015
Commonwealth Conference Center
Second Floor
Board Room 4

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 9:40 a.m.

PRESIDING: Cindy Warriner, Chair

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Sheila Elliott
Ryan Logan
Ellen Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Sharon Davenport, Administrative Assistant
James Rutkowski, Assistant Attorney General
Corie Tillman Wolf, 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.

KILEY J. KESSLER
Registration No. 0230-023259

A formal hearing was held in the matter of Kiley J. Kessler to discuss allegations that she may have violated the laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Kessler was not present at the hearing. The Board proceeded with the hearing in Ms. Kessler's absence as the Notice of Hearing was mailed to her legal address of record, both by regular and certified mail. Ms. Warriner ruled that adequate notice was provided to Ms. Kessler.

Corie Tillman Wolf, Assistant Attorney General, presented the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Jennifer Challis, DHP Senior Investigator; and David Flamia, Kroger District Manager, testified on behalf of the Commonwealth. Further, Daniel Sikes, former Kroger Loss Prevention Manager, testified by telephone for the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Allen, 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 Kiley J. Kessler. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran 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. Elliott, and duly seconded by Ms. Allen, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Tillman Wolf, amended by the Board, and read by Mr. Rutkowski.

Upon a motion by Ms. Elliott and duly seconded by Ms. Allen, the panel voted 6-0 to revoke the right of Ms. Kessler to renew her registration to practice as a pharmacy technician.

EMILE S. BROWN
Registration No: 0230-014591

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice by Emile S. Brown as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Emile S. Brown to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Ms. Brown for the revocation of her pharmacy technician registration.

Adjourn:	With all business concluded, the meeting adjourned at 11:45 a.m.

Cindy Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, August 11, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 10:20 a.m.

PRESIDING: Cindy Warriner, Committee Chair

MEMBERS PRESENT: Ryan Logan, Committee Member

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

THE WELLNESS PHARMACY
Permit No: 0201-003469

Bruce K. Kowiatek, Pharmacist in Charge of The Wellness Pharmacy, appeared with Margaret Hardy, their attorney, to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 16, 2015, Notice.

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

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

Decision: Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order imposing a $10,000 monetary penalty.

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

BRUCE K. KOWIATEK
License No: 0202-205739

Bruce K. Kowiatek appeared with Margaret Hardy, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the conduct of pharmacy as stated in the July 16, 2015, Notice.

Closed Meeting:

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

Reconvene:

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

Decision:

Upon a motion by Mr. Logan, and duly seconded by Ms. Warriner, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order reprimanding Mr. Kowiatek.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Kowiatek unless a written request is made to the Board within that time from Mr.

Kowiatek requesting a formal hearing on the allegations made against it. 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 1:00 p.m.

Cindy Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, August 11, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 1:20 p.m..

PRESIDING: Jody Allen, Committee Chair

MEMBERS PRESENT: Ryan Logan, Committee Member

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

JULIE N. WALKER
Registration No: 0230-008511

Julie N. Walker, appeared with her husband, Ronnie Wilson, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians and to discuss her request for the reinstatement of her registration as stated in the July 15, 2015, Notice.

Closed Meeting: Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, 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 Julie N. Walker. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision:

Upon a motion by Mr. Logan, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order requiring Ms. Walker, pursuant to § 54.1-2400(15) of the Code, to submit to a mental health evaluation with a report being submitted to the Board no later than December 31, 2015.

Said Order cannot be appealed.

ADJOURN:

With all business concluded, the meeting adjourned at 4:15 p.m.

Jody Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board **as of September 11, 2015**

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Prohibition against incentives to transfer prescriptions [Action 4186] NOIRA - *At Governor's Office for 25 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Collection sites for disposal of unused drugs [Action 4337] NOIRA - *Register Date: 6/1/15* Adoption of Proposed Regulations: 9/29/15
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Governor's Office for 25 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	(E) Placement of chemicals in Schedule I [Action 4376] Final - *Register Date: 7/13/15* *Effective: 8/12/15*

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

Staff Note:

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

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of Code section § 54.1-3443

Copy of regulation to schedule certain chemicals

Board action:

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

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on September 29, 2015** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 1, 2015 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

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

1. **Acetyl fentanyl (other name: desmethylfentanyl)**

   Acetyl fentanyl is a powerful synthetic opioid similar in structure to fentanyl and has been identified in DFS laboratories; however, acetyl fentanyl has not been approved for medical use in the United States. The Drug Enforcement Administration (DEA) issued a notice of intent on May 21, 2015 to temporarily place acetyl fentanyl into Schedule I. Upon finalization of this proposed action, DFS recommends placing acetyl fentanyl into Schedule I (§ 54.1-3446(1)).

2. **Etizolam**

   Etizolam is chemically related to the class of drugs referred to as benzodiazepines which are central nervous system depressants. Etizolam has been approved for medical use in some countries; however, Etizolam has not been approved for medical use in the United States and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. **4-Iodo-2,5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH)**

   25I-NBOH is classified as a research chemical and is similar in structure to 25I-NBOMe – a schedule I compound. 25I-NBOH has been identified in DFS laboratories including post mortem toxicology cases. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

4. **alpha-Pyrrolidinohexiophenone (other name: alpha-PHP)**

   Alpha-PHP is classified as a research chemical and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

5. **alpha-Pyrrolidinoheptiophenone (other name: PV8)**

   PV-8 is classified as a research chemical and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

6. **1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201)**

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

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

§ 54.1-3443. Board to administer article

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

1. The actual or relative potential for abuse;

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

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

4. The history and current pattern of abuse;

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

6. The risk to the public health;

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

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

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

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

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Courts of Justice and Senate Courts of Justice Committees of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to Schedule I or II. Nothing in this subsection shall preclude the Board from adding substances to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under

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

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

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

1972, c. 798, § 54-524.84:1; 1976, c. 614; 1988, c. 765; 1993, c. 866; 1996, c. 408;2014, cc. 674, 719

Project 4220 - none

BOARD OF PHARMACY

Placement of chemicals in Schedule I

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

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

1. Cannabimimetic agents:

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

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

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

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

2. Substituted cathinones:

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

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

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

1. Acetyl fentanyl (other name: desmethylfentanyl)

2. Etizolam

3. 4-Iodo-2, 5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH)

4. Cannabimimetic agent:

a. 1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201)

5. Substituted cathinones:

a. Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP)

c. Alpha-Pyrrolidinoheptiophenone (other name: PV8)

D. The placement of drugs listed in subsection A shall remain in effect until February 8, 2017, and the placement of drugs listed in subsection B shall remain in effect until (18 months from the effective date), unless enacted into law in the Drug Control Act.

Agenda Item: Adoption of proposed regulations for pharmacies with drug collection boxes

Staff Note: Included in your package are copies of:

- Copy of NOIRA
- Fact sheet from DEA on the Disposal Act to allow ultimate users to deliver unused controlled substance to authorized entities for disposal
- Draft amended regulations for consideration by the Board.

Action:

Motion to adopt proposed amendments as presented or as modified

	VA.R. Document Number: R____-_____
	Virginia Register Publication Information Date: 6/1/2015 Issue: 20 Volume: 31
5/11/2015 2:06 pm Date / Time filed with the Register of Regulations	

Transmittal Sheet: Notice of Intended Regulatory Action

Regulatory Coordinator: Elaine J. Yeatts
(804)367-4688
elaine.yeatts@dhp.virginia.gov

Promulgating Board: Board of Pharmacy

NOIRA Notice:	Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending the following regulations
Chapters Affected:	
18 vac 110 - 20:	Virginia Board of Pharmacy Regulations
Action Title:	Collection sites for disposal of unused drugs
Agency Summary:	The purpose of the proposed action is summarized as follows: The intent of this regulatory action is to establish standards for collection sites similar to those required by the DEA in order to register as an "authorized collector." In order for the Virginia Board to inspect for and enforce standards for collection on controlled substances, they must be set in regulations adopted by the Board. If requirements for collection and destruction are not followed, there may be opportunity for diversion of donated drugs or adulteration of controlled substances if there is risk of co-mingling with existing stocks. Designation of authorized collection sites will facilitate the disposal of unused prescription drugs, which in turn reduces the supply of such drugs for abuse and diversion. However, the collection must be handled in a manner that protects the drugs until destruction in compliance with local, state, and federal laws.
Statutory Authority:	State: Chapters 33 and 34 of Title 54.1 Federal:

Is a public hearing planned for the proposed stage? Yes

Public comments may be submitted until 5:00 p.m. on 7/1/2015.

Does the Agency Background Document include an announcement of a periodic/small business impact review?	No
If this stage is the result of a small business impact review does the Agency Background Document include a report of findings?	No
Agency Contact:	Caroline Juran, RPh Executive Director (804)367-4416 (804)527-4472 ()- caroline.juran@dhp.virginia.gov
Contact Address:	Department of Health Professions 9960 Mayland Drive Suite 300 Richmond, VA23233-1463
APA Compliance:	This regulation has been adopted in accordance with the Administrative Process Act.

Action ID: 4337 Stage ID: 7187 RIS Project ID: 004325

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DISPOSAL REGULATIONS: REGISTRANT FACT SHEET

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 ("Disposal Act"). The final rule is available for public view at http://www.federalregister.gov/public-inspection. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on http://www.regulations.gov, and our website, http://www.DEAdiversion.usdoj.gov. This Registrant Fact Sheet contains a general summary of some of the effects of the new rule on registrants. For detailed information, please visit our website or contact your local DEA office.

1. What is the Disposal Act?

- The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

2. What do the implementing regulations do?

- Effective October 9, 2014, the implementing regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

- The new regulations reorganize and consolidate previously existing regulations on disposal, including the role of reverse distributors. Effective October 9, 2014, the existing regulation on disposal of controlled substances, 21 C.F.R. 1307.21, will be removed. New requirements on proper disposal procedure and security will be in a new part 1317.

- As of October 9, 2014, all Memoranda of Agreement (MOA) and Memoranda of Understanding (MOU) issued pursuant to current 21 C.F.R. 1307.21 will be null and void. Registrants should consult 21 C.F.R. 1317.05(a) for information on new MOAs and MOUs for the disposal of controlled substances.

- Effective October 9, 2014, the existing regulation on return and recall, 21 C.F.R. 1307.12, will be removed. New return and recall requirements for registrants and non-registrants are incorporated into new 21 C.F.R. 1317.10 and 1317.85.

- Effective October 9, 2014, registrants must use DEA Form 41 to record the destruction of controlled substances. However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (*e.g.*, some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as "drug wastage" and "pharmaceutical wastage"). Such remaining substance must be properly recorded, stored, and

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destroyed in accordance with DEA regulations (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

3. **Who is an "ultimate user"?**

   - The CSA defines an "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."

4. **What is "collection"?**

   - "Collection" means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term "collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

5. **How can a registrant become an "authorized collector"?**

   - Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at http://www.DEAdiversion.usdoj.gov. Once authorized, these entities are "authorized collectors."

   - Eligible registrants must have authority to handle schedule II controlled substances.

   - Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

6. **Who can operate a collection receptacle for the collection of pharmaceutical controlled substances?**

   - Authorized collectors may maintain collection receptacles inside their registered location; and Federal, State, tribal, or local law enforcement may continue to maintain collection receptacles inside their physical location.

   - Authorized hospitals/clinics with an on-site pharmacy, and retail pharmacies, may maintain collection receptacles at long-term care facilities.

7. **Who can operate a mail-back program for the collection of pharmaceutical controlled substances?**

   - Authorized collectors with an on-site method of destruction may operate a mail-back program.

8. **If I become an authorized collector and decide to stop, how do I do so?**

   - *Collection receptacle:* Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical controlled substances in their possession in accordance with the new rule, and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

- *Mail-back program:* Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

9. **What can I collect as an authorized collector?**

- An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.

- Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (*i.e.*, registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

10. **Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?**

- No. Ultimate users may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

11. **I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?**

- No. A collector shall not require any person to provide any personally identifying information.

12. **How does a registrant dispose of controlled substances when 21 C.F.R. 1307.21 is removed?**

- The authorized methods and procedures regarding disposal are outlined, in 21 C.F.R. 1317.05, according to whether the substances being disposed of are practitioner inventory, non-practitioner inventory, or collected controlled substances.

13. **How can a registrant destroy controlled substances?**

- The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceutical controlled substances must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.

- "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

Draft Regulations for Collection Sites

Chapter 20. Regulations Governing the Practice of Pharmacy

18VAC110-20-10. Definitions.

"*Collector*" means a registered manufacturer, wholesale distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or pharmacy that is authorized by the Drug Enforcement Administration to receive controlled substances from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility for the purpose of destruction.

18VAC110-20-211. Disposal of drugs by authorized collectors.

Any narcotic treatment program, hospital/clinic with an on-site pharmacy, or pharmacy wishing to accept for return a previously dispensed controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility must first be authorized by DEA as a collector. The process used to collect and destroy controlled substances, along with any required recordkeeping, shall comply with applicable federal and state law.

1. Prior to collecting controlled substances, an authorized collector shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method(s) of collection (i.e., collection receptacle and/or mail-back program); and,

c. Signature of PIC or medical director of a narcotic treatment program.

2. If an entity chooses to cease acting as a collector, the PIC or medical director shall notify the board within 30 days.

3. A narcotic treatment program that does not have an in-house pharmacy shall obtain a controlled substance registration.

Chapter 50. Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers

18VAC110-50-51 Disposal of drugs by authorized collectors.

Any manufacturer, wholesale distributor, or reverse distributor wishing to accept for return a previously dispensed controlled substance for the purpose of destruction from an ultimate user, or a person lawfully entitled to dispose of an ultimate user decedent's property must first be authorized by DEA as a collector.

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The process used to collect and destroy controlled substances, along with any required recordkeeping, must comply with federal and state law.

1. Prior to collecting controlled substances, the manufacturer, wholesale distributor, or reverse distributor shall submit in writing to the board:

a. The name, address, and license number, if applicable, of the facility;

b. The intended method(s) of collection (i.e., collection receptacle and/or mail-back program); and,

c. Signature of the responsible party.

2. If an entity chooses to cease acting as a collector, the responsible party shall notify the board within 30 days.

48.B

(FINAL/APPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

May 11, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Cynthia Warriner, Committee Chairman

MEMBERS PRESENT:
Michael Elliott
Ryan Logan
Empsy Munden
Ellen Shinaberry

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

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

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

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

pharmacy benefit management companies (PBMs) and stated that the major concern is the clinical aspect. He stated that there have been issues with delays in treatment because of the PBMs and their prior authorization system. Additionally, he discussed with the board written comment provided by VPhA which summarized numerous negative interactions Virginia pharmacists have had with PBMs. The question to be addressed is who is making the decisions regarding the patient's care and who has the oversight. Mr. Musselman referenced regulations where he feels the Board has jurisdiction to regulate the PBMs. He requested that the committee recommend proposed regulations that would allow the Board to take regulatory action against PBMs.

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

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

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

Kerri Musselman, Director of Bon Secours Pharmacy, expressed concerns with PBMs based on personal experiences involving prior authorizations and certain drugs inexplicably being deemed specialty drugs. She referenced an example wherein a PBM classified enoxaparin as a specialty drug, but did not classify the lesser expensive drug, heparin,

as a specialty drug even though heparin requires more intensive treatment monitoring. She indicated it was a difficult process to navigate as a pharmacist and expressed concern for those patients who do not have her level of understanding of PBMs. She feared these patients may not being able to receive their medications in a timely manner.

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

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

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

EMERGENCY REGULATIONS FOR OUTSOURCING FACILITIES:

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

MOTION:

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

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

MOTION:

The committee voted unanimously to recommend to the full board at the September 2015 full board meeting that it adopt the draft

proposed regulations for outsourcing facilities as amended. (motion by Munden, second by Elliott)

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

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

MOTION:

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

MOTION:

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

MOTION:

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

REGULATIONS FOR PACE FACILITIES:

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

MOTION:

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

POSSIBLE LEGISLATIVE PROPOSALS:

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

Ms. Juran presented to the committee possible legislative proposals for the upcoming General Assembly session. The proposals were on the following topics: replace current pedigree requirements with a requirement for wholesale distributors to comply with federal track and trace requirements; create licensure categories for third-party logistic providers, non-resident third-party logistic providers, non-resident manufacturers, and nonresident medical equipment suppliers; whether

wholesale distributors should be required to obtain Verified-Accredited Wholesale Distributors accreditation (VAWD); clarification that a manufacturer may ship without obtaining a wholesale distributor permit; and, the consideration of creating a separate permit for those pharmacies that compound sterile drugs. The Board requested counsel to research whether the Board may identify sterile compounding pharmacies through a subcategory of the pharmacy permit in regulation, in lieu of creating a new licensing category in statute. The Board also requested staff to research definitions for "co-licensed partner" and "track and trace" that could be incorporated into the proposed legislative proposal.

MOTION:

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

Nonresident Medical Equipment Suppliers:

MOTION:

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

Separate License for Pharmacies Performing Sterile Compounding:

MOTION:

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

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

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

- PMP legislation:

Ralph A. Orr, Program Manager, Prescription Monitoring Program (PMP) gave a brief update on the PMPs current legislative proposals for the 2016 General Assembly. The PMP advisory committee recommended a legislative proposal to amend §54.1-2523 to expand a pharmacist's ability to access PMP data when consulting on a specific patient and not simply dispensing a drug. Mr. Orr also stated that the

and that access, safety and cost were areas that could be addressed with a broader work group. After discussion, Dr. Brown agreed that he and Ms. Juran would contact Secretary Hazel to explore possible next steps.

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

Cynthia Warriner, Committee Chairman

5/16/15
Date

Caroline D. Juran, Executive Director

6/15/15
Date

Agenda Item: Adoption of Emergency Regulations for Outsourcing Facilities and Compounding

Included in your agenda package are:

A copy of the 2015 legislation mandating issuance of permits to resident and non-resident outsourcing facilities

A copy of the emergency regulations as recommended by the Regulation Committee

Board action:

Adoption of emergency regulations as recommended by the Regulation Committee

CHAPTER 300

An Act to amend and reenact §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5, relating to outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration.

[H 1737]

Approved March 17, 2015

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5 as follows:

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a

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

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

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

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

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

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

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

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

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

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

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

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

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

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

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

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

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

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

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

"Manufacturer" means every person who manufactures.

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

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

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

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions

of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

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

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

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

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

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

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

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

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

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

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

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

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

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not

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include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

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

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

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

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

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

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

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

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

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

§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with §54.1-3410.2.

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

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

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

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

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

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to

commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

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

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

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

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

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

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

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

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

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

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

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

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

H. Pharmacists shall not engage in the following:

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

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

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid

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prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

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

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

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

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

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

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

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

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. Every outsourcing facility shall compound in compliance with the requirements of state and

federal law and regulations except §54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

§ 54.1-3434.4. Prohibited acts.

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy ~~which~~ *or compounding services of an outsourcing facility that* has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy *or outsourcing facility* to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board, or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.

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

Chapter 20
REGULATIONS GOVERNING THE PRACTICE OF PHARMACY

Part I. General Provisions

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Pharmacy permit	$270
5. Permitted physician licensed to dispense drugs	$270
6. Medical equipment supplier permit	$180
7. Humane society permit	$20
8. Outsourcing facility permit	$270
~~8.~~9. Nonresident pharmacy registration	$270
10. Nonresident outsourcing facility registration	$270
~~9.~~11. Controlled substances registrations	$90
~~10.~~12. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
~~11.~~13. Approval of a pharmacy technician training program	$150
~~12.~~14. Approval of a continuing education program	$100
~~13.~~15. Approval of a repackaging training program	$50

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy permit – due no later than April 30	$270
5. Physician permit to practice pharmacy – due no later than February 28	$270
6. Medical equipment supplier permit – due no later than February 28	$180
7. Humane society permit – due no later than February 28	$20
8. Outsourcing facility permit – due no later than April 30	$270
~~8.~~9. Nonresident pharmacy registration– due no later than April 30	$270
10. Nonresident outsourcing facility registration – due no later than the date of initial registration	$270 $90
~~9.~~11. Controlled substances registrations –due no later than February 28	

~~10.~~12. Innovative program continued approval based on board order not to exceed $200 per approval period.	
~~11.~~13. Approval of a pharmacy technician training program	$75 every two years
~~12.~~14. Approval of a repackaging training program	$30 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy permit	$90
5. Physician permit to practice pharmacy	$90
6. Medical equipment supplier permit	$60
7. Humane society permit	$5
8. Outsourcing facility permit	$90
~~8.~~9. Nonresident pharmacy registration	$90
10. Nonresident outsourcing facility registration	$90
~~9.~~11. Controlled substances registrations	$30
~~10.~~12. Approval of a pharmacy technician training program	$15
~~11.~~13. Approval of a repackaging training program	$10

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$210
2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Humane society permit	$30
e. Outsourcing facility permit	$240
~~e.~~f. Nonresident pharmacy registration	$115
g. Nonresident outsourcing facility registration	$240
~~f.~~h. Controlled substances registration	$180
~~g.~~i. Approval of a pharmacy technician training program	$75

G. Application for change or inspection fees for facilities or other entities.

1. Change of pharmacist-in-charge	$50
2. Change of ownership for any facility	$50
3. Inspection for remodeling or change of location for any facility	150
4. Reinspection of any facility	$150
5. Board-required inspection for a robotic pharmacy system	$150
6. Board-required inspection of an innovative program location	$150
7. Change of pharmacist responsible for an approved innovative program	$25

H. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. Returned check	$35

Part IV. Pharmacies

18VAC110-20-215. Outsourcing facilities.

A. Any facility in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient shall obtain a permit as an outsourcing facility from the board in accordance with § 54.1-3434.05. Any outsourcing facility located outside of the Commonwealth that delivers in any manner Schedule II through VI drugs or devices into the Commonwealth without a prescription for a specific patient shall be registered with the board in accordance with § 54.1-3434.5.

B. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV and VI, with the following exceptions:

1. Subsections D and E of 18VAC110-20-190, relating to dispensed prescriptions.

2. Subsection A of 18VAC110-20-200, relating to prescriptions awaiting delivery.

3. Subsections B and C of 18VAC110-20-240, relating to prescriptions and chart orders.

4. Section 18VAC110-20-250, relating to automated data processing prescription records.

5. Subsections C, D, E, and F of 18 VAC110-20-270, relating to preparation and dispensing of prescriptions.

C. In addition to applicable requirements for pharmacies, outsourcing facilities shall comply with the following:

1. Pharmacist supervision.

At all times, such facilities shall be under the supervision of a PIC who routinely practices at the location designated on the permit application. A pharmacist shall be present at all times when the facility is open for business.

2. Records.

a. All records, including the receipt and disposition of drugs or devices, shall be maintained by the facility for a period of five years and shall be available to the board upon request.

Original DRAFT b. Compounding records shall include identification of the drugs and shall provide the active ingredient; the source of such active ingredient, 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 individuals units produced; and the national drug code number of the final product, if assigned.

DRAFT as adopted by Regulation Committee b. Compounding records shall include identification of the drugs and shall provide the ingredients; 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 individuals units produced; and the national drug code number of the final product, if assigned, or lot number.

c. Outsourcing facilities shall maintain quality control records to include stability and sterility testing for determining beyond use dating.

Renewal.

a. Upon initial application and at each renewal, outsourcing facilities shall submit to the board documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

b. Upon initial registration and at renewal, outsourcing facilities shall submit to the board a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5.

c. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations and requirements, except it shall compound in compliance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

d. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5 shall not meet the requirements for renewal of registration.

18VAC110-20-321. Compounding.

A. The compounding of both sterile and non-sterile drug products by a pharmacy that does not share the same physical space with an outsourcing facility shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

Agenda Item: Adoption of Emergency Regulations for Permitting Facilities in which Practitioners of the Healing Arts dispense controlled substances

Included in your agenda package are:

A copy of the 2015 legislation mandating issuance of permits to facilities in which practitioners of the healing arts dispense drugs

A copy of the emergency regulations as recommended by the Regulation Committee

Board action:

Adoption of emergency regulations as recommended by the Regulation Committee

CHAPTER 117

An Act to amend and reenact § 54.1-3304.1 of the Code of Virginia, relating to Board of Pharmacy; practitioners dispensing controlled substances.

[H 2192]

Approved March 16, 2015

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3304.1. Authority to license and regulate practitioners; permits.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. *Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.*

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

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

Regulations for Implementation of HB2192

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. ~~Fee for initial license for a practitioner of the healing arts to sell controlled substances.~~ Initial application fees.

~~1. The application fee for initial licensure shall be $240.~~
~~2. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.~~

1. License for practitioner of the healing arts to sell controlled substance license	$180
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$240

C. ~~Renewal of license for a practitioner of the healing arts to sell controlled substances.~~ Annual renewal fees.

~~1. The annual fee for renewal of an active license shall be $90. For the annual renewal due on or before December 31, 2009, the fee shall be $50.~~
~~2. The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee.~~

1. License for practitioner of the healing arts to sell controlled substance	$90
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$240

D. Late fees.

The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substance	$30
2. Permit for facility in which practitioners of the healing arts sell controlled substance	$40

~~3. The fee for reinstatement of a license expired for more than one year shall be $210.~~

E. Reinstatement fees.

Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. Practitioner of the healing arts to sell controlled substance license	$150
2. Practitioner of the healing arts to sell controlled substance facility permit	$240

3. The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.

F. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing facility permit.

~~D.~~G. The fee for reinspection of any facility shall be $150.

~~E.~~H. The fee for a returned check shall be $35.

PART II. LICENSURE REQUIREMENTS.

18VAC110-30-20. Application for practitioner licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After (6 months from effective date of the regulation), the practitioner shall engage in such sale from a location that has been issued a facility permit.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

18VAC110-30-21. Application for facility permit.

A. After (6 months from effective date of the regulation), any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1. A licensed practitioner shall make application for the facility permit on a form provided by the board.

~~C.~~B. For good cause shown, the board may issue a limited-use ~~license~~ facility permit, when the scope, degree or type of services provided to the patient is of a limited nature. The ~~license~~ permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. 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; and

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

3. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-30. Renewal of license and permit.

A. A license or facility permit so issued shall be valid until December 31 of the year of issue. Renewal of the license or facility permit shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or facility permit, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a ~~license~~ facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted ~~unless another practitioner at the same location has held an active license to sell controlled substances during that period~~. A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on expired status. If no other practitioner of the healing arts to sell controlled substances intends to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license or facility permit pursuant to this section may request that it be made current again at anytime within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

18VAC110-30-70. ~~Maintenance of a common stock of controlled substances~~ Practitioner in charge in a permitted facility.

~~Any two or more licensees who elect to maintain a common stock of controlled substances for dispensing shall~~ A facility with a permit for practitioners of the healing arts to sell controlled substances shall:

1. Designate a ~~licensee~~ practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the ~~first license~~ facility permit to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for ~~licenses~~ facility permits which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

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

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

F. No ~~license~~ or facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within the ~~immediate vicinity~~ 20 feet of the selling and storage area and not located within an examination room or restroom; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided the office is at least 40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18VAC110-30-120. Safeguards against diversion of controlled substances.

A device for the detection of breaking shall be installed in the controlled substances selling and storage area. The installation and the device shall be based on accepted burglar alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device;

2. The device shall be maintained in operating order;

3. The device shall fully protect the immediate controlled substance selling and storage areas and shall be capable of detecting breaking by any means whatsoever in the area when the area is closed;

4. The alarm system must have an auxiliary source of power;

5. The alarm system shall be capable of being activated and operated separately from any other alarm system in the area or the business in which the controlled substance selling and storage area is located;
6. The alarm system is controlled only by the licensee; and

7. An emergency key or access code to the system may be maintained as set forth in 18VAC110-30-130 B of this chapter.

Agenda Item: Adoption of Fast-track Regulations for repackaging of drugs at PACE sites

Included in your agenda package are:

A copy of the 2015 legislation mandating promulgation of regulations relating to training, packaging, labeling, and recordkeeping for such repackaging

A copy of the fast-track regulations as recommended by the Regulation Committee

Board action:

Adoption of regulations as recommended by the Regulation Committee by a Fast-track action

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 505

An Act to amend and reenact § 54.1-3420.2 of the Code of Virginia, relating to delivery of prescription drug orders; PACE programs.

[H 1733]

Approved March 23, 2015

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3420.2 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain circumstances chemical degradation of drugs may occur; and

2. Written notice shall be placed in each shipment providing a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs.

B. If a prescription drug order for a Schedule VI controlled substance is not personally hand delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to the residence of the patient, the delivery location shall hold a current permit, license, or registration with the Board that authorizes the possession of controlled substances at that location. The Board shall promulgate regulations related to the security, access, required records, accountability, storage, and accuracy of delivery of such drug delivery systems. Schedule II through Schedule V controlled substances shall be delivered to an alternate delivery location only if such delivery is authorized by federal law and regulations of the Board.

C. Prescription drug orders dispensed to a patient and delivered to a community services board or behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by a community services board or behavioral health authority facility for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and ~~record keeping~~ *recordkeeping* for such repackaging.

D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health or local health department clinic upon the signed written request of a patient, a patient's legally authorized representative, or a Virginia Department of Health district director or his designee may be stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.

E. Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3 upon the signed written request of the patient or the patient's legally authorized representative may be stored, retained, and repackaged at the site on behalf of the patient for subsequent delivery or administration. The repackaging of a dispensed prescription drug order retained by the PACE site for the purpose of assisting a client with self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy technician, nurse, or other person who has successfully completed a Board-approved training program for repackaging of prescription drug orders as authorized by this subsection. The Board shall promulgate regulations relating to training, packaging, labeling, and recordkeeping for such repackaging.

Regulations for Implementation of HB1733

Part XVI. Controlled Substances Registration for Other Persons or Entities.

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"PACE" means a program of all-inclusive care for the elderly licensed by the Department of Social Services pursuant to § 63.2-1701 and overseen by the Department of Medical Assistance Services in accordance with § 32.1-330.3.

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

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

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

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

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, ~~or~~ BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose

of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB, ~~or~~ BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

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

18VAC110-20-725. Repackaging by a CSB, ~~or~~ BHA, or PACE site.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB, ~~or~~ BHA, or PACE site, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB, ~~or~~ BHA, or PACE site using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB, ~~or~~ BHA, or PACE site.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB, ~~or~~ BHA, or PACE site.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB, ~~or~~ BHA, or PACE site.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB, ~~or~~ BHA, or PACE site for subsequent repackaging. If retained by the CSB, ~~or~~ BHA, or PACE site, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB, ~~or~~ BHA, or PACE site that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB, ~~or~~ BHA, or PACE site shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;
b. Name of client;
c. Prescription number of the originally dispensed prescription drug order;
d. Pharmacy name;
e. Drug name and strength;
f. Quantity of drug repackaged; and
g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB, ~~or~~ BHA, or PACE site and shall include the following:

a. Date of destruction:
b. Name of client;
c. Prescription number of the originally dispensed prescription drug order;
d. Drug name and strength;
e. Quantity of drug destroyed; and
f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB, ~~or~~ BHA, or PACE site for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation, and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any

jurisdiction in the United States or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB, BHA, PACE site, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval. A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB, ~~or~~ BHA, or PACE site.

A. As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB, ~~or~~ BHA, or PACE site may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging under the following conditions:

1. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier;

2. The compliance packaging shall comply with the requirements of 18VAC110-20-340 B;

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3. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

4. Any portion of a prescription drug order remaining at the CSB, ~~or~~ BHA, or PACE site that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB, ~~or~~ BHA, or PACE site shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

B. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

Request to Amend Guidance Document 110-36 *Compliance with USP Standards for Compounding*

Staff Note: Included in your agenda packet:

- Letter from VPhA requesting amendment to Guidance Document 110-36 to allow for alternative sterility testing methods
- Excerpt from June full board meeting minutes
- Current version of Guidance Document 110-36

Actions:

- Amend guidance document to allow for alternative sterility testing methods, OR
- Seek additional guidance from USP expert or consultant and table issue, OR
- Deny request

VIRGINIA PHARMACISTS ASSOCIATION

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June 1, 2015

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

Dear Dr. Shinaberry,

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

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

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

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

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

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

Laser Scanning Cytometry (LSC) – Benefits to patient safety over USP <71> for sterility testing

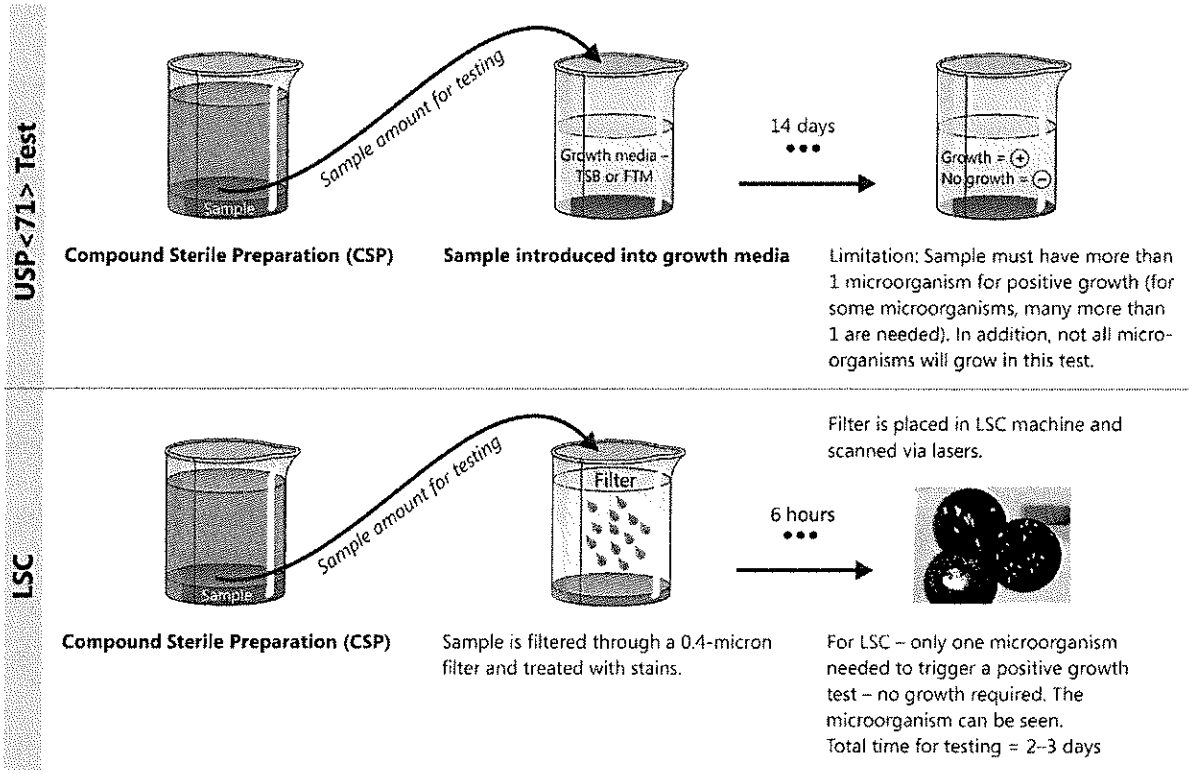
Background: USP <71>

First described in the 1930s, what is now known as the USP <71> test has been generally accepted test to evaluate a drug product's sterility before its release to be used in patients. A general overview of the test is provided in the graphic below. At the core, the test has three steps and has remained essentially unchanged for 80+ years. First, a predetermined amount (outlined in the test guideline) is removed from the final product – the "sample". This sample is then introduced to microorganism growth media (either Trypticase Soy Casein Digest Broth [TSB] or Fluid Thioglycollate Medium [FTM]) and allowed to incubate for fourteen days to promote growth of the microorganisms, since the test must have enough growth of the microorganism (depending on the type) to give a positive test. At the end of the fourteen days, the sample is read to see if there is growth (a positive result) or not (a negative result). The USP <71> test is widely accepted as the reference standard for sterility testing, both by the pharmacy and manufacturing communities.

Laser Scanning Cytometry (LSC) – what is it?

LSC was developed in the late 1990s as an answer to two limitations of the USP test: time and sensitivity. With LSC, the same amount is used for the sample as described in USP <71>. From there, the sample is filtered through a 0.4 micron filter (the same sized filter used in <71> for products that can be tested via filtration) and treated with proprietary background and viability stains to improve visibility of microorganisms. This step effectively captures 100% of microorganisms in the sample. The filter is then aseptically transferred to the LSC machine where lasers scan the filter for the presence of microorganisms. With the technology used in LSC, the test has the ability to detect a single microorganism in the sample. Also, since growth promotion (growth media with incubation) is not required, LSC is much more accurate than <71> in detecting the presence of microorganisms. This test can be performed in as little as six hours.

USP <71> vs LSC – graphical representation of how is the testing done



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Test sensitivity - <USP> 71 versus LSC

Comparison of the limits of detection (cells / mL^{-1})

Organism	LSC	USP <71>	LSC more sensitive by:
Clostridium sporogenes	0.000070	0.002992	**4,274%**
Propionibacterium acnes	0.000153	0.002805	**1,833%**
Escherichia coli	0.000805	0.003846	**477%**
Pseudomonas aeruginosa	0.001172	0.017179	**1,465%**
Staphylococcus aureus	0.000489	0.002871	**587%**
Bacillus sutilis	0.000192	0.001832	**954%**
Aspergillus niger	0.000690	0.003199	**463%**
Candida albicans	0.000178	0.005370	**30,168%**

"The ScanRDI® method (LSC) for detection of microbes was demonstrated to be statistically non-inferior to the reference sterility test (USP <71>) and numerically superior in that it had a likelihood of detecting microbes that was significantly greater at all dilution levels. As such, the ScanRDI® method is appropriate for use as a rapid alternative to the growth-based sterility test method."[1]

Problems with USP <71> & <797>

USP <71> testing procedures have a major flaw – the growth media (TSB or FTM) used to promote the growth of all microorganisms in the sample (if they are present). It has been widely reported for years in the scientific literature that these two media will not foster the growth of all microorganisms which could be harmful to humans. Additionally, questions arise about the accepted incubation time and if fourteen days is long enough to ensure enough growth of the microorganisms, if present, to ensure detection.

LSC advantages for patient safety

As described in the table and the illustration above, LSC allows for detection of microorganisms that is orders of magnitude more sensitive than the traditional USP <71> test, while providing these results in a more timely manner. With these orders of magnitude, LSC can detect much lower levels of contamination in relation to the <71> test. LSC looks directly for the microorganisms without the need for growth to a critical mass for detection as needed in <71>. Utilizing the LSC technology by a compounding pharmacy allows the pharmacy to be confident they are releasing a sterile product in a shorter time frame. Also, unlike USP <71>, all microorganisms can be detected in a single test. In order to detect all possible microorganisms present in a product, the USP <71> requires an additional test for fungal-type microorganisms.

Additionally, as per 21CFR612, current regulators are encouraging biological drug manufacturers to identify more rapid sterility test for their products as these items have very short shelf lives. LSC is one of the options manufactures are utilizing to perform sterility tests for these products.

Many pharmaceutical manufacturers have implemented LSC technology in their operations to perform sterility tests for their final products (e.g. Alcon, GlaxoSmithKline, etc). However, the technology has not had wide spread uptake by the manufacturing community for two primary reasons: cost (LSC costs more to run than the <71> test) and lack of need (manufacturing facilities that already have <71> implemented do not see a need for faster testing, despite the limitations of <71>). LSC has one additional limitation – with the fact that the sample must be filtered, only aqueous solutions can be tested via LSC.

Conclusion

The differences between USP <71> testing and utilizing LSC are stark – **LSC is superior in accuracy, orders of magnitude more sensitive and more timely than <71>**, all of which lead to higher confidence that a compounded sterile preparation is indeed sterile and thus provides a **greater benefit to patient safety**.

The Virginia Board of Pharmacy could allow the use of LSC or any other technology yet to be developed in future by adding in the follow verbiage:

"An alternate sterility test method to USP <71> may be used if verification results demonstrate the alternative is at least as effective and reliable as the USP <71> Sterility Test Method." USP provides guidance on how this process should be done (USP <1223> - Validation of Alternative Microbiological Methods) if the Board would like to also reference this chapter.

Footnotes / Bibliography

[1] Smith, Rex, et. al. "Evaluations of the ScanRDI as a Rapid Alternative to the Pharmacopoeial Sterility Test Method: Comparison of the Limits of Detection." *PDA Journal of Pharmaceutical Science and Technology*. 2010, 64: 356-363

Moldenhauer, Jeanne and Sutton, Scott. "Towards an Improved Sterility Test". *PDA Journal of Pharmaceutical Science and Technology*. 58.6 (2004): 284-286

Sutton, S. "The Sterility Tests" *Rapid Sterility Testing.* 2001. J. Moldenhauer (ed) PDA/DHI Publ pp 7-24

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DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 15, 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 9:15am

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Michael Elliott
Dinny Li
Ryan Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
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
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: Ms. Shinaberry requested that an additional item be included on the agenda. She requested the Board consider whether it's an appropriate time to initiate a periodic review of regulations. Additionally, she stated that the Virginia Pharmacists Association requested that discussion regarding its letter to amend Guidance Document 110-36 be tabled until the September board meeting. Ms. Juran also asked the Board to disregard the minutes from the March 11, 2015 Special Conference Committee meeting that was included in the agenda packet since the minutes were previously approved at the March 24th full board meeting. The agenda was approved as amended.

APPROVAL OF MINUTES: Staff provided to the board amended handouts of the May 13, 2015

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Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***Are there specific educational and training requirements regarding personnel?***

   Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in

their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***What BUD must be assigned to a single dose vial used in preparing a compounded sterile product?***

- If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;
- If the single dose vial is puntured within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;
- A puntured single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center For Disease Control (CDC) and USP Appendix);
- A closed system transfer device (CSTD) should not be used to extend the BUD of a single-dose vial to exceed the 1 hour BUD when punctured outside of an ISO Class 5 environment or the 6 hour BUD when punctured within and not removed from an ISO Class 5 environment.

5. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***
No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

6. ***How may stability information be taken into consideration when assigning a BUD?***

Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the

pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

7. ***What concepts, at a minimum, should be taken into consideration when determining drug stability?***

Pharmacists should use professional judgment to determine appropriate references of chemical stability information and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:

- Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
- Stability of the drug is not concentration-dependent; and,
- The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

8. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

9. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

10. ***Do batches less than 25 require sterility testing to be performed?***

No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:

- high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
- in multiple-dose vials (MDVs) for administration to multiple patients or

- CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

11. How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?

Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.
***Note- this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

13. How often must media-fill testing be performed?

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note - the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively. Annual media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

14. If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note- this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

15. Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?

Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

16. Does USP-NF address how long a CSP may hang for infusion?

No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

17. May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

18. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

19. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.

- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

20. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

21. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

22. How should a dilution or stock bag for pediatrics be treated?

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.

23. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.

24. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing). Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

25. How often must air and surface sampling be performed?

USP requires air sampling to be performed at least every 6 months. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). USP requires surface sampling to be performed "periodically". The Board advises that surface sampling should be performed at least quarterly. It may be performed by pharmacy personnel or outsourced.

26. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

27. What minimally should be taken into consideration when compounding multidose vials?

Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.

28. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

29. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

30. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- Not more than 3520 particles (0.5 μm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

31. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

32. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

33. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

34. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes.

35. In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?

USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and

radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

36. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (v) quantity.

37. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

38. What risk-level is associated with repackaging an undiluted multi-dose vial?

The repackaging of an undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.

Agenda Item: Adoption of Revised Guidance Document

Included in your agenda package are:

A Draft of Guidance Document 110-18 on Preparation for Administration

Staff Note:

At its March, 2013 meeting, the Board eliminated the final paragraph relating to advance preparation of drugs for school field trips. The Department of Education has requested re-insertion of that paragraph. There is a modification in the "new" paragraph to clarify who is authorized to prepare or package the drugs.

Board action:

Adoption of Guidance Document 110-18 as presented in the agenda package.

Guidance document: 110-18

Revised: ~~March 12, 2013~~
September 29, 2015

Virginia Board of Pharmacy

Interpretation of "administer" to include preparation for administration

The Board of Pharmacy finds that the term "administer", as defined in § 54.1-3401, can be reasonably interpreted to include the advance preparation or "set up" of medications to be administered to patients provided such advance preparation is performed only by a person licensed to dispense or administer drugs (medical practitioner, pharmacist, registered nurse, licensed practical nurse, or physician assistant) and the advance preparation is reasonably concurrent with the actual administration and should not extend beyond the next scheduled dosage administration.

However, if the advance preparation is to assist a patient, living in a private residence, in the administration of drugs which would normally be self administered, including insulin, such advance preparation shall not exceed a fourteen (14) day supply.

If the advance preparation, as performed by a person licensed to dispense or administer drugs, is to assist in the administration of medications to students during a single-day field trip, such advance preparation shall not be made prior to the last working day before the day of the field trip and shall not exceed a one-day supply. Any packaging used in such advance preparation shall include the student's name and any other appropriate student identifier; physician's name; drug name and strength, and quantity; and appropriate directions for administration. For any field trip which is longer than one day in length, a student's prescription medication should be provided by the student's parent or guardian in a properly labeled prescription vial which has been dispensed from a pharmacy and, for oral medications, which contains only the quantity needed for the duration of the field trip.

Adopted: June 11, 1998
Revised: ~~March 12, 2013~~ September 29, 2015

Virginia Board of Pharmacy

Wholesale Distributor Licensure Guidance

The holder of a New Drug Application or Abbreviated new Drug Application located in Virginia, regardless of whether it physically receives, stores or ships prescription drugs into the Commonwealth is deemed to be engaged in the practice of manufacturing ~~or wholesale distributing~~ and therefore must obtain a non-restricted manufacturer permit ~~or a nonresident wholesale distributor registration, whichever is applicable,~~ prior to engaging in business in Virginia.

A non-resident wholesale distributor does not need to obtain a Virginia Controlled Substances Registration in order to distribute Schedule II-V controlled substances. This registration is required for a licensed wholesale distributor or manufacturer located within Virginia that possesses Schedule II-V controlled substances.

To comply with the requirements for submission of a social security number or control number as required in Regulation 18VAC110-50-70, the following individuals shall provide a social security number or control number:

- the person serving as the responsible party, and;
- the individual owner or sole proprietor, or;
- each partner, or corporate officer and director, who is specifically responsible for the operations of the facility listed on the application.

Virginia Board of Pharmacy

Re-dispensing Drugs Previously Dispensed in Compliance Packaging

Subsection A, 2 of 54.1-3411.1 states:

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law;

The board interprets "sealed individual dose" to include drugs packaged in compliance packaging, e.g., bingo cards, when the following conditions are met:

- the compliance packaging meets official compendium class A or B container requirements, or better;
- only one drug is contained in the sealed dose; and,
- an appropriately assigned expiration date for the package is known.

Drug may only be re-dispensed when official compendium storage requirements are assured. Drug removed from a sealed individual dose may not be returned to a manufacturer stock bottle. Drug that has exceeded its expiration date or in packaging that was not assigned an expiration date at the time of the original dispensing may not be re-dispensed. Sealed doses containing more than one type of drug may not be re-dispensed. Drugs in Schedule II-V may not be returned to a pharmacy for re-dispensing unless authorized under federal law.

Drug removed from the sealed individual dose for re-dispensing may be repackaged in accordance with §54.1-3411.1. When repackaging in advance of dispensing the drug, the repackaging records required in Regulation 18VAC110-20-355 should include the original lot number from which the drug was first dispensed or if unknown, the originally assigned prescription number; the assigned expiration date may not exceed the originally assigned expiration date when first dispensed.

§ 54.1-3411.1. Prohibition on returns, exchanges, or re-dispensing of drugs; exceptions.

A. Drugs dispensed to persons pursuant to a prescription shall not be accepted for return or exchange for the purpose of re-dispensing by any pharmacist or pharmacy after such drugs have been removed from the pharmacy premises from which they were dispensed except:

1. In a hospital with an on-site hospital pharmacy wherein drugs may be returned to the pharmacy in accordance with practice standards;

2. In such cases where official compendium storage requirements are assured and the drugs are in manufacturers' original sealed containers or in sealed individual dose or unit dose packaging that meets official compendium class A or B container requirements, or better, and such return or exchange is consistent with federal law; or

3. When a dispensed drug has not been out of the possession of a delivery agent of the pharmacy.

B. (For contingent expiration - see Editor's note) Pursuant to a voluntary agreement between a nursing home or a hospital and a pharmacy, drugs may be transferred in accordance with subdivision A 2 between the nursing home or the hospital and the pharmacy for re-dispensing to indigent patients, either through hospitals, or through clinics organized in whole or in part for the delivery of health care services without charge, or to the indigent, free of charge, if the following procedures are satisfied:

1. The physical transfer shall be accomplished by a person authorized to do so by the pharmacy;

2. The person or his authorized representative from whom the prescription medication was obtained shall provide written consent for the donation and such consent shall be maintained on file at the licensed nursing home or hospital;

3. The person's name, prescription number, and any other patient identifying information, shall be obliterated from the packaging prior to removal from the licensed nursing home or hospital;

4. The drug name, strength, and expiration date or beyond-use date shall remain on the medication package label;

5. An inventory list of the drugs shall accompany the drugs being transferred that shall include, but not be limited to, the medication names, strengths, expiration dates, and quantities; and

6. Outdated drugs shall not be transferred and shall be destroyed in accordance with regulations adopted by the Board.

The pharmacist-in-charge at the pharmacy shall be responsible for determining the suitability of the product for re-dispensing. A re-dispensed prescription shall not be assigned an expiration date beyond the expiration date or beyond-use date on the label from the first dispensing and no product shall be re-dispensed more than one time. No product shall be accepted for re-dispensing by the pharmacist where integrity cannot be assured.

B. (For contingent effective date - see Editor's note) The Board of Pharmacy shall promulgate regulations to establish a Prescription Drug Donation Program for accepting unused previously dispensed prescription drugs that meet the criteria set forth in subdivision A2, for the purpose of re-dispensing such drugs to indigent patients, either through hospitals, or through clinics organized in whole or in part for the delivery of health care services to the indigent. Such program shall not authorize the donation of Schedule II-V controlled substances if so prohibited by federal law. No drugs shall be re-dispensed unless the integrity of the drug can be assured.

C. Unused prescription drugs dispensed for use by persons eligible for coverage under Title XIX or Title XXI of the Social Security Act, as amended, may be donated pursuant to this section unless such donation is prohibited.

D. A pharmaceutical manufacturer shall not be liable for any claim or injury arising from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient, or any other activity undertaken in accordance with a drug distribution program established pursuant to this section.

E. Nothing in this section shall be construed to create any new or additional liability, or to abrogate any liability that may exist, applicable to a pharmaceutical manufacturer for its products separately from the storage, donation, acceptance, transfer, or dispensing of any drug provided to a patient in accordance with a drug distribution program established pursuant to this section.

Request for Guidance regarding Issuance of Controlled Substances Registrations to Multiple Medical Clinics located within a Medical Office Building

Staff Note: Large medical clinics with multiple practitioners treating patients often apply for a controlled substances registration (CSR) and DEA registration in order to possess a shared stock of drugs under the facility's name as opposed to individual physician's stocking their own drugs. These clinics usually represent various types of practice, e.g., pediatric primary care, maternal and fetal medicine, pediatric outpatient rehabilitation services, teen and young adult health center, outpatient surgery, clinical trials, etc. and are often located within a single medical office building.

Pursuant to §54.1-3423 D, the board has historically issued a 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, the board has required a pharmacist or prescriber to serve as the supervising practitioner on the CSR application per Regulation 18VAC110-20-700 and a responsible party (usually a nurse directly accessing meds daily and responsible for recordkeeping) who is authorized by law to administer drugs.

DEA has recently indicated it will consider issuing a single DEA registration to a medical office building when the medical practices have the same owner. Staff is requesting guidance on whether it should approve a single CSR for a medical office building when the medical practices have the same owner.

Included in the agenda packet:

- Relevant law and regulations

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

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

1. Maintenance of effective controls against diversion of controlled substances into other than legitimate medical, scientific, or industrial channels;

2. Compliance with applicable state and local law;

3. Any convictions of the applicant under any federal and state laws relating to any controlled substance;

4. Past experience in the manufacture or distribution of controlled substances, and the existence in the applicant's establishment of effective controls against diversion;

5. Furnishing by the applicant of false or fraudulent material in any application filed under this chapter;

6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or dispense controlled substances as authorized by federal law; and

7. Any other factors relevant to and consistent with the public health and safety.

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

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

D. The Board may register other persons or entities to possess controlled substances listed on Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of the registration is consistent with the public interest, (iii) the possession and subsequent use of the controlled substances complies with applicable state and federal laws and regulations, and (iv) the subsequent storage, use, and recordkeeping of the controlled substances will be under the general supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the factors listed in subsection A of this section in determining whether the registration shall be issued. Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances registration for sites maintaining certain types and quantities of Schedules II through VI controlled substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register a public or private animal shelter as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase,

possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs 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.

F. The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.

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

H. Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within 14 days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

Part XVI. Controlled Substances Registration for Other Persons or Entities.

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

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

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

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

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

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

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

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

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

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are

being used as common stock by multiple practitioners and that one or more of the following factors exist:

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

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

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

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

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

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

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

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

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB or BHA as authorized in § 54.1-3420.2 of the Code

of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

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

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

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

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

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

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

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

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, and teaching institutions possessing only Schedule VI drug.

18VAC110-20-720. Requirements for recordkeeping.

The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedule II through VI drugs in accordance with provisions of §54.1-3404 of the Code of Virginia and the following:

1. Inventories and administration records of Schedule II drugs shall be maintained separately from all other records and shall be kept in chronological order by date of administration.

2. All records shall be maintained at the same location as listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. In the event that an inventory is taken as the result of a theft of drugs, the inventory shall be used as the opening inventory within the current biennial period. Such an inventory does not preclude the taking of the required inventory on the required biennial inventory date. All inventories required by §54.1-3404 of the Code of Virginia shall be signed and dated by the person taking the inventory and shall indicate whether the inventory was taken prior to the opening or after the close of business on that date. An entity which is open 24 hours a day shall clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken.

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

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

Possible Dates for 2016

Full Board Meetings:

March

Wednesday, March 2nd- Board Room 2
Thursday, March 3rd- Board Room 2
Tuesday, March 29th- Board Room 2
Wednesday, March 30th- Board Room 2
Thursday, March 31st, Board Room 2

June

Monday, June 13th- Board Room 2
Tuesday, June 14th- Board Room 2 (preferred)
Tuesday, June 28th- Board Room 2
Wednesday, June 29th- Board Room 2
Thursday, June 30th, Board Room 2

September

Wednesday, September 7th, Board Room 2
Thursday, September 8th- Board Room 2
Wednesday, September 28th, Board Room 2 (preferred)
Thursday, September 29th, Board Room 2 (preferred)

December

Monday, December 5th, Board Room 2
Monday, December 12th, Board Room 2
Thursday, December 15th, Board Room 4

Tentative Regulation Committee Meetings:

May

Wednesday, May 11th, Board Room 4
Thursday, May 26th, Board Room 2
Tuesday, May 31st, Board Room 2

November

Tuesday, November 1st, Board Room 2
Tuesday, November 8th, Board Room 4
Tuesday, November 29th, Board Room 2

Virginia Board of Pharmacy
Inspection Report
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Licenses Issued

	3/1/14-5/31/14	6/1/14-8/31/14	9/1/14-11/30/14	12/1/14 - 2/28/15	3/1/15 - 5/31/15	6/1/15-8/31/15	Current Active 9/1/2015
Business CSR	48	58	37	16	23	24	1,111
CE Courses	2	2	1	1	2	0	12
Limited Use Pharmacy Technician	0	2	0	0	0	0	22
Medical Equipment Supplier	21	25	26	24	16	13	642
Non-resident Pharmacy	30	43	23	31	41	24	654
Non-resident Wholesale Distributor	14	22	11	13	34	17	818
Non-restricted Manufacturer	0	1	0	0	0	2	25
Permitted Physician	0	0	0	0	0	0	3
Pharmacist	127	480	199	123	177	489	13,687
Pharmacist Volunteer Registration	0	2	0	0	0	4	0
Pharmacy	20	12	28	13	15	17	1,830
Pharmacy Intern	256	104	317	147	106	125	2015
Pharmacy Technician	574	579	412	429	518	564	13,995
Pharmacy Technician Training Program	1	13	4	6	2	4	118
Physician Selling Controlled Substances	50	52	45	36	26	44	694
Physician Selling Drugs Location	8	8	9	7	7	7	229
Pilot Programs	2	0	1	0	0	3	10
Repackaging Training Program	0	0	0	0	0	0	1
Restricted Manufacturer	1	0	0	0	0	0	71
Warehouser	1	5	2	0	0	0	48
Wholesale Distributor	3	0	0	2	0	1	121
Total	**1,158**	**1,408**	**1,115**	**848**	**967**	**1,338**	**36,106**

Virginia Board of Pharmacy
Inspection Report
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Inspections Completed

	3/1/14 - 5/31/14		6/1/14 - 8/31/14		9/1/14-11/30/14		12/1/14 - 2/28/15		3/1/15 - 5/31/15		6/1/15 - 8/31/15	
License Type												
Controlled Substances Registration	115		150		91		49		70		83	
Medical Equipment Supplier	24		51		30		10		7		25	
Non-restricted Manufacturer	2		1		1		1		1		3	
Permitted Physician	0		0		0		0		0		0	
Physician Selling Drugs Location	17		13		7		7		17		60	
Restricted Manufacturer	1		3		1		0		2		3	
Warehouse	3		9		3		1		6		4	
Wholesale Distributor	13		15		8		7		14		19	
Pharmacy	320		261		298		227		246		239	
Pilot											1	
Total	**495**		**503**		**439**		**302**		**363**		**437**	
Pharmacy (0201) Inspections												
Change of Location	7		8		10		8		5		5	
New	22		9		27		14		16		16	
Reinspection	6		7		7		7		8		10	
Remodel	24		37		51		45		37		34	
Routine	245		198		200		151		161		171	
Focus	1		2		3		2		3		2	
Federal Agency	15		0		0		0		15		0	
Compliance	0		0		0		0		1		1	
Total	**320**		**261**		**298**		**227**		**246**		**239**	
Pharmacy Routine Inspections												
No Deficiency	85	35%	70	35%	69	34%	35	23%	42	26%	45	26%
Deficiency	72	29%	71	36%	53	27%	56	37%	48	30%	63	37%
Deficiency & IPHCO	88	36%	57	29%	78	39%	60	40%	71	44%	63	37%
Total	**245**		**198**		**200**		**151**		**161**		**171**	

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Major Deficienices

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/14 - 2/15	3/15 - 5/15	6/15 -8/15	Total	Repeat Cumulative
Routine Inspections Completed	**248**	**198**	**200**	**151**	**161**	**171**	**1129**	
Total Major Deficiencies	**131**	**92**	**129**	**111**	**124**	**112**	**699**	**60**
Average Deficiencies per Inspection	**0.5**	**0.5**	**0.6**	**0.7**	**0.8**	**0.7**	**0.6**	
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	1	0	0	1	1	0	3	
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	1	0	2	2	0	1	6	
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	3	3	7	3	2	2	20	
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	0	1	0	0	1	
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	0	0	0	0	0	1	1	
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	1	0	1	1
7. Change of location or remodel of pharmacy without submitting application or Board approval	6	2	4	7	5	4	28	
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	3	3	4	3	2	2	17	
9. Alarm not operational or not being set	5	1	1	0	1	3	11	
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	0	1	3	1	0	2	7	1
10. Unauthorized access to alarm or locking device to the prescription department	0	3	2	4	4	1	14	

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Major Deficienices

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/14 - 2/15	3/15 - 5/15	6/15 -8/15	Total	Repeat
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	0	0	0	1	0	0	1	
12. Storage of prescription drugs not in the prescription department	9	4	8	9	12	7	49	
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	1	0	0	1	1	0	3	1
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	3	6	7	2	2	3	23	
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	11	8	15	10	11	10	65	3
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	28	16	23	15	22	21	125	33
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	7	2	8	3	6	5	31	1
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	1	2	1	0	0	0	4	
18. Records of dispensing not maintained as required	1	1	0	2	0	0	4	
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	4	4	2	1	2	3	16	1
20. Pharmacist not checking and documenting repackaging or bulk packaging	2	9	6	8	9	3	37	7

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Major Deficienices

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/14 - 2/15	3/15 - 5/15	6/15 -8/15	Total	Repeat
20a. Pharmacist not documenting final verification of non-sterile compounding	9	11	16	7	8	9	60	
20b. Pharmacist not documenting final verification of sterile compounding	7	4	4	8	13	5	41	
21. No clean room	3	0	0	1	1	0	5	
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	1	0	0	0	2	1	4	
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	1	1	0	2	0	0	4	
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	5	2	0	1	2	1	11	1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	1	1	0	2	4	
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	3	1	1	1	6	
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	3	1	0	0	4	
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0	
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0	

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Major Deficienices

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/14 - 2/15	3/15 - 5/15	6/15 -8/15	Total	Repeat
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	13	5	4	10	9	12	53	11
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	1	0	1	0	2	
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	1	0	1	
28. Compounding copies of commercially available products	0	0	0	0	0	0	0	
29. Unlawful compounding for further distribution by other entities	0	0	0	0	0	0	0	
30. Security of after-hours stock not in compliance	0	1	0	0	0	0	1	
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	1	0	0	1	
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	2	1	2	3	5	7	20	
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	3	0	2	0	0	0	5	
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0	
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	1	2	0	1	0	6	10	

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Minor Deficiencies

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/4-2/15	3/15-5/15	6/15-8/15	Total	Repeat Cumulative
Routine Inspections Completed	**248**	**198**	**200**	**151**	**161**	**171**	**1129**	
Total Minor Deficiencies	**227**	**174**	**168**	**165**	**192**	**217**	**1143**	**75**
Average Deficiencies per Inspection	**0.9**	**0.9**	**0.8**	**1.1**	**1.2**	**1.3**	**1.0**	
1. Repealed 6/2011	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**
2. Special/limited-use scope being exceeded without approval	0	0	0	0	0	1	**1**	
3. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	N/A	N/A	N/A	N/A	N/A	N/A	**0**	
4. Sink with hot and cold running water not available within the prescription department.	4	4	2	3	10	3	**26**	1
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	5	5	6	12	7	4	**39**	4
6. Prescription department substantially not clean and sanitary and in good repair	2	2	1	0	0	1	**6**	
7. Current dispensing reference not maintained	5	3	2	3	2	3	**18**	2
8. Emergency access alarm code/key not maintained in compliance	13	11	16	10	8	8	**66**	3
9. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	11	11	13	12	15	15	**77**	7
10. Storage of paraphernalia/Rx devices not in compliance	0	0	1	0	0	0	**1**	
11. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	0	1	0	1	4	1	**7**	
12. Biennial taken late but within 30 days	0	0	0	0	1	0	**1**	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	31	21	23	23	29	19	**146**	16
14. Records of receipt (e.g. invoices) not on site or retrievable	0	0	0	0	0	0	**0**	
15. Other records of distributions not maintained as required	2	0	1	0	2	0	**5**	

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Minor Deficiencies

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/4-2/15	3/15-5/15	6/15-8/15	Total	Repeat
16. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	2	1	0	1	4	0	**8**	
17. Minor 17 combined with Minor 16 – 6/2011	1	0	0	0	0	0	**1**	
18. Schedule II emergency oral prescriptions not dispensed in compliance	0	0	0	0	0	0	**0**	
19. Not properly documenting partial filling of prescriptions	30	25	22	23	15	10	**125**	13
20. Offer to counsel not made as required	0	0	0	0	0	0	**0**	
21. Prospective drug review not performed as required	0	0	0	0	0	0	**0**	
22. Engaging in alternate delivery not in compliance	3	4	1	2	0	7	**17**	
23. Engaging in remote processing not in compliance	0	2	1	0	1	6	**10**	
24. Labels do not include all required information	21	11	15	11	17	19	**94**	3
25. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	3	2	1	2	3	4	**15**	2
26. Special packaging not used or no documentation of request for non-special packaging	0	0	3	0	0	1	**4**	3
Repackaging, specialty dispensing, compounding:						0	**0**	
27. Repackaging records and labeling not kept as required or in compliance	6	7	8	14	11	7	**53**	9
28. Unit dose procedures or records not in compliance	0	0	0	0	0	0	**0**	
29. Robotic pharmacy systems not in compliance	1	1	0	0	0	0	**2**	
30. Required compounding/dispensing/distribution records not complete and properly maintained	32	28	25	20	27	23	**155**	5
30a. Compounded products not properly labeled	17	9	10	10	8	10	**64**	
31. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	1	1	0	0	0	0	**2**	
32. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	1	0	0	1	1	1	**4**	
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	0	0	0	**0**	

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Minor Deficiencies

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/4-2/15	3/15-5/15	6/15-8/15	Total	Repeat
Hospital specific or long-term care specific:							**0**	
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	2	1	0	0	0	0	**3**	
35. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	**0**	
36. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	**0**	
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	0	0	0	1	4	**5**	
38. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	4	2	0	3	2	1	**12**	
39. Emergency medical services procedures or records not in compliance	6	1	0	1	0	1	**9**	1
40. Emergency kit or stat-drug box procedures or records not in compliance	2	2	2	0	2	3	**11**	2
41. Maintaining floor stock in a long-term care facility when not authorized	1	0	0	0	0	1	**2**	
42. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	0	0	0	0	1	41	**42**	
43. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	0	0	0	2	0	**2**	
44. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	8	10	8	6	9	8	**49**	2
45. Insufficient enclosures or locking devices (Added 12/12/13)	7	5	4	3	2	5	**26**	2

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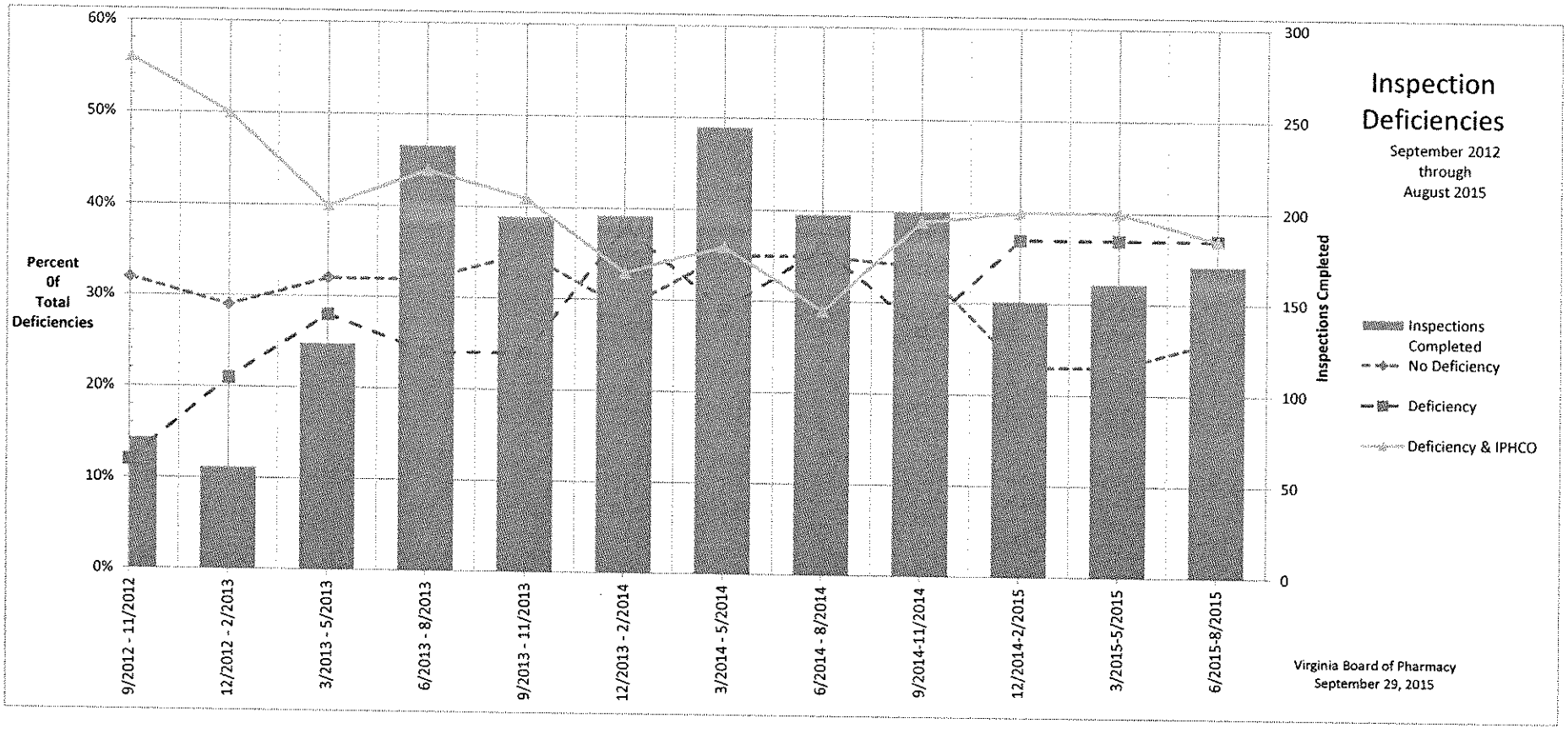
Minor Deficiencies

	3/14 - 5/14	6/14-8/14	9/14-11/14	12/4-2/15	3/15-5/15	6/15-8/15	Total	Repeat
46. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13)	2	4	1	2	5	4	**18**	
47. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	4	0	2	2	3	6	**17**	


Inspection Deficiencies
September 2012 through August 2015
Percent Of Total Deficiencies
Inspections Cmpleted
60%
50%
40%
30%
20%
10%
0%
300
250
200
150
100
50
0
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
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