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 7, 2016
9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Scheduling Certain Substances: Rebecca Thornbury, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
Call for Public Comment:	
• Possible scheduling of the Certain Chemicals in Schedule I of the Drug Control Act	1-4
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Call to Order of Full Board Meeting: Rebecca Thornbury, Chairman	
• Approval of Agenda	
• Approval of Previous Board Meeting Minutes:	
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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	
Regulatory Actions: Elaine Yeatts	
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o Permit Pharmacist to Dispense Quantity of Schedule VI Greater than Face Amount Prescribed, up to Total Amount Authorized	83-88

- Permit Use of Electronic Devices In lieu of Manual Emergency Kits and Stat Drug Boxes 89-94

Old Business: Caroline Juran

- Consideration for Accepting Inspection from Bestech GMP Contracting, Inc. in lieu of FDA inspection for Outsourcing Facilities 95-126

New Business:

- Amend Bylaws 127-130
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Reports:

- Chairman's Report – Rebecca Thornbury
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr. Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report –Caroline D. Juran Handout

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

Adjourn

****The Board will have a working lunch at approximately 12pm and recognize former board member Dinny Li. ****

****A panel of the board will convene at 1:30pm 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 7, 2016** 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 10, 2016 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:

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

The following compounds are classified as stimulants. Other drugs of this type have been placed in Schedule I
(§ 54.1-3446(5)) in previous legislative sessions.

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

The following compounds are powerful synthetic opioids. DFS recommends placing these compounds into Schedule I (§ 54.1-3446(6)).

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl)

6. 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]-benzenesulfonamide (other name: W-18)

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.

To: Caroline Juran, Executive Director, Board of Pharmacy
From: Scott Maye, Chemistry Program Manager, Virginia Department of Forensic Science
Date: July 29, 2016
RE: **Recommendation for Emergency Scheduling of Controlled Substances - UPDATE**

Ms. Juran,

This recommendation supersedes the recommendation dated July 15, 2016. Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified five (5) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description and chemical name for each compound.

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

The following compounds are classified as stimulants. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(5)) in previous legislative sessions.

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

The following compound is a powerful synthetic opioid. DFS recommends placing this compound into Schedule I (§ 54.1-3446(6)).

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide
(other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

M. Scott Maye
Chemistry Program Manager

Scheduling of Chemicals in Schedule I

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

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

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)

2. Flubromazolam

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)

4. Cannabimimetic agents:

a. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA)

b. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA)

c.Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA)

The placement of drugs listed in this subsection shall remain in effect until December 13, 2017, unless enacted into law in the Drug Control Act.

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

1. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)

2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone)

3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)

4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP)

5. 4-Chloroethcathinone (other name: 4-CEC)

6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone)

7. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)

8. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)

9. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl)

10. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)

11. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)

12. Clonazolam

13. Cannabimimetic agents:

a. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate

(other names: AMB-FUBINACA, FUB-AMB)

b. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)

c. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)

d. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005)

e. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide

(other name: AB-CHMICA)

The placement of drugs listed in this subsection shall remain in effect until March 7, 2018, unless enacted into law in the Drug Control Act.

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

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until (18 months after the effective date of the regulation), unless enacted into law in the Drug Control Act.

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, June 8, 2016
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 ("Board") was called to order at 9:45 a.m.

PRESIDING: Ryan K. Logan, Committee Chair

MEMBERS PRESENT: Rebecca Thornbury, Committee Member

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

STUART L. BEASLEY, JR.
License No. 0202-009029

Stuart L. Beasley, Jr., appeared with his attorney, Hunter W. Jamerson, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the April 12, 2016, 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 ("Code"), for the purpose of deliberation to reach a decision in the matter of Stuart L. Beasley, Jr. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, the Committee unanimously voted to refer the matter to a formal administrative hearing. In addition, a consent order for indefinite suspension shall be offered.

Adjourn:	With all business concluded, the meeting adjourned at 1:45 p.m.

Ryan K. Logan, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

June 14, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:17am

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Freeda Cathcart (departed at 3:00pm)
Michael I. Elliott
Sheila K. W. Elliott
Ryan K. Logan
Rafael Saenz
Ellen B. Shinaberry
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Heather W. Hurley, Licensing Specialist
David Brown, Director, DHP
James Rutkowski, Assistant Attorney General (absent 10:00am-11:08am)
Elaine J. Yeatts, Senior Policy Analyst, DHP

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

APPROVAL OF AGENDA: The agenda was amended to not include the June 8, 2016 Special Conference Committee minutes for adoption. The agenda was approved as amended.

APPROVAL OF MINUTES: In addition to the minutes included in the agenda packet, a handout of the May 26, 2016 Regulation Committee Meeting minutes was provided to the Board. The following minutes were considered for approval:

- March 24, 2016, Regulation Committee Meeting
- March 25, 2016, Full Board Meeting
- March 25, 2016, Public Hearing for Scheduling Certain Chemicals
- April 13, 2016, Special Conference Committee
- May 26, 2016, Regulation Committee Meeting

MOTION:

The Board voted unanimously to adopt the minutes from March 24, 2016 through May 26, 2016 as presented.
(motion by Saenz, second by Logan)

PUBLIC COMMENTS:

John Lubkowski, Director, Augusta Health, thanked the Board for escalating the brown bagging/white bagging issues to the National Associations of Board s of Pharmacy (NABP). However, he wanted the Board to be aware that in some instances, patients such as hemophiliacs may need to carry the drugs with them and that brown bagging may be necessary.

Rusty Maney, President of Virginia Association of Chain Drug Stores (VACDS), addressed the Board concerning the legislative proposal requiring PTCB certification for initial registration of pharmacy technicians. He stated even though the VACDS supported the Board 's decision, it wanted the following to be taken into consideration:

- Grandfather existing technicians;
- Acceptance of other examinations, e.g., ExCPT;
- May be prudent to wait until 2020;
- Extend 9 month allowance for performing pharmacy technician duties prior to obtaining registration to 12 months to accommodate the 600 hours of practical experience required in an ASHP-accredited training program.

DHP DIRECTOR'S REPORT:

Dr. Brown shared with the Board the success of the Department of Health Professions agency-wide training that was held in May. The overall rating was 4.4 out of 5 based off of a survey that was given to the employees regarding the sessions, and there was a lot of positive feedback. Dr. Brown also stated that the employees seemed to enjoy Secretary Hazel's opening remarks for the training. Dr. Brown also informed the Board that there will be another board member training scheduled sometime for the fall of this year that will be for all new and current board members.

UPDATE ON VCU COMPOUNDING CENTER:

Joseph T. DiPiro, Dean of VCU School of Pharmacy and Barbara Jones Exum, Director, VCU Center for Compounding Practice and Research (CCPR) updated the Board on the progress of the new compounding center. The facility is a 5000 square foot learning center that will be utilized to teach pharmacy students sterile/non-sterile compounding as well as perform research and testing. There are very few pharmacy schools with similar facilities and VCU has the only compounding center in this region. Compounding was previously not a part of the core curriculum at the school and became more of a specialized training. Since the necessity of more patient-specific drugs and recent shortages of drugs, the need for compounding has increased. The purpose of the center is to help students to become adequately prepared with hands-on technology and advances. The center will also be focused on continuing education and certification programs for sterile and non-sterile compounding. Those who wish to enhance their skillset may also have access to the facility. VCU will be making basic compounding a required course that

will be included in the curriculum with advanced training available. Dr. Quamrun N. Masuda, Ph.D, RPh, Associate Professor, Pharmaceutics, Assistant Director, CCPR, stated that they hope that one of the functions of the center will be to work directly with the physicians there at the hospital and be able to provide medication to their special need patients.

REGULATORY UPDATE:

Ms. Yeatts reviewed with the board the status report for pending regulatory actions which was provided in the board agenda packet. She stated that the regulation for the inclusion of diazepam rectal gel in emergency kits was passed in approximately 60 days from start to finish and will become final on August 1, 2016.

ADOPTION OF REGULATION TO SCHEDULE CERTAIN CHEMICALS INTO SCHEDULE I:

Ms. Yeatts stated the Board needed to take action on the adoption of the amendments to section 18VAC 110-20-322 regarding the placements of certain chemicals in Schedule I. Stricken language represents chemicals that need to be deleted from regulation as they have been permanently scheduled in Virginia Code. This is an exempt action which will become effective 30 days from publishing in the Registrar, after permission is received to publish.

MOTION:

The Board voted unanimously to amend Regulation 18VAC 110-20-322 as presented which places the following chemicals into Schedule I:

Classified as research chemicals:

- **Beta-keto-N, N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)**
- **1-(1,3-benzodioxol-5-yl)-2(ethylamino)-1pentanone (other name : N-ethylpentylone)**
- **1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)**
- **1-[1-(4-methoxyphenyl)cyclohexyl]piperidine(other name: 4-methoxy PCP)**
- **4-Chloroethcathinone (other name: 4-CEC),**
- **3-Methoxy-2(methylamino)-1-(4-mehtylphenyl)-1-propanone (other name: Mexedrone)**

Classified as cannabimimetic agents:

- **Methyl 2-({1-[4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB)**
- **N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)**
- **N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)**
- **Naphthalen-1-yl 1-pentyl-1H-indazole-3carboxylate (other name: SDB-005)**
- **N-(1-amino-3-methyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)indole-3-carboxamide (other name: AB-**

CHMICA)

Classified as synthetic opioids:

- **3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)**
- **3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)**
- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other nam: Pentanoyl fentanyl)**
- **N-phenyl-N-{1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)**
- **N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)**

Classified as a benzodiazepine:

- **Clonazolam**

(motion by Shinaberry, second by S. Elliott)

REPORT FROM REGULATION COMMITTEE

- CONSIDERATION FOR CONVENING A REGULATORY ADVISORY PANEL (RAP) FOR PHARMACEUTICAL PROCESSORS TO PRODUCE AND DISPENSE CANNABIDIOL OIL AND THC-A OIL:

Ms. Shinaberry gave an overview of the discussion at the May 26, 2016 Regulation Committee meeting concerning the authorization of manufacturing and dispensing of Cannabidiol Oil and THC-A Oil for the treatment and alleviation of symptoms of intractable epilepsy. The Regulation Committee decided that the board chairman should appoint persons to a Regulatory Advisory Panel (RAP) that would consist of board members and other various stakeholders. The panel would meet 2-3 times over the summer and present the full board with proposed regulatory language at the September 7, 2016 full board meeting. Ms. Juran stated that a general notice was posted to Regulatory Town Hall for those persons interested in being appointed. Ms. Warriner announced the names of the persons appointed to the panel and that the individuals would be contacted following the meeting. Additionally, she announced that the RAP would meet on July 1, 2016, July 26, 2016, and August 30, 2016 (if 3rd meeting is necessary).

- FAST-TRACK REGULATIONS FOR AMENDING REGULATIONS FOR "PUBLIC PARTICIPATION GUIDELINES":

Ms. Shinaberry reviewed the proposed amendment made to 18VAC 110-11-20 concerning the Public Participation Guidelines to conform the regulation to the recently amended law. Ms. Shinaberry stated that the committee recommends adopting the amended regulation as presented as a fast-track action.

MOTION:

The Board voted unanimously to amend the Public Participation Guidelines, Regulation 18VAC110-11-20, by inserting into subsection A "and (ii) be accompanied by and represented by counsel or other

representative." as a fast-track action as recommended by the Regulation Committee.

- ADOPTION OF RE-PROPOSED REGULATIONS ON SETTING CERTAIN CONDITIONS ON WORK HOURS FOR PHARMACISTS:

Based on questions and comments that staff has recently received regarding the proposed regulations on setting certain conditions on work hours for pharmacists, Ms. Shinaberry stated that staff is concerned that the language adopted by the board at the March 2016 full board meeting may not accurately represent the board's intent. Staff indicated to the Regulation Committee that licensees were reading the originally proposed language to allow a permit holder to require a pharmacist to work more than 12 continuous hours as long as the permit holder offers 6 hours of off-time between consecutive shifts. It was recommended by the Regulation Committee that the amendment be "re-proposed" and sent for an additional 30 day comment period.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to adopt the re-proposed amendment to Regulation 18VAC110-20-110 by stating in subsection B, "Except in an emergency, a permit holder shall note require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break."

- RECOMMEND THAT PMP ADVANCE LEGISLATIVE PROPOSAL TO AMEND "COVERED SUBSTANCES" TO INCLUDE SCHEDULE V:

Ms. Shinaberry provided the board with background regarding the Regulation Committee's recommendation that the Prescription Monitoring Program (PMP) advance a legislative proposal to amend "covered substance" to include Schedule V. The Virginia Pharmacist Association (VPhA) offered comment at the March 25, 2016 board meeting requesting that the Board should consider deeming promethazine with codeine a drug of concern and require dispensers to report dispensations of the drug to the PMP. Promethazine with codeine is classified as a Schedule V drug and the abuse of the drug appears to have occurred periodically over recent years, not continuously. The law currently only requires drugs in Schedules II-IV be reported to the PMP. Virginia is one of 18 states that does not require the reporting of Schedule V drugs to the state PMP. Every state surrounding Virginia and the District of Columbia does require the reporting of Schedule V controlled substances. The Regulation Committee therefore, recommended that the board not deem promethazine with codeine as drug of concern at this time, but rather recommend that the PMP advance a legislative proposal to expand the definition of "covered substance" to include drugs in Schedule V.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to recommend to the Prescription Monitoring Program (PMP) that it advance a legislative proposal to amend the definition

of "covered substance" in §54.1-2519 and its reference in §54.1-2520 to include Schedule V controlled substances.

- RECOMMEND GATHERING OF ADDITIONAL INFORMATION FROM NABP DISCUSSIONS REGARDING WHITE BAGGING AND BROWN BAGGING:

Ms. Shinaberry stated that the Pharmacy Benefits Manager Workgroup (PBM Workgroup) agreed that the Board of Pharmacy should address any identified issues of concern with white bagging and brown bagging, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the process. At the March 25, 2016 Board meeting, it was agreed that the Regulation Committee discuss the issues of white bagging and brown bagging. Oregon is the only state that staff is aware of that addresses white bagging in regulation and it appears to only address reconstitution, but not any other forms of compounding. There is no mention of brown bagging in Oregon's regulations. The Regulation Committee recommends gathering additional information from upcoming NABP discussions on white bagging and brown bagging based on a recently adopted NABP resolution on this matter.

MOTION:

The Board voted unanimously to accept the Regulation Committee recommendation to gather additional information from upcoming NABP discussions on white bagging and brown bagging based on a recently adopted NABP resolution on the matter.

- RECOMMENDED MEETING OF PBM TASK FORCE SUBGROUP TO ADDRESS CONCERNS WITH DESIGNATION OF SPECIALTY DRUGS:

The Regulation Committee recommends forming a subgroup with representation from those PBM Workgroup members who supported the policy option of the board considering the issue of specialty drugs to identify possible actions that would effectively address the concerns involving specialty drugs as identified in the PBM Workgroup report. Dr. Brown recommended that the board not limit itself to a subgroup of the PBM Workgroup, but to rather form an ad hoc committee and ensure that the committee's charge is aligned with the board's mission to protect the public. It was discussed that the main focus of the committee would be to address patient access to drugs. Those members expressing interest in participating on the committee included Freeda Cathcart, Michael Elliott, and Jody Allen.

MOTION:

The Board voted unanimously for the chairman to appoint members to an ad hoc committee to address concerns with specialty drugs as identified by the Pharmacy Benefit Manager Workgroup and that representation from the following groups, at a minimum, would be invited to participate on the ad hoc committee: board members, health plans, health system pharmacists, the Medical Society of Virginia, and the Virginia Pharmacists Association.
(motion by Shinaberry, second by S. Elliott)

RECOMMENDED ADOPTION OF 2017 LEGISLATIVE

PROPOSALS:

- COLLABORATIVE PRACTICE AGREEMENTS:

Ms. Shinaberry reviewed with the board the proposed legislative proposal concerning collaborative practice agreements. It was explained that the statement in §54.1-3300.1 "Nothing in this section shall be construed to supersede the provisions of §54.1-3303." appears to legally conflict with the authorization in the law for a pharmacist to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols and therefore, has led to questions as to how a pharmacist may legally perform these activities. The legislative proposal does not intend to expand on the pharmacist's authority to participate in collaborative practice agreements, but to clarify and support the existing authority in law. It was discussed that, if adopted, the legislative proposal should be shared with the Board of Medicine as well since the two boards jointly regulate collaborative practice.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to adopt the legislative proposal to amend the last sentence of §54.1-3300.1 to read "Notwithstanding the provisions of §54.1-3303, a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement."

- REQUIRING PTCB CERTIFICATION FOR INITIAL PHARMACY TECHNCIAN REGISTRATION:

Ms. Shinaberry reviewed with the Board the proposed legislative proposal concerning requiring Pharmacy Technician Certification Board (PTCB) certification for initial pharmacy technician registration. Ms. Juran informed the board that the American Society of Health-System Pharmacists had recently approved a national distance learning training program and that several other distance learning training programs were at various stages of applying for accreditation. It was also discussed that 5 states currently require PTCB certification for registration as a pharmacy technician and that the *Virginia's Pharmacy Technician Workforce, 2015* report indicates 66% of the workforce holds PTCB certification while 8% hold ExCPT certification. Ms. Yeatts commented that while the legislative proposal has a delayed effective date of July 1, 2018, PTCB will not require completion of an ASHP-accredited training program until 2020. There was discussion that the phrase "has satisfactorily completed a training program" should not be stricken as presented in the legislative proposal as the board wanted to require completion of a training program and not simply allow the passing of the PTCB exam. These training programs would not have to be ASHP-accredited until 2020. This proposal does not apply to existing pharmacy technicians holding a current active registration.

MOTION:

The Board voted unanimously to reinsert the phrase "has satisfactorily completed a training program" into the legislative proposal and adopt the legislative proposal as amended to require PTCB certification for initial registration as a pharmacy technician.

(motion by Saenz, second by Boone)

This issue was revisited later in the meeting, but no additional action was taken.

OTHER 2017 LEGISLATIVE PROPOSALS CONSIDERED:

- ADDRESSING COMPOUNDING BEST PRACTICES:

It was reported that the Regulation Committee reviewed The Pew Charitable Trusts' Best Practices for State Oversight of Drug Compounding. The Regulation Committee recommended no action on this subject. Much of the discussion at the full board meeting focused on the possible need to report adverse events to the board. There was not consensus on the subject. Some members did not want to require adverse event reporting solely from compounding pharmacists.

MOTION:

The Board voted unanimously to adopt a substitute motion to refer the matter back to the Regulation Committee for further review to determine if additional best practices in overseeing compounding should be required in law. (motion by Logan, second by Thornbury)

- REMOVING ONE PRESCRIPTION PER BLANK PROHIBITION:

The Regulation Committee reported that it reviewed the legislative proposal concerning the one prescription per blank prohibition and recommended to the Board that it take no action at this time based on concerns for patient safety which could result from difficulty in reading multiple prescriptions manually written on the same form. Ms. Elliott commented that the allowance could also preclude a patient from obtaining the best cost on individual drugs as it would prevent the patient from being able to present the individual prescriptions to different pharmacies. Ms. Warriner commented that chart orders containing multiple prescriptions is currently allowed in certain environments identified in law.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to take no action at this time regarding the draft legislative proposal to remove the prohibition of one prescription per blank in §54.1-3408.01.

- REQUIRING TEMPERATURE MONITORING DEVICES:

Ms. Shinaberry reported that the Regulation Committee reviewed the request from Michael Rush, Executive Director of Global Health Policy at Temptime Corporation to require temperature-sensitive drugs that are shipped via mail to be accompanied with a device to monitor temperature during shipping. The Regulation Committee recommended that the board take no action at this time.

MOTION:

The Board voted unanimously, as recommended by the Regulation Committee, to take no action at this time to require temperature-sensitive drugs that are shipped via mail to be accompanied with a device to monitor temperature during shipping.

NEW BUSINESS:

- CONSIDERATION FOR ACCEPTING INSPECTIONS OR DOCUMENTATION, IN LIEU OF FDA INSPECTION OF OUTSOURCING FACILITY FROM THE FOLLOWING:

- Bestech GMP Contracting, Inc.:

Matthew Bestercy, Owner and Principal Consultant for Bestech GMP Contacting, Inc. requested that the Board allow non-resident outsourcing facilities to be able to utilize their inspection report for initial licensure in lieu of the FDA inspection report. Virginia law requires an outsourcing facility needs to produce an FDA inspection report which is no older than one year from the date of applying for licensure. However, the FDA does not routinely perform annual inspections which will make it difficult for these facilities to obtain licensure in Virginia. Mr. Bestercy presented an overview of his company, the inspectors' qualifications, and the process to be used to inspect outsourcing facilities. His company would inspect in a manner similar to FDA and does a complete and thorough inspection. Mr. Bestercy agreed to map out their process, finalize inspection forms, and provide them to board staff prior to the September 7, 2016 board meeting for further consideration.

- Florida Department of Health:

The Florida Department of Health inspectors have received training from the FDA on how to inspect facilities operating under current Good Manufacturing Practices, and have been performing outsourcing facility inspections within Florida and in other states. Florida has not finalized their inspection report, so it was not available for review. The Board decided to table the discussion of whether it could accept a Florida inspection report from a nonresident outsourcing facility in lieu of an FDA inspection until the Florida inspection report was available for review.

- RESULTS FROM 2015 HEALTHCARE WORKFORCE SURVEYS:

Dr. Elizabeth Carter, Ph.D., Director, HWDC presented the Board with handouts that updated the Board with the results from the 2015 Healthcare Workforce Surveys for pharmacists and pharmacy technicians. Dr. Carter said that there has been an increase of female pharmacists from last year, it went up from 62%-63%. Also, diversity increased to 47%, the amount of PharmDs went up to 57% and there is

now a 38%-40% that state they still have educational debt. The amount of pharmacists who work for chain stores dropped from 32% to 30% and 57% of the pharmacists are salaried employees. Dr. Carter also stated that there is a younger population of pharmacists which creates a good pipeline meaning that pharmacists will be in practice when the baby boomers retire. Dr. Carter reviewed the pharmacy technician 2015 survey with the board and there is now 6% of the pharmacy technician workforce that is not practicing. There is also another 14% that did not renew in 2015. The survey also showed that there are approximately 20% of pharmacy technicians that have an Associate Degree and 59% that has their high school diploma or GED.

OLD BUSINESS:

- AMEND GUIDANCE DOCUMENT 110-29, PHYSICIANS DISPENSING DRUGS, COUNSEL TO RESEARCH:

Ms. Juran briefed the board on the suggested amendments made to the language in Guidance Document 110-29 regarding physicians dispensing drugs. Counsel opined that he agrees with the following information: a physician licensed to sell controlled substances may only dispense to his own patients. However, with this license the physician may dispense pursuant to a prescription written by a nurse practitioner or physician assistant under the following conditions:

- The physician has a bona fide practitioner-patient relationship with the patient whom the nurse practitioner or physician assistant has prescribed a drug; and,
- The physician is the supervising physician of the physician assistant or the physician who has entered into a practice agreement with the nurse practitioner.

A physician may also dispense a refill of a prescription written by another physician licensed to sell controlled substances if the physician has a bona fide practitioner-patient relationship with the patient.

There was concern by the board that the determination of whether a bona fide relationship actually exists could be difficult and that incorporating these complex legal scenarios in the guidance document may cause confusion. It was recommended that it would be more appropriate to capture counsel's research in the minutes rather than the guidance document.

MOTION:

The Board voted unanimously to:

- **strike the following statements from the draft Guidance Document 110-29, but capture in the minutes: "A physician licensed to sell controlled substances may only dispense to his own patients. However, with this license the physician may dispense pursuant to a prescription written by a nurse practitioner or physician assistant under the following conditions:**
  - **The physician has a bona fide practitioner-patient relationship with the patient whom the nurse**

practitioner or physician assistant has prescribed a drug; and,

- **The physician is the supervising physician of the physician assistant or the physician who has entered into a practice agreement with the nurse practitioner.**

A physician may also dispense a refill of a prescription written by another physician licensed to sell controlled substances if the physician has a bona fide practitioner-patient relationship with the patient.";

- **amend Guidance Document 110-29 by adding the following information under the section entitled "Physicians Selling Drugs":**
  - **"With this license a physician ~~may only dispense to his own patients,~~ must comply with a set of regulations which relate specifically to this license~~, and dispensing under this license may not be delegated to anyone else, such as to a nurse practitioner, physician assistant, nurse, or pharmacy technician~~. If there is more than one physician dispensing within a single practice, each dispensing physician must obtain this license ~~and may only dispense to his own patients.~~ Effective June 4, 2016, a permit from the Board of Pharmacy must also be obtained for the facility from which practitioners of the healing arts dispense controlled substances and it shall meet compliance with the regulations for practitioners of the healing arts to sell controlled substances. Physicians licensed to sell controlled substances may dispense from any facility permitted for this purpose."**
  - **"While the regulation allows for a pharmacy technician, or trained nurse or trained physician assistant to assist the licensed physician in preparing the drug for dispensing, the physician is responsible for conducting a prospective drug review, offering to counsel the patient, inspecting the prescription product to verify its accuracy in all respects, and placing his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. The physician may not delegate the responsibility of dispensing a drug to a nurse practitioner or physician assistant; hence, no drug may be dispensed when a physician is not on-site."**
- **and amend by updating with the current language for §54.1-3301 and §54.1-3304.1. (motion by Shinaberry, second by M. Elliott)**

ELECTION OF OFFICERS:

MOTION: **The Board voted unanimously to elect Ms. Thornbury as chairman for the term beginning July 1, 2016 and ending June 30, 2017. (motion by Allen, second by Warriner)**

MOTION: **The Board voted unanimously to elect Mr. Logan as vice-chairman for the term beginning July 1, 2016 and ending June 30, 2017. (motion by Thornbury, second by Boone)**

REPORTS:

- CHAIRMAN'S REPORT: Ms. Warriner thanked the board for their service and support over the past year while serving as chairman. She also reminded the members of the upcoming NABP/AACP Districts 1 & 2 Meeting being held in West Virginia this September. She stated that those who wish to attend will need to register soon.

- REPORT ON THE BOARD OF HEALTH PROFESSIONS: Mr. Logan gave a brief update on the Board of Health Professions. He reported that they discussed the new requirements for when prescribers must query the PMP program and the formation of a PMP Advisory Committee.

- REPORT ON LICENSURE PROGRAM: Mr. Johnson reported the board currently licenses 35,551 individuals and facilities. The Board issued 914 licenses and registrations for the period of March 1, 2016 through May 31, 2016. Inspectors conducted 474 facility inspections including 162 routine inspections of pharmacies: 45 (28%) resulted in no deficiency, 48 (30%) with deficiencies and 69 (42%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Inspection Deficiencies. The report reflects changes approved at the March 25, 2016 removing the terms major and minor. Deficiencies numbered between 1 and 100 reflect the former major deficiencies. Deficiencies numbered above 100 reflect the former minor deficiencies. It was noted that deficiency 142, regarding compliance with CQI requirements, is the most frequently cited deficiency. Other frequently cited deficiencies include 16 regarding the perpetual inventory and 113 regarding other drug inventories.

  Mr. Johnson reported that of the 1,826 permitted (in-state) pharmacies, 453 (25%) have not been inspected within the past two years. Of the 453 pharmacies, 24 are more than two years past due. Of the 1,324 pharmacies that engage in compounding, 289 (22%) have not been inspected within 2 years. Thirty-five pharmacies that engage in sterile compounding have not been inspected within 2 years.

In response to a request made at the December 1, 2015 board meeting, Mr. Johnson reported he is working with the data department to break out hospital statistics from other pharmacies in the licensure report.

- REPORT ON 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 28, 2015; November 30, 2015; March 24, 2016; and June 13, 2016. For the final date, she reported that there was one case at the entry stage; 63 at the investigation stage; 171 at the probable cause stage; four at the administrative proceedings division stage; twelve at the informal stage; one at the formal stage; and 124 at the pending closure stage.

- EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran congratulated Ms. Warriner and Ms. Thornbury for their re-appointment to the Board for a second full term. She reported on the NABP Annual Meeting which she, Ms. Warriner, Ms. Allen, and Leo Ross attended May 14th -16th. She referenced the resolutions voted on during the meeting and that she was elected to serve on the 2016-2017 NABP Executive Committee representing District 2. The NABP District 1 & 2 meeting is being held at the Greenbrier in White Sulphur Spring, West Virginia this September 15th-17th. Ms. Juran stated that a "save-the-date" will be emailed out this week and registration is tentatively opening on June 24th. Ms. Juran gave an update on some of the meetings she had attended since the last Board meeting. She attended the Rx Partnership meeting on April 28, 2016, the Forensic Science Board meeting on May 11, 2016 and assisted with the Board of Medicine's Buprenorphine Workshop that was held on May 13, 2016.

SUMMARY SUSPENSION:

ADRIAN S. MOORE
Registration No: 0230-018157

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 Mr. Elliott, and duly seconded by Mr. Boone, the Board voted 9-0 in favor of the motion that, according to the evidence presented, the continued practice by Adrian S. Moore, as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Adrian S. Moore to practice as a pharmacy technician be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Mr. Moore for the indefinite suspension of his pharmacy technician registration for two years.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:

Upon a motion by Ms. Thornbury, and duly seconded by Ms. Warriner,

the Board voted 9-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran and James Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

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

MOTION: Upon a motion by Ms. Elliott and duly seconded by Mr. Saenz, the Board voted 9-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Adrian S. Moore, a pharmacy technician.

ADJOURN: With all business concluded, the meeting adjourned at approximately 4:05pm.

_____
Cynthia Warriner, Chairman

_____
DATE:

_____
Caroline D. Juran, Executive Director

_____
DATE:

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

June 14, 2016
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 9:10a.m.

PRESIDING: Cynthia Warriner, Chairman

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

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Heather W. Hurley Licensing Specialist
David E. Brown, D.C., Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

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

Pursuant to subsection D of 54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. 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.

CALL FOR COMMENT: Ms. Warriner called for comment to consider placement of the following chemical substances:

These compounds are classified as research chemicals:

- Beta-keto-N, N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)
- 1-(1,3-benzodioxol-5-yl)-2(ethylamino)-1pentanone (other name : N-ethylpentylone)
- 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)
- 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine(other name: 4-methoxy PCP)
- 4-Chloroethcathinone (other name: 4-CEC),
- 3-Methoxy-2(methylamino)-1-(4-mehtylphenyl)-1-propanone (other name: Mexedrone)

These compounds are classified as canabimimetic agents:

- Methyl 2-({1-[4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB)
- N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)
- N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)
- Naphthalen-1-yl 1-pentyl-1H-indazole-3carboxylate (other name: SDB-005)
- N-(1-amino-3-methyl-1-oxobutan-2-yl)-1(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA)

These compounds are classified as synthetic opioids:

- 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)
- 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)
- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other nam: Pentanoyl fentanyl)
- N-phenyl-N-{1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)
- N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)

This compound is classified as a benzodiazepine:

- Clonazolam

Scott Maye, Chemistry Program Manager, Department of Forensic Science stated that the 17 compounds have been identified in their

laboratories. Additionally, he stated the laboratories have recently seen an increase in the number of chemicals submitted for analysis.

No additional public comment was received.

ADJOURN: The public hearing adjourned at 9:17am.

Cynthia Warriner, Chairman

Date

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, June 15, 2016
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 9:00 a.m.

PRESIDING: Rebecca Thornbury, Committee Chair

MEMBERS PRESENT: Melvin L. Boone, Sr., Committee Member

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

MARK BOWIE
Pharmacist License
#0202207961

Mark Bowie, Pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 4, 2016 Notice.

Closed Meeting: Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Mark Bowie. 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. Boone, and duly seconded by Ms. Thornbury, the Committee found that no violation had occurred and unanimously voted to dismiss this matter.

BENISH QURESHI Pharmacy Technician Registration #0230018493	Benish Qureshi, pharmacy technician, appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 4, 2016 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Benish Qureshi 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. Boone, and duly seconded by Ms. Thornbury, the Committee that no violation had occurred and unanimously voted to dismiss this matter.
TAMEKA HICKS Pharmacy Technician Registration #0230017491	Tameka Hicks, 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 4, 2016 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Tameka Hicks. 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. Boone, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Tameka Hicks in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $50 monetary penalty and requires the submission of five (5) hours of continuing education.

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

HEATHER McINTYRE
Pharmacy Technician Registration
#0230021321

Heather McIntyre, 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 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Heather McIntyre. 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. Boone, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Heather McIntyre in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $50 monetary penalty and requires the submission of five (5) hours of continuing education.

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

LORAINE W. ROBINSON
Pharmacy Technician Registration
#0230006550

Loraine W. Robinson, 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 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Loraine W. Robinson. 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. Boone, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Loraine W. Robinson in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $50 monetary penalty and requires the submission of five (5) hours of continuing education.

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

JENEISHA SILVERA
Pharmacy Technician Registration
#0230015412

Jeneisha Silvera, 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 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jeneisha Silvera. 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. Boone, and duly seconded by Ms. Thornbury, the Committee made certain Findings of Facts and Conclusions of Law found Jeneisha Silvera in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $100 monetary penalty and requires the submission of ten (10) hours of continuing education.

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

WALGREENS #05783
Permit# 0201003719

Brian A. Humpf, Pharmacist-In-Charge, did not appear to discuss allegations that Walgreens #05783 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Walgreens #05783. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Logan, and duly seconded by Ms. Thornbury, the Committee accepts allegations #1 and #2a and b as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $500 monetary penalty. Additional documentation of evidence of corrective action for all violations must be submitted to the Board within 30 days.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Walgreens #05783, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Walgreens #05783 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.

BATTLETOWN PHARMACY
Permit #0201004539

Patricia L. White, Pharmacist-In-Charge, appeared to discuss allegations that Battletown Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Battletown Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee accepts allegations #1, 2a through e, and #3 as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $250 monetary penalty. Additional documentation of evidence of corrective action for all violations must be submitted to the Board within 30 days. As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Battletown Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Battletown Pharmacy within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.
PATIENTS CHOICE DISCOUNT PHARMACY Permit #0201004565	Preston Grobes, Pharmacist-In-Charge, appeared to discuss allegations that Patients Choice Discount Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 4, 2016 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Patients Choice Discount Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations
Reconvene:	Having certified that the matters discussed in the

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

Decision:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee accepts allegations #1, #2a through f, and #3 as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $850 monetary penalty. Additionally documentation of corrective action for all violations shall be provided to the Board within thirty (30) days.

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

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

AKINA PHARMACY
Permit #0201004538

Bassem Wadid Girgis, Pharmacist-In-Charge, and Hunter W. Jamerson, Attorney for Macaulay & Jamerson, P.C., appeared to discuss allegations that Akina Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Akina Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations

Reconvene:

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

Decision:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee accepts allegations #1, #2a, #2b, #2c and #3 as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $5,250 monetary penalty. Additionally documentation of corrective action for all violations shall be provided to the Board within thirty (30) days.

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

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

ACARIAHEALTH PHARMACY, INC.
Permit #0201004179

James R. Whitford, Pharmacist-In-Charge, Elizabeth A. Scully, Attorney, Lee H. Rosebush, Attorney, and Steve Cobb, VP for fulfillment AcariaHealth, appeared to discuss allegations that AcariaHealth Pharmacy, Inc. may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 4, 2016 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Ms. Thornbury, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of AcariaHealth Pharmacy, 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. Boone, and duly seconded by Ms. Thornbury, the Committee accepts allegations #1, #2a, #2b and #3 as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $5000 monetary penalty. Additionally documentation of corrective action for all violations shall be provided to the Board within thirty (30) days.

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

ADJOURN:

With all business concluded, the meeting adjourned at 3:00pm

Rebecca Thornbury, Chair

J. Samuel Johnson, Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, July 14, 2016
Commonwealth Conference Center
Second Floor
Board Room 1

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

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

PRESIDING: Jody H. Allen, Committee Chair

MEMBERS PRESENT: Michael Elliott, Committee Member

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

Gino J. Bortoluzzi
License Number 0202-007760

Gino J. Bortoluzzi appeared with his attorney, Hunter W. Jamerson, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 14, 2016, Notice.

Closed Meeting: Upon a motion by Mr. Elliott, 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 Gino J. Bortoluzzi. Additionally, he moved that J. Samuel Johnson, Beth O'Halloran 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. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order for a reprimand, requiring two additional continuing

education hours in the subject of fraud and imposing a $1,500 monetary penalty.

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

Hague Pharmacy
Permit Number 0201-002286

Gino J. Bortoluzzi, Pharmacist in Charge, appeared with their attorney, Hunter W. Jamerson, to discuss allegations that Hague Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the June 14, 2016, Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Hague Pharmacy. Additionally, he moved that J. Samuel Johnson, Beth O'Halloran 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. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order requiring an additional three unannounced inspections over the course of two years, paid for by the licensee, and imposing a monetary penalty of $6,500.

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

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

ADJOURN: With all business concluded, the meeting adjourned at 12:50 p.m.

Jody H. Allen , Chair

Date

J. Samuel Johnson
Deputy Executive Director

Date

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, July 14, 2016
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 1:00 p.m.

PRESIDING: Jody H. Allen, Committee Chair

MEMBERS PRESENT: Michael Elliott, Committee Member

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

David L. Keith, Jr.
Registration Number 0230-023833

David L. Keith, Jr., did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the June 2, 2016,, Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Mr. Keith's legal address of record.

Closed Meeting: Upon a motion by Mr. Elliott, 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 David L. Keith, Jr. 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. Elliott, and duly seconded by Ms. Allen, the Committee voted to offer a Consent Order for the indefinite suspension of Mr.

Keith's right to renew his pharmacy technician registration.

ADJOURN: With all business concluded, the meeting adjourned at 3:50 p.m.

Jody H. Allen, Chair

Cathy M. Reimers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, August 15, 2016

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on August 15, 2016, at 9:00 a.m., to consider the summary suspension of the registration of Angela-Fee Lynch to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Rebecca Thornbury, Chair

MEMBERS PRESENT:
Ryan Logan
Ellen Shinaberry
Freeda Cathcart
Cindy Warriner
Rafael Saenz

STAFF PRESENT:
Caroline D. Juran, Executive Director
Rose E. DeMatteo, Compliance Case Manager
Mykl Egan, DHP Adjudication Specialist
James Rutkowski, Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General/Chief

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension 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.

ANGELA-FEE LYNCH
Registration No. 0230-026930

James Schliessmann presented a summary of the evidence in this case.

Upon a motion by Ms. Warriner and duly seconded by Ms. Shinaberry, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Angela-Fee Lynch poses a substantial danger to the public; and therefore, the registration of Ms. Lynch shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Lynch for the revocation of her registration for a period of not less than three years.

ADJOURN: With all business concluded, the meeting adjourned at 9:30 a.m.

Caroline D. Juran
Executive Director

Rebecca Thornbury, Chair

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 August 22, 2016

Action: **None – provided for information only**

Chapter		Action / Stage Information
[18 VAC 110 - 11]	Public participation guidelines	Conforming to Code [Action 4594] Fast-Track - *At Secretary's Office for 31 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] NOIRA - *Register Date: 7/11/16* *Comment period ended: 8/10/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Outsourcing facilities [Action 4452] Proposed - *At Governor's Office for 39 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Proposed - *At Governor's Office for 39 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Inclusion of diazepam rectal gel in emergency kits [Action 4536] Fast-Track - *Register Date: 6/27/16* *Effective: 8/11/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals [Action 4595] Final - *Register Date: 8/8/16* *Effective: 9/7/16*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Addressing hours of continuous work by pharmacists [Action 3755] Final - *At Secretary's Office for 27 days*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Permits for facilities [Action 4451] Proposed - *At Governor's Office for 39 days*

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 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 7, 2016** 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 10, 2016 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:

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

The following compounds are classified as stimulants. Other drugs of this type have been placed in Schedule I
(§ 54.1-3446(5)) in previous legislative sessions.

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

The following compounds are powerful synthetic opioids. DFS recommends placing these compounds into Schedule I (§ 54.1-3446(6)).

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide
(other name: para-fluorobutyrylfentanyl)

6. 4-chloro-N-[1-[2-(4-nitrophenyl)ethyl]-2-piperidinylidene]-benzenesulfonamide (other name: W-18)

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.

To: Caroline Juran, Executive Director, Board of Pharmacy
From: Scott Maye, Chemistry Program Manager, Virginia Department of Forensic Science
Date: July 29, 2016
RE: **Recommendation for Emergency Scheduling of Controlled Substances - UPDATE**

Ms. Juran,

This recommendation supersedes the recommendation dated July 15, 2016. Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified five (5) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description and chemical name for each compound.

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

The following compounds are classified as stimulants. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(5)) in previous legislative sessions.

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

The following compound is a powerful synthetic opioid. DFS recommends placing this compound into Schedule I (§ 54.1-3446(6)).

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide
(other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

M. Scott Maye
Chemistry Program Manager

Scheduling of Chemicals in Schedule I

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

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

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)

2. Flubromazolam

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)

4. Cannabimimetic agents:

    a. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA)

    b. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA)

    c.Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA)

The placement of drugs listed in this subsection shall remain in effect until December 13, 2017, unless enacted into law in the Drug Control Act.

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

1. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)

2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone)

3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)

4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP)

5. 4-Chloroethcathinone (other name: 4-CEC)

6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone)

7. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)

8. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)

9. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl)

10. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)

11. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)

12. Clonazolam

13. Cannabimimetic agents:

a. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate

(other names: AMB-FUBINACA, FUB-AMB)

b. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)

c. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)

d. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005)

e. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide

(other name: AB-CHMICA)

The placement of drugs listed in this subsection shall remain in effect until March 7, 2018, unless enacted into law in the Drug Control Act.

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

1. 1-propionyl lysergic acid diethylamide (other name: 1P-LSD)

2. (2-Methylaminopropyl)benzofuran (other name: MAPB)

3. Ethyl phenyl(piperidin-2-yl)acetate (other name: Ethylphenidate)

4. 2-(3-fluorophenyl)-3-methylmorpholine (other name: 3-fluorophenmetrazine)

5. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: para-fluorobutyrylfentanyl), its optical, positional, and geometric isomers, salts and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until (18 months after the effective date of the regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Proposed Fast-track Action

Staff note:

HB528 of the 2016 General Assembly did the following:

Eliminates the requirement that the Board of Pharmacy establish and implement a pedigree system for recording each distribution of a controlled substance from sale by a pharmaceutical manufacturer to a dispenser or person who will administer the controlled substance; defines "co-licensed partner" as a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law, and specifies that a co-licensed partner may be a manufacturer of a controlled substance; and defines "third-party logistics provider" as a person who provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product. The bill specifies that bulk drug substances used for compounding drugs distributed by a supplier other than a licensed wholesale distributor or registered nonresident wholesale distributor must be provided by a supplier who is approved by the Board of Pharmacy as well as the federal Food and Drug Administration and requires every pharmacy, nonresident pharmacy, wholesale distributor, and nonresident wholesale distributor to comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed. The bill authorizes the Board of Pharmacy to deny, revoke, suspend, or take other disciplinary actions against holders of a third-party logistics provider permit, manufacturer permit, or nonresident manufacturer permit; applies the inspection and audit requirements that apply to wholesale distributors to nonresident wholesale drug distributors, third-party logistics providers, manufacturers, and nonresident manufacturers; creates a permitting process for third-party logistics providers; allows holders of a manufacturer permit to distribute the drug manufactured, made, produced, packed, packaged, repackaged, relabeled, or prepared to anyone other than the end user without the need to obtain a wholesale distributor permit; and creates a process for registration of nonresident manufacturers of prescription drugs.

Enclosed in your package:

A copy of HB528

Copy of draft amendments to18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, manufacturers, and Warehousers

Board action:

Adoption of draft amendment by fast-track action or

Revision of the draft.

CHAPTER 221

An Act to amend and reenact §§ 2.2-4006, 54.1-3307, 54.1-3401, 54.1-3410.2, 54.1-3434, 54.1-3434.1, 54.1-3435, 54.1-3435.01, 54.1-3435.1, and 54.1-3437 of the Code of Virginia; to amend the Code of Virginia by adding a section numbered 54.1-3435.4:1 and by adding in Article 4 of Chapter 34 of Title 54.1 a section numbered 54.1-3442.01; and to repeal § 54.1-3401.1 of the Code of Virginia, relating to manufacture and distribution of prescription drugs in the Commonwealth.

[H 528]

Approved March 4, 2016

Be it enacted by the General Assembly of Virginia:

1. That §§ 2.2-4006, 54.1-3307, 54.1-3401, 54.1-3410.2, 54.1-3434, 54.1-3434.1, 54.1-3435, 54.1-3435.01, 54.1-3435.1, and 54.1-3437 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3435.4:1 and by adding in Article 4 of Chapter 34 of Title 54.1 a section numbered 54.1-3442.01 as follows:

§ 2.2-4006. Exemptions from requirements of this article.

A. The following agency actions otherwise subject to this chapter and § 2.2-4103 of the Virginia Register Act shall be exempted from the operation of this article:

1. Agency orders or regulations fixing rates or prices.

2. Regulations that establish or prescribe agency organization, internal practice or procedures, including delegations of authority.

3. Regulations that consist only of changes in style or form or corrections of technical errors. Each promulgating agency shall review all references to sections of the Code of Virginia within their regulations each time a new supplement or replacement volume to the Code of Virginia is published to ensure the accuracy of each section or section subdivision identification listed.

4. Regulations that are:

a. Necessary to conform to changes in Virginia statutory law or the appropriation act where no agency discretion is involved. However, such regulations shall be filed with the Registrar within 90 days of the law's effective date;

b. Required by order of any state or federal court of competent jurisdiction where no agency discretion is involved; or

c. Necessary to meet the requirements of federal law or regulations, provided such regulations do not differ materially from those required by federal law or regulation, and the Registrar has so determined in writing. Notice of the proposed adoption of these regulations and the Registrar's determination shall be published in the Virginia Register not less than 30 days prior to the effective date of the regulation.

5. Regulations of the Board of Agriculture and Consumer Services adopted pursuant to subsection B of § 3.2-3929 or clause (v) or (vi) of subsection C of § 3.2-3931 after having been considered at two or more Board meetings and one public hearing.

6. Regulations of the regulatory boards served by (i) the Department of Labor and Industry pursuant to Title 40.1 and (ii) the Department of Professional and Occupational Regulation or the Department of Health Professions pursuant to Title 54.1 that are limited to reducing fees charged to regulants and applicants.

7. The development and issuance of procedural policy relating to risk-based mine inspections by the Department of Mines, Minerals and Energy authorized pursuant to §§ 45.1-161.82 and 45.1-161.292:55.

8. General permits issued by the (a) State Air Pollution Control Board pursuant to Chapter 13 (§ 10.1-1300 et seq.) of Title 10.1 or (b) State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), Chapter 24 (§ 62.1-242 et seq.) of Title 62.1 and Chapter 25 (§ 62.1-254 et seq.) of Title 62.1, (c) Virginia Soil and Water Conservation Board pursuant to the Dam Safety Act (§ 10.1-604 et seq.), and (d) the development and issuance of general wetlands permits by the Marine Resources Commission pursuant to subsection B of § 28.2-1307, if the respective Board or Commission (i) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01, (ii) following the passage of 30 days from the publication of the Notice of Intended Regulatory Action forms a technical advisory committee composed of relevant stakeholders, including potentially affected citizens groups, to assist in the development of the general permit, (iii) provides notice and receives oral and written comment as provided in § 2.2-4007.03, and (iv) conducts at least one public hearing on the proposed general permit.

9. The development and issuance by the Board of Education of guidelines on constitutional rights and restrictions relating to the recitation of the pledge of allegiance to the American flag in public schools pursuant to § 22.1-202.

10. Regulations of the Board of the Virginia College Savings Plan adopted pursuant to § 23-38.77.

11. Regulations of the Marine Resources Commission.

12. Regulations adopted by the Board of Housing and Community Development pursuant to (i) Statewide Fire Prevention Code (§ 27-94 et seq.), (ii) the Industrialized Building Safety Law (§ 36-70 et seq.), (iii) the Uniform Statewide Building Code (§ 36-97 et seq.), and (iv) § 36-98.3, provided the Board (a) provides a Notice of Intended Regulatory Action in conformance with the provisions of § 2.2-4007.01, (b) publishes the proposed regulation and provides an opportunity for oral and written comments as provided in § 2.2-4007.03, and (c) conducts at least one public hearing as provided in §§ 2.2-4009 and 36-100 prior to the publishing of the proposed regulations. Notwithstanding the provisions of this subdivision, any regulations promulgated by the Board shall remain subject to the provisions of § 2.2-4007.06 concerning public petitions, and §§ 2.2-4013 and 2.2-4014 concerning review by the Governor and General Assembly.

13. Amendments ~~to the list of drugs susceptible to counterfeiting adopted by the Board of Pharmacy pursuant to subsection B of § 54.1-3307 or amendments~~ to regulations of the Board to schedule a substance in Schedule I or II pursuant to subsection D of § 54.1-3443.

14. Waste load allocations adopted, amended, or repealed by the State Water Control Board pursuant to the State Water Control Law (§ 62.1-44.2 et seq.), including but not limited to Article 4.01 (§ 62.1-44.19:4 et seq.) of the State Water Control Law, if the Board (i) provides public notice in the Virginia Register; (ii) if requested by the public during the initial public notice 30-day comment period, forms an advisory group composed of relevant stakeholders; (iii) receives and provides summary response to written comments; and (iv) conducts at least one public meeting. Notwithstanding the provisions of this subdivision, any such waste load allocations adopted, amended, or repealed by the Board shall be subject to the provisions of §§ 2.2-4013 and 2.2-4014 concerning review by the Governor and General Assembly.

B. Whenever regulations are adopted under this section, the agency shall state as part thereof that it will receive, consider and respond to petitions by any interested person at any time with respect to reconsideration or revision. The effective date of regulations adopted under this section shall be in accordance with the provisions of § 2.2-4015, except in the case of emergency regulations, which shall become effective as provided in subsection B of § 2.2-4012.

C. A regulation for which an exemption is claimed under this section or § 2.2-4002 or 2.2-4011 and that is placed before a board or commission for consideration shall be provided at least two days in advance of the board or commission meeting to members of the public that request a copy of that regulation. A copy of that regulation shall be made available to the public attending such meeting.

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

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

The Board's regulations shall include criteria for:

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

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

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

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

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

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

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

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

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

B. ~~The Board's regulations to implement the criteria set forth in subsection A shall include, but shall not be limited to, the establishment and implementation of a pedigree system, as defined in subsection D. The Board shall structure the implementation of the pedigree with limited application to certain schedules or certain drugs, upon finding that such drugs are more subject to counterfeiting. In order to~~

~~maintain a current and appropriate list of drugs susceptible to counterfeiting, the Board may amend such list in its regulations. Such amendments to the list shall be exempt from the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. The Board shall establish in regulation a process for amending such list that provides notice and opportunity for public comment. The Board shall limit the implementation of a pedigree system to those drugs that have left the normal distribution channel as defined in subsection D. The pedigree shall also satisfy the requirements of 21 U.S.C. § 353 (e), regarding requirements for wholesale distributors of drugs in interstate commerce. The Board may provide for exceptions to the pedigree requirements of this section for emergency medical reasons as defined in regulation.~~

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

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

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

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

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more

of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Co-licensed partner" means a person who, with at least one other person, has the right to engage in the manufacturing or marketing of a prescription drug, consistent with state and federal law.

"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, *a manufacturer's co-licensed partner, or a repackager.*

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis. Marijuana shall not include industrial hemp as defined in § 3.2-4112 that is possessed, cultivated, or manufactured by a grower licensed pursuant to § 3.2-4115.

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

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

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

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

"Third-party logistics provider" means a person that provides or coordinates warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device but does not take ownership of the product or have responsibility for directing the sale or disposition of the product.

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

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

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the ~~exceptions set forth in § 54.1-3401.1~~ *exemptions set forth in the federal Drug Supply Chain Security Act.*

"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~~ *other than a manufacturer, a manufacturer's co-licensed partner, a third-party logistics provider, or a repackager that engages in wholesale distribution.*

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

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

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

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

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

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

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned

control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

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

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

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

A pharmacist may provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry to administer to their patients, 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*; or are manufactured by an establishment that is registered by the FDA*; *and*

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

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

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

H. Pharmacists shall not engage in the following:

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

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

an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

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

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

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

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

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

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

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

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

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

The application for such permit 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 pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any

pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

Every pharmacy shall be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. Nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Every pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

Each day during which a person is in violation of this section shall constitute a separate offense.

§ 54.1-3434.1. Nonresident pharmacies to register with Board.

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) 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 nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed 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.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

F. Pharmacies subject to this section shall comply with the requirements set forth in § 54.1-3408.04 relating to dispensing of an interchangeable biosimilar in the place of a prescribed biological product.

G. Every nonresident pharmacy shall comply with federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed.

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

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in the Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in the Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within 30 days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

C. A wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection B unless the notice was given in bad faith or with malicious intent.

D. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a wholesale distributor pursuant to subsection B.

E. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent

diversion of prescription drugs, and to protect the public.

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

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

A. Any person located outside the Commonwealth who engages in the wholesale distribution of prescription drugs into the Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within 30 days of any substantive change in the information previously submitted to the Board; and remit a fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

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

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

D. A nonresident wholesale distributor that ceases distribution of Schedule II through V drugs to a pharmacy, licensed physician dispenser, or licensed physician dispensing facility located in the Commonwealth due to suspicious orders of controlled substances shall notify the Board within five days of the cessation. For the purposes of this section, "suspicious orders of controlled substances" means, relative to the pharmacy's, licensed physician dispenser's, or licensed physician dispensing facility's order history and the order history of similarly situated pharmacies, licensed physician dispensers, or licensed physician dispensing facilities, (i) orders of unusual size, (ii) orders deviating substantially from a normal pattern, and (iii) orders of unusual frequency.

E. A nonresident wholesale distributor shall be immune from civil liability for giving notice in accordance with subsection D unless the notice was given in bad faith or with malicious intent.

F. The Board shall not impose any disciplinary or enforcement action against any licensee or permit holder solely on the basis of a notice received from a nonresident wholesale distributor pursuant to subsection D.

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

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

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

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

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

2. Violations of licensing requirements under previously held licenses;

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

4. Violations of the minimum requirements for qualifications, personnel, storage, and handling of prescription drugs and maintenance of prescription drug records as set forth in the federal ~~Prescription Drug Marketing Act of 1987 (21 U.S.C. §§ 333, 353 and 381) and Part 205~~ *Drug Supply Chain Security Act of 2013, Title II of P. L. 113-54, and the requirements* of Chapter 21 of the Code of Federal Regulations.

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

§ 54.1-3435.4:1. Permitting of third-party logistics provider; renewal.

A. It shall be unlawful for any person to operate as a third-party logistics provider in the Commonwealth without a valid, unrevoked permit issued by the Board. The third-party logistics provider shall renew such permit annually on a date determined by the Board in regulation and shall notify the Board within 30 days of any substantive change in the information reported on the application form

previously submitted.

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

§ 54.1-3437. Permit to manufacture drugs.

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

§ 54.1-3442.01. Registration of nonresident manufacturer; renewal.

A. Any manufacturer located outside the Commonwealth who ships prescription drugs into the Commonwealth shall be registered with the Board. The nonresident manufacturer shall renew such registration annually on a date determined by the Board in regulation and shall notify the Board within 30 days of any substantive change in the information previously submitted.

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

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

2. That § 54.1-3401.1 of the Code of Virginia is repealed.

Commonwealth of Virginia

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-50-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date:

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Part I. General Provisions

18VAC110-50-10. Definitions.

In addition to words and terms defined in §§54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Authorized distributor of record" means a wholesale distributor with whom a manufacturer has entered into a written agreement under which such wholesale distributor is either authorized to distribute all of that manufacturer's prescription drug products, or only those products listed in the agreement, for such a period of time or number of shipments as specified in the agreement.

"Control number" means the unique identifying customer number assigned by the Virginia Department of Motor Vehicles to an individual when issuing a driver's license, learner's permit, or official identification card. This number is displayed on the driver's license or ID card in lieu of the social security number.

"DEA" means the United States Drug Enforcement Administration.

"Drop shipment" means the sale and distribution of a prescription drug in which a manufacturer~~,~~ or third party logistics provider~~, or the manufacturer's exclusive distributor~~ directly ships the prescription drug to a pharmacy, chain drug warehouse, or other person authorized to dispense or administer the prescription drug, and the pharmacy, chain drug warehouse or other authorized person is invoiced by a wholesale distributor that took title to the prescription drug during the shipping, but did not take physical possession of the prescription drug.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

"FDA" means the United States Food and Drug Administration.

~~"Manufacturer's exclusive distributor" means a distributor licensed by the board as a wholesale distributor or registered as a nonresident wholesale distributor who contracts with a manufacturer to provide or coordinate warehousing, distribution or other services on behalf of a manufacturer for a prescription drug and who takes title to that manufacturer's prescription drug, but who does not have general responsibility to direct the sale or disposition of the prescription drug.~~

~~"Third-party logistics provider" means an entity licensed by the board as a wholesale distributor or registered as a nonresident wholesale distributor who contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer for a prescription drug, but does not take title to the prescription drug and who only sells, distributes, or otherwise disposes of the prescription drug at the direction of the manufacturer.~~

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

18VAC110-50-20. Fees.

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

B. Initial application fees.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90
7. Third party logistics provider permit	$270
8. Nonresident manufacturer registration	$270

C. Annual renewal fees shall be due on February 28 of each year.

1. Nonrestricted manufacturer permit	$270
2. Restricted manufacturer permit	$180
3. Wholesale distributor license	$270
4. Warehouser permit	$270
5. Nonresident wholesale distributor	$270
6. Controlled substances registration	$90
7. Third party logistics provider permit	$270
8. Nonresident manufacturer registration	$270

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. 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. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90
5. Nonresident wholesale distributor	$90
6. Controlled substances registration	$30
7. Third party logistics provider permit	$90
8. Nonresident manufacturer registration	$90

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date 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.

2. 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. 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.

3. 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. Nonrestricted manufacturer permit	$240
b. Restricted manufacturer permit	$210
c. Wholesale distributor license	$240
d. Warehouser permit	$240
e. Nonresident wholesale distributor	$240
f. Controlled substances registration	$180
g. Third party logistics provider permit	$240
h. Nonresident manufacturer registration	$240

F. Application for change or inspection fees.

1. Reinspection fee	$150
2. Inspection fee for change of location, structural changes, or security system changes	$150
3. Change of ownership fee	$50
4. Change of responsible party	$50

G. The fee for a returned check shall be $35.

H. The fee for verification of license or permit shall be $25.

18VAC110-50-30. Application; location of business; inspection required.

A. Any person or entity desiring to obtain a license as a wholesale distributor, registration as a non-resident wholesale distributor, or permit as a manufacturer, ~~or~~ warehouse, or third party logistics provider shall file an application with the board on a form approved by the board. An application shall be filed for a new license, registration, or permit, or for acquisition of an existing wholesale distributor, manufacturer, ~~or~~ warehouse, or third party logistics provider.

B. A licensee or permit holder proposing to change the location of an existing license or permit, or make structural or security system changes to an existing location, shall file an application for approval of the changes following an inspection conducted by an authorized agent of the board.

C. A license or permit shall not be issued to any wholesale distributor, manufacturer, ~~or~~ warehouse, or third party logistics provider to operate from a private dwelling or residence or to operate without meeting the applicable facility requirements for proper storage and distribution of drugs or devices. Before any license or permit is issued, the applicant shall demonstrate compliance with all federal, state and local laws and ordinances.

D. If a wholesale distributor, manufacturer, ~~or~~ warehouse, or third party logistics provider engages in receiving, possessing, storing, using, manufacturing, distributing, or otherwise disposing of any Schedule II – V controlled substances, it shall also obtain a controlled substances registration from the board in accordance with § 54.1-3422 of the Code of Virginia, and shall also be duly registered with DEA and in compliance with all applicable laws and rules for the storage, distribution, shipping, handling, and transporting of controlled substances.

E. The proposed location, structural changes, or security system changes shall be inspected by an authorized agent of the board prior to issuance of a license.

1. Applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days prior to conducting a scheduled inspection.

3. At the time of the inspection, the proposed prescription drug storage area shall be in compliance with 18 VAC 110-50-40 and 18 VAC 110-50-50, and wholesale distributors shall meet the requirements of 18 VAC 110-50-90.

4. If an applicant substantially fails to meet the requirements for issuance of a 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 18 VAC 110-50-20 prior to a reinspection being conducted.

F. Prescription drugs shall not be stocked within the proposed location or moved to a new location until approval is granted by the inspector or board staff.

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer, ~~or~~ warehouse, or third party logistics provider shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking 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 installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be operable, centrally-monitored, and have an auxiliary source of power.

4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, ~~or~~ warehouser, or third party logistics provider and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

18VAC110-50-50. Storage.

A. All prescription drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements of USP-NF.

B. If no specific storage requirements are established for a drug or a device, it may be held at controlled room temperature, as defined in USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

C. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, or logs shall be utilized to document proper storage of prescription drugs.

D. Packaging of the prescription drugs should be in accordance with USP-NF standards.

E. Schedule II – V controlled substances shall be separated from Schedule VI prescription drugs and stored in a secure area in accordance with DEA security requirements and standards.

F. Any facility shall be of adequate size and construction and have the proper equipment necessary for the proper storage of prescription drugs and devices as set forth in this section.

Part II. Wholesale Distributors and Third Party Logistic Providers.

18VAC110-50-60. Special or limited-use licenses.

The board may issue a limited-use wholesale distributor license or limited-use third party logistics provider permit to entities that do not engage in the wholesale distribution of prescription drugs or in the acts of a third party logistics provider except medical gases and may waive certain requirements of regulation based on the limited nature of such distribution.

18VAC110-50-70. Minimum required information.

A. The application form for a new license, ~~or for~~ registration as a non-resident wholesale distributor, or permit as a third party logistics provider or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee;

3. The federal employer identification number of the applicant or licensee;

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility;

(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.

(4) The name, federal employer identification number, and state of incorporation of the parent company.

d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;

e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;

5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and

9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors and permitting of third party logistic providers:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor or third party logistics provider, who shall be responsible for managing the wholesale distribution or third party logistics provider operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor or third party logistics provider licensed or permitted in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license or third party logistics provider permit at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor or third party logistics provider;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor or third party logistics provider during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor or third party logistics provider and all applicable state and federal laws related to wholesale distribution of prescription drugs or the legal acts of a third party logistics provider.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A criminal history record check through the Central Criminal Records Exchange; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs or those of third party logistics providers in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs or the legal acts of a third party logistics provider.

2. Requiring any employee who has access to prescription drugs to attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs or that of a third party logistics provider.

3. Maintaining current working knowledge of requirements for wholesale distributors or third party logistic providers and assuring continued training for employees.

4. Maintaining proper security, storage and shipping conditions for all prescription drugs.

5. Maintaining all required records.

E. Each non-resident wholesale distributor or nonresident manufacturer shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor or nonresident manufacturer that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal

process in any action or proceeding against such non-resident wholesale distributor or nonresident third party logistics provider. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor or nonresident third party logistics provider by the board by certified mail at the address of record.

18VAC110-50-90. Minimum requirements for the storage, handling, transport, and shipment of prescription drugs.

A. All locations where prescription drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:

1. Be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with the labeling of such drugs and devices or with official USP-NF compendium standards;

2. Be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;

3. Have adequate storage areas to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

4. Have a quarantine area for storage of drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed secondary containers that have been opened;

5. Be maintained in a clean and orderly condition; and

6. Be free from infestation of any kind.

B. The facility shall provide for the secure and confidential storage of information with restricted access and policies and procedures to protect the integrity and confidentiality of the information.

C. The facility shall provide and maintain appropriate inventory controls in order to detect and document any theft, counterfeiting, or diversion of prescription drugs.

18VAC110-50-100. Examination of drug shipments and accompanying documents.

A. Upon receipt, each shipping container shall be visually examined for identity to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit, or damaged drugs, or drugs or devices that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected counterfeiting, or other damage to the contents.

B. Upon receipt of drugs, a wholesale distributor or third party logistics provider must review records for accuracy, completeness, and the integrity of the drugs considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved.

C. Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

18VAC110-50-110. Returned, damaged and counterfeit drugs; investigations.

A. Any drug or device returned to a manufacturer or another wholesale distributor or third party logistics provider shall be kept under the proper conditions and documentation showing that proper conditions were maintained shall be provided to the manufacturer or wholesale distributor or third party logistics provider to which the drugs are returned.

B. Any drug or device that, or any drug whose immediate or sealed outer or secondary container or labeling, is outdated, damaged, deteriorated, misbranded, adulterated, counterfeited, suspected of being counterfeited or adulterated, or otherwise deemed unfit for human consumption shall be quarantined and physically separated from other drugs and devices until its appropriate disposition.

C. When a drug or device is adulterated, misbranded, counterfeited, or suspected of being counterfeit or when the immediate or sealed outer or secondary container or labeling of any drug or device is adulterated, misbranded other than misbranding identified by the manufacturer through a recall or withdrawal, counterfeited, or suspected of being counterfeit, the wholesale distributor or third party logistics provider shall:

1. Provide notice to the board and the manufacturer, and to the other wholesale distributor or third party logistics provider if applicable, from which such drug or device was acquired within three business days of that determination.

2. Maintain any such drug or device, its containers and labeling, and its accompanying documentation or any evidence of criminal activity until its disposition by the appropriate state and federal government authorities.

D. The wholesale distributor or third party logistics provider shall fully cooperate with authorities conducting any investigation of counterfeiting or suspected counterfeiting to include the provision of any records related to receipt or distribution of the suspect drug or device.

18VAC110-50-120. Policies and procedures.

All wholesale distributors and third party logistic providers shall establish, maintain, and adhere to written policies and procedures for the proper receipt, security, storage, inventory, and distribution of prescription drugs. Wholesale distributors and third party logistic providers shall include in their policies and procedures at least the following:

1. A procedure for reporting thefts or losses of prescription drugs to the board and other appropriate persons;

2. A procedure whereby the oldest approved stock of a prescription drug is distributed first. The procedure may permit deviation from this process provided the deviation is temporary and appropriate for the distribution;

3. A procedure for handling recalls and withdrawals of prescription drugs and devices;

4. Procedures for preparing for, protecting against, and handling emergency situations that affect the security and integrity of drugs or the operations of the wholesale distributor or third party logistics provider;

5. A procedure to ensure that outdated drugs are segregated from other drugs to include the disposition of such drugs;

6. A procedure to ensure initial and ongoing training of all employees;

7. A procedure for ensuring, both initially and on an ongoing basis, that persons with access to prescription drugs have not been convicted of a drug law or any law related to the manufacture, distribution, or dispensing of prescription drugs or that of a third party logistics provider; and

8. A procedure for reporting counterfeit or suspected counterfeit prescription drugs or counterfeiting or suspected counterfeiting activities to the board and other appropriate law enforcement or regulatory agencies.

18VAC110-50-130. Recordkeeping.

A. All records and documentation required in this subsection shall be maintained and made available for inspection and photocopying by an authorized agent of the board for a period of three years following the date the record was created or received by the wholesale distributor or third party logistics provider. A wholesale distributor or third party logistics provider shall establish and maintain the following:

1. Inventories and records of all transactions regarding the receipt and distribution, or other disposition of all prescription drugs, including the dates of receipt and distribution or other disposition;

2. Records documenting monitoring of environmental conditions to ensure compliance with the storage requirements as required in 18VAC110-50-50;

3. Documentation of visual inspection of drugs and accompanying documents required in 18VAC110-50-100, including the date of such inspection and the identity of the person conducting the inspection;

4. Documentation of quarantine of any product and steps taken for the proper reporting and disposition of the product shall be maintained, including the handling and disposition of all outdated, damaged, deteriorated, misbranded, or adulterated drugs;

5. An ongoing list of persons or entities from whom it receives prescription drugs and persons or entities to whom it distributes prescription drugs or provides prescription drugs as a third party logistics provider; and

6. Copies of the mandated report of thefts or unusual losses of Schedule II-V controlled substances in compliance with the requirements of §54.1-3404 of the Code of Virginia.

B. Records shall be either (i) be kept at the inspection site or immediately retrievable by computer or other electronic means and made readily available at the time of inspection or (ii) if kept at a central location and not electronically retrievable at the inspection site, be made available for inspection within 48 hours of a request by an authorized agent of the board.

C. All facilities shall have adequate backup systems to protect against the inadvertent loss or deliberate destruction of data.

18VAC110-50-140. Due diligence.

A. Prior to the initial purchase of prescription drugs from another wholesale distributor or third party logistics provider not residing and licensed in Virginia, a wholesale distributor or third party logistics provider shall obtain, and update annually, the following information from the selling wholesale distributor or third party logistics provider :

1. A copy of the license to wholesale distribute or act as a or third party logistics provider from the resident state. If the resident state does not require licensure as a third party logistics provider, documentation confirming active licensure with the US Food and Drug Administration is acceptable.;

2. The most recent facility inspection report, if available;

3. A list of other names under which the wholesale distributor or third party logistics provider is doing business, or was formerly known as;

4. A list of principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation;

5. A list of all disciplinary actions by state and federal agencies;

6. A description, including the address, dimensions, and other relevant information, of each facility or warehouse used for drug storage and distribution or for the legal acts of a third party logistics provider ; and

7. A listing of any manufacturers for whom the wholesale distributor or third party logistics provider is an authorized distributor of record.

B. If the selling third party logistics provider or wholesale distributor's facility has not been inspected by the resident board or the board's agent within three years of the contemplated purchase, the purchasing wholesale distributor or third party logistics provider may conduct an inspection of the third party logistics provider or wholesale distributor's facility prior to the first purchase of drugs or devices from another wholesale distributor or third party logistics provider, to ensure compliance with applicable laws and regulations relating to the storage and handling of drugs or devices. A third party may be engaged to conduct the site inspection on behalf of the purchasing wholesale distributor or third party logistics provider.

C. Prior to the first purchase of drugs from another wholesale distributor or third party logistics provider not residing in and licensed in Virginia, the purchasing wholesale distributor or third party logistics provider shall secure a national criminal background check of all of the wholesale distributor's owners, corporate officers, and the person named as the responsible party with the resident board or licensing agency.

Part III. Manufacturers.

18VAC110-50-150. Good manufacturing practices.

A. The Good Manufacturing Practice for Finished Pharmaceuticals regulations set forth in 21 CFR 211 are adopted by reference.

B. Each manufacturer or nonresident manufacturer of drugs shall comply with the requirements set forth in the federal regulations referred to in subsection A of this section.

~~**Part IV. Pedigree Requirements.**~~

~~**18VAC110-50-160. Susceptible drugs.**~~

~~A. The list of drugs susceptible to counterfeiting for which a pedigree is required shall be all prescription drugs in Schedules II through VI, except that a pedigree is not required for those prescription drugs that do not leave the normal distribution channel or those that include one or more of the following additional distributions or variations to the normal distribution channel:~~

~~1. Distribution by a manufacturer's exclusive distributor;~~

~~2. Distribution by a third-party logistics provider;~~

~~3. Drop shipments;~~

~~4. Distributions to a veterinarian for veterinary use;~~

~~5. Distribution from an authorized distributor of record to one other authorized distributor of record to an office-based healthcare practitioner authorized by law to dispense or administer such drug to a patient; and~~

~~6. Distributions for emergency medical reasons, defined as those in which (i) a state of emergency has been declared by the Governor in accordance with §54.1-3307.3 of the Code of Virginia, or (ii) there is a documented shortage of a drug, where the failure to acquire and dispense a prescription drug could result in imminent danger to patient health, and the wholesale distributor, in lieu of a pedigree, complies with the following requirements:~~

~~a. Obtains and maintains documentation from the manufacturer attesting to a shortage of the prescription drug and its non-availability through normal distribution channels;~~

~~b. Purchases the prescription drug only through an authorized distributor of record and maintains the name of such distributor;~~

~~c. Maintains a list of pharmacies or other authorized entities to which the prescription drug was distributed; and~~

~~d. Notifies the board within 24 hours of such a distribution.~~

~~B. Not less than annually, the board shall evaluate whether the list of susceptible drugs in subsection A of this section should be amended. The board may modify the list under its authority to adopt exempt regulations, pursuant to §2.2-4006 of the Administrative Process Act, in accordance with the following process:~~

~~1. The board shall conduct a public hearing on any proposed amendments to subsection A of this section. Thirty days prior to conducting such hearing, the board shall give written notice of the date, time, and~~

~~place of the hearing to all persons requesting to be notified of the hearings and publish proposed amendments to the list in the Virginia Register of Regulations.~~

~~2. During the public hearing, interested parties shall be given reasonable opportunity to be heard and present information prior to final adoption of any amendments. Final amendments of the list shall also be published, pursuant to §2.2-4031 of the Code of Virginia, in the Virginia Register of Regulations.~~
~~3. Final amendments to the list of susceptible drugs shall become effective upon filing with the Registrar of Regulations.~~

~~18VAC110-50-170. Requirements of a pedigree.~~

~~A. For distributions of prescription drugs that require a pedigree in accordance with §54.1-3307 of the Code of Virginia and 18VAC110-50-160, the pedigree shall list all distributions starting with the sale by a manufacturer through acquisition and sale by any wholesale distributor until final sale to a pharmacy or other person authorized to administer or dispense the prescription drug.~~

~~B. When required by law and regulation to provide a pedigree, a wholesale distributor shall provide an authenticated pedigree for drugs sold or returned to another wholesale distributor before or at the time the drug is shipped to such wholesale distributor.~~

~~C. The pedigree shall minimally include the following information on a prescription drug for which a pedigree is required:~~

~~1. The trade or generic name of the drug;~~

~~2. The dosage form and strength, the container size, number of containers, and lot number;~~

~~3. The name of the manufacturer of the finished drug product;~~

~~4. Each transaction in which the drug is shipped or received by a manufacturer or wholesale distributor showing the following:~~

~~a. The business name and address of each entity involved in the chain of the drug's physical custody;~~

~~b. Telephone number and other contact information needed to authenticate the pedigree;~~

~~c. Sales invoice number or other unique shipping document number that identify each transaction; and~~

~~d. The dates of the transactions to include shipping dates when a seller ships the product and the receiving dates when a purchaser receives the product.~~

~~5. A statement of certification that the information contained in the pedigree is true and accurate and the name and signature of the individual certifying the authenticity of the pedigree at the time of shipment of the drug.~~

~~D. The requirement for a pedigree shall be effective February 20, 2009.~~

~~18VAC110-50-180. Authentication of a pedigree.~~

~~A. Each person who is engaged in the wholesale distribution of a drug, who is provided a pedigree as specified in 18VAC110-50-160 and attempts to further distribute that drug, shall affirmatively verify before any distribution of a prescription drug that each transaction listed on the pedigree has occurred.~~

~~B. Upon request of a wholesale distributor who is attempting to authenticate a pedigree for a drug as specified in 18VAC110-50-160, any manufacturer or wholesale distributor listed on the pedigree shall provide requested information in a timely manner, only for those applicable transactions outside the normal chain of distribution conducted by that manufacturer or wholesale distributor, to include the following:~~

~~1. Dates of receipt or shipment of the drug as well as the name, address, and other contact information of those entities from whom they received the drug or to whom they shipped the drug;~~

~~2. Lot number;~~

~~3. Sales invoice number or other unique shipping document numbers that identify each transaction; and~~

~~4. Name of the person who is providing the requested information.~~

~~C. The wholesale distributor shall record the above information and maintain the information in accordance with 18VAC110-20-190.~~

~~D. If a wholesale distributor that is attempting to authenticate the distribution of a drug back to a manufacturer is unable to authenticate each distribution, the wholesale distributor shall quarantine the drug and report to the board and the FDA within three business days after completing the attempted authentication.~~

18VAC110-50-190. Recordkeeping.

A. ~~Wholesale~~ Unless otherwise indicated in federal law, wholesale distributors and third party logistics providers shall establish and maintain inventories and records of all transactions relating to the receipt and distribution or other disposition or provision of drugs ~~as specified in 18VAC110-50-160,~~ to include records ~~of authentication of pedigrees~~ related to the federal requirements for an electronic, interoperable system to identify, trace, and verify prescription drugs as they are distributed, for a period of not less than three years.

B. All records shall be made available to the board or its authorized agent upon request. If records are not kept on premises at the address of record, they shall be made available within 48 hours of such request.

Agenda Item: **Regulatory Action – Adoption of Final Regulations**

Exempt action – required by passage of legislation in 2016

Included in agenda package:

Copy of HB527 – Registration of nonresident medical equipment suppliers

Amendment to regulation: 18VAC110-20-680. Medical equipment suppliers

Staff Note:

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006 because it is conforming regulation to a change in the statute.

Board action:

Adoption of final regulation

CHAPTER 88

An Act to amend the Code of Virginia by adding a section numbered 54.1-3435.3:1, relating to registration of nonresident medical equipment suppliers.

[H 527]

Approved March 1, 2016

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding a section numbered 54.1-3435.3:1 as follows:

§ 54.1-3435.3:1. Registration of nonresident medical equipment suppliers; renewal; fee.

A. Any person located outside the Commonwealth other than a nonresident pharmacy registered pursuant to § 54.1-3434.1 that ships, mails, or delivers to a consumer in the Commonwealth any hypodermic syringes or needles, medicinal oxygen, Schedule VI controlled device, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, sterile water and saline for irrigation, or solutions for peritoneal dialysis pursuant to a lawful order of a prescriber shall be registered with the Board as a nonresident medical equipment supplier. Registration as a nonresident medical equipment supplier shall be renewed by March 1 of each year. Applicants for registration or renewal of a registration shall submit a fee specified by the Board in regulations at the time of registration or renewal. A nonresident medical equipment supplier registered in accordance with this section shall notify the Board within 30 days of any substantive change in the information previously submitted to the Board.

B. The nonresident medical equipment supplier shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located, if required by the resident state, and shall furnish proof of such license, permit, or registration upon application for registration or renewal. If the resident state does not require a license, permit, or registration to engage in direct consumer supply of the medical equipment described in subsection A, the applicant shall furnish proof that it meets the minimum statutory and regulatory requirements for medical equipment suppliers in the Commonwealth.

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

Project 4831

BOARD OF PHARMACY

Non-resident medical equipment suppliers

18VAC110-20-680. Medical equipment suppliers.

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

E. A nonresident medical equipment supplier shall register and practice in accordance with § 54.1-3435.3:1 of the Code of Virginia.

Agenda Item: Petitions for rulemaking

Included in your package are:

2 petitions for rulemaking

Copies of the *Requests for Comment*

Copies of comment on petitions

Copies of applicable regulations

Board action: The Board will consider each petition separately:

1) Phillips – Permit pharmacist to dispense a quantity of a Schedule VI substance greater than the amount initially prescribed – (1 comment in support)

2) StClair – Permit use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes (comment period ends 8/31/16 – any comment will be provided to Board as a handout at the meeting)

The Board may reject the petition's request. If rejected, the Board must state their reasons for denying the petition.

OR

The Board may initiate rulemaking by adoption of an amendment by publication of a Notice of Regulatory Action.

Request for Comment on Petition for Rulemaking

Promulgating Board: Board of Pharmacy

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

Agency Contact: Caroline Juran, RPh
Executive Director
(804)367-4416
caroline.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Suite 300
Richmond, VA 23233

Chapter Affected:
18 vac 110 - 20: Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Date Petition Received 05/06/2016

Petitioner Derek Phillips

Petitioner's Request:

If deemed appropriate by the pharmacist, a patient may receive, upon request, drug quantities in excess of the face amount of a prescription for a Schedule VI substance, up to the total amount authorized.

Agency Plan
In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on May 30, 2016. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until June 29, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for September 7, 2016, and the petitioner will be informed of the Board's decision on his request after that meeting.

Publication Date 05/30/2016 *(comment period will also begin on this date)*

Comment End Date 06/29/2016

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

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

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below: (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,) PHILLIPS, DEREK, M		
Street Address 936 UPPER HASTINGS WAY	Area Code and Telephone Number 757-652-7385	
City VIRGINIA BEACH	State VA	Zip Code 23452
Email Address (optional) DEREK.UNC@GMAIL.COM	Fax (optional)	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-320. REFILLING OF SCHEDULE III THROUGH VI PRESCRIPTIONS

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

As a pharmacist, it is necessary to stay current with new processes, ideas, and methods. The intent of this request is to amend 18VAC110-20-320: REFILLING OF SCHEDULE III THROUGH VI PRESCRIPTIONS. Authorization for prescription refills is presumed to be within the prescribed dosage or normal therapeutic use. The pharmacist should have the right to refill a prescription if they believe that filling the prescription is in the best interest of the patient. Any refills may only be dispensed in reasonable conformity with recommended dosage and the exercise of sound professional judgment.

Therefore, I propose that if deemed appropriate in the pharmacist's professional judgment, a patient may receive upon request drug quantities in excess of the face amount of a prescription for a Schedule VI substance, up to the total amount authorized. The pharmacist should not dispense in excess of the face amount of a prescription for a Schedule III, IV, V substance or psychotherapeutic drug without authorization from the prescriber.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference.

VIRGINIA BOARD OF PHARMACY HAS LEGAL AUTHORITY FOR REGULATIONS GOVERNING THE PRACTICE OF PHARMACY
§ 54.1-2400 OF THE CODE OF VIRGINIA

Signature:

Date: 4/27/16

CVSHealth

June 28, 2016

Caroline D. Juran, Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

RE: Public Comment for Proposed Amendment to the Regulations Governing the Practice of Pharmacy 18VAC110-20.

Dear Executive Director Juran:

CVS Health appreciates the opportunity to submit comments regarding the proposed amendment to 18VAC110-20 as requested by Mr. Derek Phillips. This proposal if promulgated, will allow a pharmacist upon patient request, to dispense a quantity of Schedule VI medication in excess of the amount noted on the face of the prescription, not to exceed the total amount authorized by the prescriber provided the pharmacist deems the request appropriate for the patient.

As a leader in the pharmacy industry and an advocate for increased patient access to prescription medication, CVS Health supports the proposal as published in the Virginia Regulatory Town Hall Public Comment Forum.

Granting the pharmacist authority to dispense a quantity of a Schedule VI substance greater than the amount initially noted on the prescription include, but are not limited to, the following benefits to the patient and prescriber community.

- The patient will be afforded increased access to medication as well as the ability to receive them in a more convenient manner.
- Pharmacists will have increased opportunities to engage in patient care activities with the elimination of unnecessary communication with prescribers and office staff regarding this type of request.
- Enabling this activity will allow patients greater flexibility to obtain quantities of medication from their pharmacy of choice based on individual need.
- Allowing this type of request will align the patient to manage their healthcare from a more balanced position which should lead to improved medication adherence and positive outcome.

In closing, CVS Health appreciates the opportunity to provide these comments to the Board of Pharmacy for their review and consideration regarding this proposal and look forward to a favorable outcome for the patients of the Commonwealth of Virginia.

CVSHealth

Sincerely,

Bill Irvin, R.Ph.
Director, Pharmacy Regulatory Affairs
CVS Health
13 Commerce Avenue
Londonderry, NH 03053
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William.irvin@omnicare.com

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

A. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

B. A pharmacist shall determine the number of pharmacy interns, pharmacy technicians, and pharmacy technician trainees he can safely and competently supervise at one time; however, no pharmacist shall supervise more than four persons acting as pharmacy technicians at one time.

C. After the prescription has been prepared and prior to the delivery of the order, a pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. If more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. Such record showing verification of accuracy shall be maintained on a pharmacy record and, if necessary, an alternate record consistent with 18VAC110-20-255 for the required time period of two years, unless otherwise specified in regulation. If the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.

D. If a pharmacist declines to fill a prescription for any reason other than the unavailability of the drug prescribed, he shall record on the back of the prescription the word "declined"; the name, address, and telephone number of the pharmacy; the date filling of the prescription was declined; and the signature of the pharmacist.

E. If a pharmacist determines from a prescriber or by other means, including the use of his professional judgment, that a prescription presented for dispensing is a forgery, the pharmacist shall not return the forged prescription to the person presenting it. The forged prescription may be given to a law-enforcement official investigating the forgery; or it shall be retained for a minimum of 30 days before destroying it, in the event it is needed for an investigative or other legitimate purpose.

F. An on-hold prescription shall be entered into the automated data processing system, if such system is employed by the pharmacy, and the pharmacist on-duty shall verify the accuracy of the data entry at that time. The pharmacist subsequently dispensing the on-hold prescription on a future date shall, at a minimum, conduct a prospective drug review consistent with § 54.1-3319 A of the Drug Control Act. If an on-hold prescription is returned to a patient prior to the initial dispensing of the drug, the pharmacist shall delete the entry in the automated data processing system.

Request for Comment on Petition for Rulemaking

Board of Pharmacy

Regulatory Coordinator:	Elaine J. Yeatts (804)367-4688 elaine.yeatts@dhp.virginia.gov
Agency Contact:	Caroline Juran, RPh Executive Director (804)367-4578 caroline.juran@dhp.virginia.gov
Contact Address:	Department of Health Professions 9960 Mayland Drive Suite 300 Richmond, VA 23233

Chapter Affected:

18 vac 110 - 20: Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Date Petition Received 07/15/2016

Petitioner Roger StClair

Petitioner's Request

To authorize use of electronic devices in lieu of manual emergency drug kits and stat-drug boxes to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Current regulation does not designate electronic devices being utilized as unit dose systems purely for first dose non-routine vs automated dispensing devices utilized for full or routine dispensing in Long Term Care facilities.

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on August 8, 2016. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until August 31, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for September 7, 2016, and the petitioner will be informed of the Board's decision after that meeting.

Publication Date 08/08/2016 *(comment period will also begin on this date)*

Comment End Date 08/31/2016

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

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

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,) StClair, Roger Dale, JR (General Manager on behalf of Remedi SeniorCare)		
Street Address 10448 Lakeridge Parkway	**Area Code and Telephone Number** 804-955-9310	
City Ashland	**State** Virginia	**Zip Code** 23005
Email Address (optional) Dale.StClair@RemediRx.com	**Fax (optional)**	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-540. Emergency drug kit, 18VAC110-20-550. Stat-drug box, 18VAC110-20-555. Use of automated dispensing devices.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

Remedi SeniorCare seeks the Board of Pharmacy to amend subsections 540 and 550, permitting registered pharmacies providing services to Long Term Care facilities to utilize electronic devices in lieu of manual emergency drug kits and stat-drug boxes to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Current regulation does not designate electronic devices being utilized as unit dose systems purely for FIRST DOSE NON-ROUTINE vs automated dispensing devices utilized for FULL OR ROUTINE DISPENSING in Long Term Care facilities. The Drug Enforcement Administration makes distinction with regard to the different utilization of such devices and is delineated in 45 FR 24128 and 21 CFR §1301.27. This petition is made with the intention of recognizing technological advances in the care of residents in Long Term Care facilities. The utilization of electronic devices to store medications in compliance with 18VAC110-20-540 and 18VAC110-20-550 provides superior control of medications stored in Long Term Care facilities and offers electronic automated tracking of medications stored within such cabinets. The utilization of electronic devices should be delineated based upon the intended utilization of such cabinets though routine or non-routine dispensing. Multiple states have recognized the advances of utilizing electronic cabinets as Emergency Drug Kits and Stat-Drug Boxes to include Pennsylvania, Tennessee, Maryland, North Carolina, Illinois, and Kansas. Electronic cabinets for Emergency/STAT drug kits increase accuracy in the nursing staff administering the correct dose by limiting access for nursing staff to the correct location within the cabinet for first dose administrations. In addition electronic cabinets maintain superior capabilities to track expiration dates of products and accessibility by nursing staff. This petition seeks to allow electronic devices under 18VAC110-20-540 and 18VAC110-20-550 and to exempt them from the requirements contained under 18VAC110-20-555 when utilized under the aforementioned subsections 540 and 550.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

45 FR 24128, April 9, 1980 permits the placement of emergency kits containing controlled substances in non-federal registered Long Term Care facilities and makes no requirement for such kits to be non-electronic.

Signature: Dale Klein **Date:** 07/14/2016

Sub selection of state regulations permitting electronic emergency/STAT kits and/or delineating non-routine dispensing from routine dispensing.

- Pennsylvania
  - PA BReg 27.1. Definitions
    - Automated medication system— ii) The term does not include an automatic counting device or unit-based dispensing cabinet.
- North Carolina
  - NC BReg .1814. Automated dispensing or drug supply devices.
    - (e) An automated dispensing or drug supply device that is used solely as an Auxiliary Medication Inventory as defined in 21 NCAC 46 .1414(d) shall be governed by the requirements of that Rule.
- Tennessee
  - TN BReg 1140-04-.09. Emergency and home care kits.
    - (1) (a) 3. The emergency kit shall be provided sealed or electronically secured by authorized personnel in accordance with established policies. The expiration date of the kit shall be clearly marked on the exterior of the kit to represent the earliest expiration date of any drug, device, or related materials contained in the kits.
- Maryland
  - MD BReg Section .05. Usage Requirements for Decentralized Automated Medication Systems.
    - A (3) Except for starter doses, a licensed pharmacist reviews each order for medication
- Illinois
  - Section 1330.680 Automated Dispensing and Storage Systems
    - B (2) Automated dispensing and storage systems shall be used only in settings that ensure medication orders and prescriptions are reviewed by a pharmacist in accordance with established policies and procedures and good pharmacy practice. This provision shall not apply when used as an after hours cabinet or emergency kit as provided in Section 1330.530(e).
- Kansas
  - KS BReg 68-7-10. Pharmacy based drug distribution systems in adult care homes; definitions; emergency medication kits.
    - (d) 3 (C) The kit shall be securely locked in a sufficiently well-constructed cabinet or cart and access to the cabinet or cart shall be available only to the nurse or nurses as determined by the pharmaceutical services committee or its equivalent.

18VAC110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.

2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL may be included.

3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.

a. The dispensing pharmacy must have a method of sealing such kits so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of item(s) removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.

5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

18VAC110-20-550. Stat-drug box.

An additional drug box called a stat-drug box may be prepared by a pharmacy to provide for initiating therapy prior to the receipt of ordered drugs from the pharmacy. Access to the stat-drug box is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the stat-drug box. Additionally, a valid prescription or lawful order of a prescriber must exist prior to the removal of any drug from the stat-drug box. A stat-drug box shall be subject to the following conditions:

1. The box is sealed in such a manner that will preclude the loss of drugs.

a. The dispensing pharmacy must have a method of sealing such boxes so that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box and maintain the record until such time as the seal is replaced.

c. In lieu of seals, a box with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.

2. The box shall have a form to be filled out upon opening the box and removing contents to write the name of the person opening the box, the date, the time and the name and quantity of item(s) removed. When the stat-drug box has been opened, it is returned to the pharmacy.

3. There shall be a listing of the contents of the box maintained in the pharmacy and also attached to the box in the facility. This same listing shall become a part of the policy and procedure manual of the facility served by the pharmacy.

4. The drug listing on the box shall bear an expiration date for the box. The expiration date shall be the day on which the first drug in the box will expire.

5. The contents of the box shall be limited to those drugs in which a delay in initiating therapy may result in harm to the patient.

a. The listing of drugs contained in the stat-drug box shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the long-term care facility.

b. The stat-drug box shall contain no more than 20 solid dosage units per schedule of Schedule II through V drugs except that one unit of liquid, not to exceed 30 ml, may be substituted for a solid dosage unit. If the unit of a liquid that may contain more than one dose is removed from the stat-box pursuant to a patient order, the remainder shall be stored with that patient's other drugs, may be used for subsequent doses administered to that patient, and shall not be administered to any other patient.

Agenda Item: Bestech GMP Contracting

Staff Note:

This issue was first discussed at the June 2016 full board meeting- refer to meeting minutes. The board requested Bestech GMP Contracting to provide additional information for consideration as to whether the board would accept an inspection report or other documentation from Bestech when an outsourcing facility or nonresident outsourcing facility has not been inspected by the FDA within the required period.

Included in your packet:

Excerpts of relevant laws

Documentation provided by Bestech regarding mock FDA audits

Sample assessment report provided by Bestech

Possible Board Action:

- Adopt guidance that the board will accept an inspection report or other documentation from Bestech when an outsourcing facility or nonresident outsourcing facility has not been inspected by the FDA within the required period OR
- Request additional information OR
- Deny acceptance of an inspection report or documentation from Bestech

§54.1-3434.05

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.

§54.1-3434.5

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.

BESTECH GMP CONTRACTING	Mock FDA Audits		
DOCUMENT NUMBER: BGC QA-0101	**VERSION NUMBER:** 1.0	**EFFECTIVE DATE:**	**REVIEW BY DATE:** N/A – NEW
PREPARED BY:	**TITLE:**	**SIGNATURE:**	**DATE:**
NANCY DANIELS	TECH WRITER	Nancy Daniels	AUG. 18, 2016
DOCUMENT APPROVER:	**TITLE:**	**APPROVAL SIGNATURE:**	**DATE:**

1. Purpose
   1.1 The purpose of this procedure is to:
      1.1.1 Outline the approach for performing mock FDA audits at Human Drug Compounding Outsourcing Facilities by Bestech GMP Contracting (Bestech) auditors.
      1.1.2 Outline auditor training and certification for performing the mock FDA audits.
   1.2 The purpose of the mock FDA audits is to identify potential contamination risks and assure pharmacy is complying with the requirements in 21 CFR parts 210 & 211.
   1.3 The audit described in this procedure is not meant to substitute an audit performed by the US FDA. The audit is performed by a third party to simulate FDA-style inspections for the purposes of continuous improvement only.

2. Scope
   2.1 The audit approach outlined in this procedure applies to facilities that compound human drugs as an FDA-registered outsourcing facility under section 503B of the Food, Drug and Cosmetic Act.
   2.2 Like an audit performed by FDA, the audit outlined in this procedure is not meant to result in an all-inclusive list of every possible deviation from law and regulation. Auditors will note only what they saw during the course of the inspection.

3. Audit Plan
   3.1 All audits will be performed by two Bestech certified Auditors. Refer to Section 7 for Auditor training and qualification requirements.
   3.2 Prior to the audit, an audit plan should be prepared and sent to the facility Quality Leadership. The plan will:
      3.2.1 Outline the scope and timing of the audit.
      3.2.2 Estimate the duration of the audit. Most audits will last anywhere from 3-5 days, depending on the size and complexity of the operation.
      3.2.3 Request information to help expedite the audit:
         3.2.3.1 Most recent FDA Form 483 (if applicable)
         3.2.3.2 Product List

4. Audit Execution

4.1 On first the day of the audit, an introduction meeting will be held and will discuss the audit scope and timetable.

4.2 A daily meeting will be held at the end of each day to discuss observations made and the proposed plan for the next day, including documents requests.

4.3 The Audit

4.3.1 Auditors shall take detailed notes during the audit and will ensure any findings are objective, accurate and quantifiable.

4.3.2 The audit approach will be to verify at least two of the six systems as outlined in FDA guidances (9.2 and 9.3), which specify that the Quality System and one other system is selected. The decision for selecting the other system should be based on inspectional history, recalls, complaints and any other verifiable data that may point to a problem area.

4.3.3 The FDA Compliance Program Guidance Manuals (References 9.2 & 9.3) should be used as the detailed guide to the audit.

4.3.3.1 For example, when the Quality System is evaluated, the following data and reports should be evaluated:

- Discrepancy and failure investigations
- Trend reports, quality reports (e.g., media fills, environmental trends, personnel monitoring)
- Complaints
- Stability
- Rejected lots

4.3.3.2 For example, when the Facility and Equipment System is evaluated, the following data, logs and/or reports should be evaluated:

- Cleaning and Disinfection
- Facility/Equipment layout and air handling system
- Material flow
- Quality control of classified areas including air pressure balance and HEPA filtration

4.3.4 One more mandatory area to assess during the audit is the presence of insanitary conditions that could cause a drug to become contaminated or rendered injurious to health. Specific examples of insanitary conditions are located in the FDA Guidance on Insanitary Conditions at Compounding Facilities (Reference 9.5). During the audit this document should be used to evaluate these types of conditions.

4.3.5 General Techniques for gathering evidence will be utilized:

4.3.5.1 Observe conditions, look for patterns

4.3.5.2 Interview people

4.3.5.3 Analyze information and data

4.3.5.4 Verify information

4.3.5.5 Investigate systems and operations, review lab records
4.3.5.6 Evaluate events
4.3.5.7 Verify whether controls exist (e.g., policies/procedures), are they used, are they working properly.

4.3.6 At the conclusion of the audit, a closeout meeting should be held with company leadership. A verbal discussion of observations should be reviewed and time for questions/comments should be allowed. If any evidence is presented by the company that proves the correction to an observation has been made, that observation can be eliminated from the audit report.

5. Audit Report

5.1 Within five business days after the closeout of the audit, the written audit report shall be sent to the company and the state Board of Pharmacy (if applicable). The report will follow a similar layout and format as the FDA form 483 and shall list observed conditions that, in the Auditors judgement, constitute violations to the current Good Manufacturing Practices.

5.2 The observations made on the report form shall be listed in order of criticality with the first observation being the most critical. An example audit report form is located in Appendix B.

6. Audit Response Requirements

6.1 The Compounding Facility is expected to respond to the observations made in the audit report to the Audit Team within 15 business days of receipt with the plan for corrective action(s).

6.2 Within 5 business days, the audit team will perform a review of the responses to the audit observations and will make a conclusion as to whether the corrective actions implemented by the facility were adequate. The audit team will also make recommendations to correct any responses not deemed to be acceptable. This review will be written in the form of a letter to the Compounding Facility with a copy to be forwarded to the state Board of Pharmacy (if applicable).

7. Auditor training and qualifications

7.1 Each Auditor shall have the education, training and experience or any combination thereof, to enable the person to perform the mock FDA GMP quality audits.

7.1.1 For example, an Auditor shall possess a minimum of ten years experience in the pharmaceutical industry or with FDA, in a role performing quality assessments, audits and/or inspections.

7.2 Each Auditor shall read and understand this procedure and pass a Knowledge Transfer Assessment (KTA) with a score of 80% or better (example provided in Appendix C).

7.3 As part of Auditor certification, each auditor shall be required to review five recent (< 2 years) FDA Form 483 inspection results from the FDA website related to compounding pharmacy operations (*http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm*) and pass a Knowledge Transfer Assessment with a score of 80% or better.

7.4 On-going Auditor recertification is required every two years. Recertification consists of a re-review of this procedure and review of three recent (< 2 years) FDA Form 483 inspection results with a passing KTA on the Form 483 reviews. Knowledge assessments are prepared and administered by the Bestech Office.

7.5 Each Auditor shall pass a background check to verify at a minimum:

- Education
- Employment
- Criminal record

7.6 Each Auditor shall pass a 10-panel drug screening within the past 12 months.

7.7 Training records will be kept on file with Bestech for 7 years following the last audit performed by the Auditor.

8. Audit documentation

8.1 Mock Form 483 Audit Report

All audit reports will be kept on file with Bestech for 7 years following issuance of the Mock Audit Report.

9. Reference Documents

9.1 21CFR Parts 210 & 211 Current Good Manufacturing Practices in Manufacturing, processing or Holding of Drugs and Finished Pharmaceuticals

9.2 FDA Compliance Program Guidance Manual – Drug Manufacturing Inspections, February 2002

9.3 FDA Compliance Program Guidance Manual – Sterile Drug Process Inspections, November 2015

9.4 Draft Guidance – cGMP Compounding Outsourcing Facilities under Section 503B of the FD&C Act US FDA, July 2014

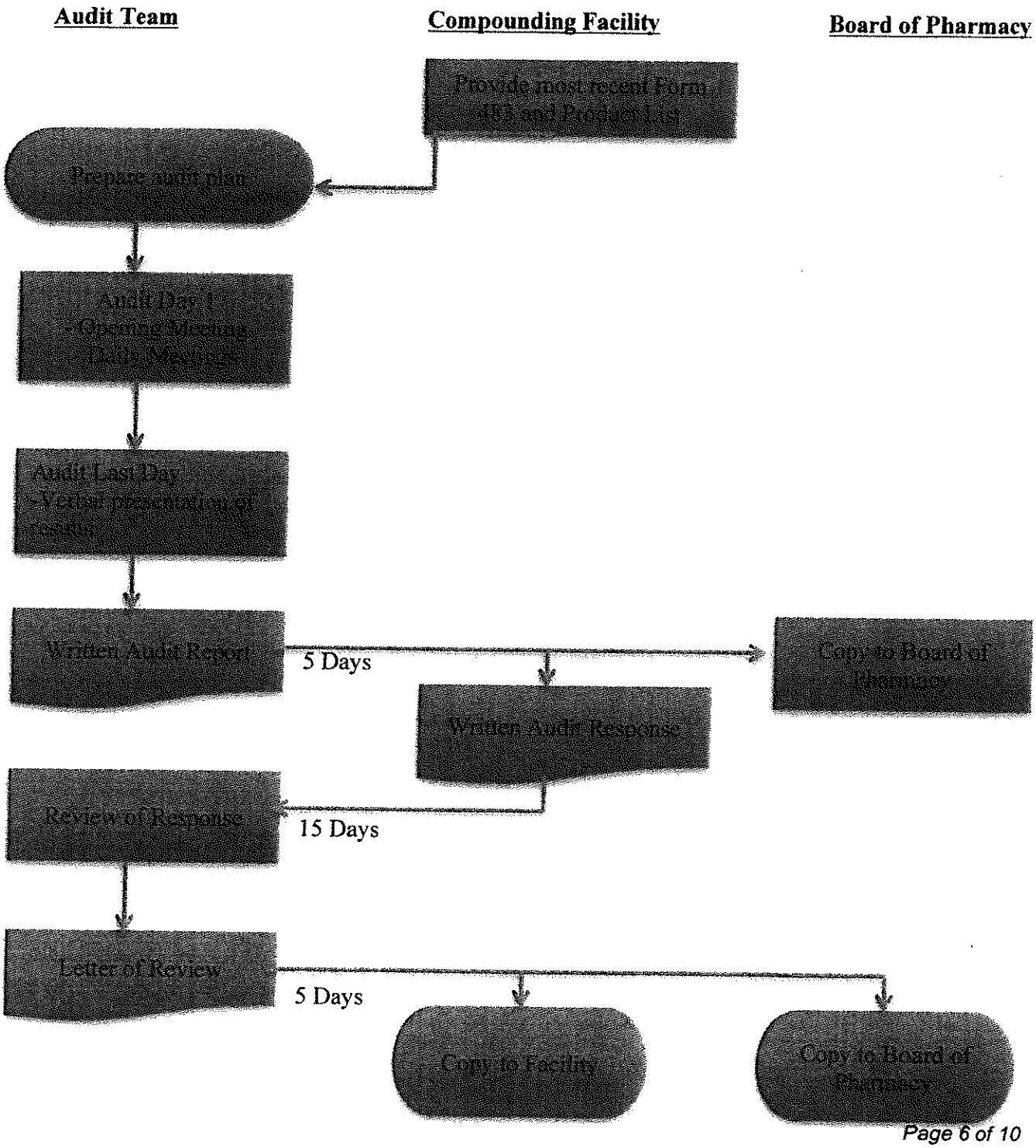
9.5 Draft Guidance – Insanitary Conditions at Compounding Facilities, US FDA, August 2016

10. Revision History

VERSION NUMBER:	REASON FOR REVISION	DATE ISSUED:
1.0	First Draft	15 AUG 2016

11. APPENDICES
    - 11.1 Appendix A: Audit Process Flow
    - 11.2 Appendix B: Example Audit Report
    - 11.3 Appendix C: Example Knowledge Transfer Assessment

APPENDIX A – Audit Process Flow Diagram



APPENDIX B: Example Audit Report

Mock FDA Audit Report	
Auditors Name & Contact Information:	Date(s) of Audit:
Name of Facility Point of Contact:	
Name of Firm:	Street Address:
City, State, Zip Code	Type of Facility

During an inspection of your facility we observed:

Example Observation #1:

Your firm failed to establish an adequate system fir maintaining equipment to control aseptic conditions.
Specifically:
a) Smoke Studies were not performed during dynamic conditions to verify that operatirs and processing equipment do not alter or impede the unidirectional cascade of air from the HEPA filters to the ISO 5 Laminar Flow Benches where sterile drug products are opened and manipulated, and to the rest of the ISO 7 Clean Room.

Observation #2:

Auditor(s) signature	Auditor(s) Name	Date of Issue

Appendix C: Example Knowledge Transfer Assessment

Trainee Name: _____

Document Number: BGC QA-KTA-0101 Version Number: 01

Directions: Circle the letter that best completes the statement.

1. The purpose of the mock FDA audits is to identify potential contamination risks and assure pharmacy is complying with the requirements in _____.
a. 21 CFR part 11 b. 21 CFR parts 210 & 211 c. 21 CFR part 820 d. All of the above

2. The audit approach outlined in this procedure applies to facilities that compound human drugs as an FDA-registered outsourcing facility under section _____.
a. 501 of the Food, Drug and Cosmetic Act b. 503A of the Food, Drug and Cosmetic Act c. 503B of the Food, Drug and Cosmetic Act d. 503C of the Food, Drug and Cosmetic Act

3. Prior to the audit, an audit plan should be prepared and sent to the facility quality leadership containing _____.
a. Outline of the scope and timing of the audit b. Estimate duration of the audit c. Request list of information required to help expedite the audit d. All of the above

4. Audit execution will include _____.
a. An introductory meeting to discuss audit scope and timetable b. Daily meetings in the morning to discuss events for that day c. Daily meetings at the end of the day with company leadership to discuss observations d. All of the above

5. The audit approach will be to verify at least two of the six systems as outlined in FDA guidances (9.2 and 9.3), which specify that the _____ and one other system is selected.

a. Production System
b. Quality System
c. Facilities and Equipment System
d. Materials System

6. The detailed guide to the audit will follow the _____.

a. Quality Audit Handbook, American Society for Quality
b. ICH Guideline on Pharmaceutical Development
c. FDA Compliance Program Guidance Manual
d. All of the above

7. During the audit, to determine the presence of insanitary conditions that could cause a drug to become contaminated or rendered injurious to health, the _____ will be used.

a. Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act
b. FDA Guidance on Insanitary Conditions at Compounding Facilities (Reference 9.5)
c. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act, Guidance for Industry
d. All of the above

8. General Techniques for gathering evidence will be utilized such as _____.

a. Observing conditions, looking for patterns
b. Interviewing people, analyzing, and verifying information/data
c. Investigating systems and operations, and reviewing lab records
d. All of the above

9. The written audit report shall be sent to the company and the Board of Pharmacy (if applicable) within _____ after closeout of the audit.

a. 5 business days
b. 5 calendar days
c. 7 calendar days
d. 3 business days

10. As part of Auditor certification, each auditor shall be required to review _____ recent (< 2 years) FDA Form 483 inspection results from the FDA website related to compounding pharmacy operations.
a. Two b. Three c. Four d. Five

Criterion 80%

Complete or Incomplete (circle one)

Auditor Candidate Printed Name:

Auditor Candidate Signature: *Date:*

Bestech Management Printed Name:

Bestech Management Signature: *Date:*

Signatures on this page indicate the Auditor Candidate has successful met the criterion of this Assessment.

I. Purpose:

The purpose of this report is to summarize the results of the assessment of the sterile compounding pharmacy operation at XYZ Compounding, Inc. The facility is located in Anytown, USA.

II. Scope:

The assessment was performed by the third party GMP expert firm Bestech GMP Contracting, Inc. The personnel who executed the audit were Mr. Matthew Bestercy, a pharmaceutical Quality Engineer and Ms. Jane Doe, a pharmaceutical Microbiologist. On site assessment of the operation took place from May 2-4 2016 and off site May 2 - June 4 2016.

The operation was assessed against the following two documents:

1. US Food and Drug Administration Draft Guidance: "*Guidance for Industry - Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*". Issued July 2014
2. United States Pharmacopeia chapter <797> "*Pharmaceutical Compounding—Sterile Preparations*" intended to be published in USP 39.

The assessment divided the operation into the following 14 areas and assessed each area for: a) compliance of existing Policies and Procedures and b) compliance of practices in use in the operation.

1. Facility Design
2. Control Systems and Procedures for Maintaining Suitable Facilities
3. Environmental Monitoring and Personnel Monitoring
4. Equipment, Containers and Closures
5. Production and Process Controls
6. Aseptic Drug Processing
7. Release Testing
8. Laboratory Controls
9. Stability/Expiration Dating
10. Packaging and Labels
11. Quality Assurance and Complaint Handling
12. Personal Hygiene and Personal Protective Equipment
13. CSP Storage, Handling, Packaging and Transport
14. Documentation

III. Primary Contacts during Assessment

Mr. John Doe, R.Ph. Director of Pharmacy

Dr. Joe Smith, Pharm D., Pharmacist

IV. Documents Reviewed

The following documents were reviewed during the execution of the assessment protocol:

(full list of company SOPs)

V. Assessment Results

The attached Assessment Table (Attachment A) divides the operation into 14 areas of review (see Section II "Scope") and compares the requirements from two primary industry guidances for compounding pharmacy quality – 1) The FDA Draft Guidance *Current Good Manufacturing Practice Compounding Outsourcing Facilities and 2) USP* draft chapter <797> "*Pharmaceutical Compounding—Sterile Preparations*".

XYZ Compounding's actual Procedures and Policies and in-use practices were compared to the requirements outlined in the guidances and the detailed results were recorded in the table.

VI. Overall Conclusion

The comprehensive assessment of XYZ Compounding Operations against industry guidances revealed the following summary observations:

1. The physical condition of the facility and equipment is not optimal.
2. The company has no established Quality Unit.
3. The company's Policies and Procedures are not always current with the latest industry guidances.
4. There were instances that the policies/procedures currently in place were not always followed.
5. The policies/procedures tend to lack detail and robustness to make them effective and sustainable.
6. Some subject areas lack procedures.
7. The policies/procedures are not well structured, i.e., subject matter and/or operational areas are dispersed among several procedures.

As a result of this assessment, a Corrective Action Plan will be developed, which will outline all of the corrective actions required to correct the gaps identified in the assessment and assign due dates for completion of the action items.

VII. Attachments

A. Assessment Table of results

Completed by: _____ Date: _____
Matthew Bestercy, Bestech GMP Contracting, Inc.

Attachment A: **Assessment Table of Results**

No.	Section 503B FDA cGMP Guidance *	USP 797 Requirement **	XYZ Compounding SOPs and Practices
	Category: A) Facility Design		
1.	All processing and controlled areas must be clean and free of visible signs of filth, dirt, mold or mildew, insects, and inappropriate items or debris Damaged, dirty, or discolored HEPA filters should not be used. Sterile drugs should be produced only in ISO 5 or better air quality.		*The pest control program is minimal and no SOP exists. No pest traps or bug lights are present near any outside facing doors. Only the boiler room has multiple rodent traps, but nowhere else. There is no log showing when/who/where/how serviced. Food can be eaten most anywhere in facility. A bag containing food, which appeared to be someone's lunch, was observed on the bench in the room where scrubs and clean room shoes are donned.* *A stained HEPA filter exists in at least one hood (in a buffer room) – a large brown stain. Many stains within the Edgeguard fins in the LMF. Hood also had some white crusty stains in ceiling light above work area in hood.*
2.	The facility should be designed and operated with cascading air quality (e.g., by proper air classification and air pressurization) to protect the ISO 5 zone (or critical area). The air cleanliness classification of the area surrounding the ISO 5 zone immediately adjacent to the aseptic processing line should meet, at a minimum, ISO 7. If an isolator is used, the surrounding area should meet at	Ante-areas must meet at least ISO Class 8 standards. Typically, personnel hand hygiene and garbing procedures, staging of components, order entry, CSP handling, and other activities that potentially generate high levels of particulates are performed in this area. A buffer area must provide at least ISO Class 7 air quality. Activities in this area must be	*Pharm-31.3: States Buffer room is ISO Class 8 for the placement of the HLFH and BSC (in at least three places in SOP). This should be a Class 7 area according to cGMP and USP 797.* *Room certs (April 2016) have all rooms (Buffers 1 & 2, Chemo and Ante) identified as Class 7. Anteroom is a Class 8 room.*

	least ISO 8. The ISO 5 zone or critical area must be qualified (i.e., shown to meet the specifications)	especially carefully controlled to avoid affecting the air quality in the area where CSP preparation occurs. Areas intended for CSP preparation must meet ISO Class 5 standards. ISO Class 5 standards are achieved through use of a PEC, such as a LAFS, BSC, CAI, CACI, or isolator. The LAFS can consist of either a LAFW or a HEPA filter alone creating an ISO Class 5 zone within an ISO Class 7 room, as long as unidirectional airflow is maintained. If used to prepare only Category 1 CSPs, the ISO Class 5 environment can be obtained by placing a LAFW in a segregated compounding area. If used to prepare Category 2 CSPs, the LAFS must be located within a restricted access buffer area with an ISO Class 7 or better air quality. All CSPs must be prepared in a PEC, which provides an ISO Class 5 environment. The compounding environment must continuously meet ISO Class 5 or better conditions for 0.5-µm particles and must exclude microbial contamination during compounding of CSPs (typical operating conditions). Unidirectional airflow must be maintained in the PEC at all times. HEPA-filtered air must be supplied to the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design and control prevents	*There is an unclassified pass-through room between the Pharmacy and Class 8 Ante Room. This pass through has no HEPA filtration and no airflow within it. No cascading air quality/differential pressure. Diff pressure not measured across pass-through from unclassified area to the anteroom.* *Pharm-31.3 Allows for NLT 20 AC/hr in Ante Room, when USP 797 suggests NLT 30. In use shows that USP spec can be met.* *Pressure differential data from Chemo Room to Anteroom is a positive value when it should be a negative value (Room certification, April 2016). However, it stated later in the documentation that it is positive (pass/fail box).* *Non-Viable particulates (NVP) are monitored every 6 months. Class 5 areas must continuously meet ISO Class 5 or better conditions for 0.5-µm particles.*

		turbulence and creation of eddies or stagnant air in the PEC. Air must be introduced through HEPA filters located at the ceiling of the buffer area containing the PEC, and returns should be mounted low on the wall, creating a general top-down dilution of area air through HEPA-filtered air. An ISO Class 7 buffer or ante-area supplied with HEPA-filtered air must measure an ACPH of not less than 30, and the ACPH may need to be higher to maintain the classification. The ACPH of 30 can include recirculated HEPA-filtered air, but at least half (a minimum of 15 ACPH) must be HEPA-filtered fresh air. A minimum differential positive pressure of 0.02-inch water column is required to separate each ISO-classified area. The pressure differential between the ISO Class 7 area and the general pharmacy area must not be less than 0.02-inch water column. A compounding facility generally consists of separate, designated operational clean areas, including an ante-area, a buffer area, and a PEC, or a segregated compounding area containing a PEC where CSPs are prepared. The ante-area must be separated from the surrounding, unclassified sections of the building to reduce the risk of contaminants being blown, dragged, tracked, or otherwise introduced into the high-efficiency particulate air (HEPA)–filtered clean environment. This	

		separation must be continuously maintained and monitored. (Note – this requirement for continuous monitoring seems to be related to physical separation of the ante-area but could be interpreted that air pressure differential is part of the control to accomplish this. The highlighted section above requires monitoring pressure differential at least once per day). When compounding Category 2 CSPs, the ISO Class 8 ante-area and the ISO Class 7 buffer area must be separate rooms, with walls and doors between them and controls to prevent the flow of lower-quality air into the more controlled areas. The PEC must be located in the buffer area or the segregated compounding area so as to avoid conditions that could adversely affect their separate operations.	
3.	Qualification should include at least the following studies and tests, which should be documented: • Airflow studies should be conducted under dynamic conditions (e.g., in-situ smoke study) to initially qualify the HVAC/HEPA unit and when any changes are made to the critical area that might affect airflow. • HEPA periodic testing/recertification should be performed at least twice a year. These tests should include integrity testing of the HEPA filters, particle counts, and air velocity checks. • If any portable ISO 5 units are moved from one location to another, re-qualification should be performed before resuming sterile compounding in the unit.	Before a facility is used to compound either Category 1 or Category 2 CSPs, it must be certified by an independent, qualified individual as meeting its design and air quality specifications. During certification of ISO Class 5 areas, air sampling must be performed inside the PEC and the surrounding ISO-classified areas. Routine staff activity during compounding-related processes must be simulated during certification. Certification of the PEC must include: **Airflow Testing** to determine acceptability of the air velocity and volume, the air exchange rate, and room pressure cascade to ensure that air consistently flows from clean to dirty areas, and that the appropriate quality of air is maintained under typical operating conditions.	*No evidence that the room and hood certifications were reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper standards* *No procedure exists for Equipment qualification and Certification of rooms. The result is inconsistent/incorrect practices and requirements during these activities.*

		HEPA Filter Integrity Testing using the most penetrating particle size. HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification. **Total Particle Counts Testing** under typical operating conditions by qualified operators using current, state-of-the-art electronic equipment. **Smoke Studies** for each PEC under full operational processing conditions to demonstrate unidirectional airflow and sweeping action over and away from the product(s). Certification of other ISO-classified areas must include: **Airflow Testing** to determine acceptability of the air velocity and volume, the air exchange rate, and room pressure cascade to ensure that air consistently flows from clean to dirty areas and that the appropriate quality of air is maintained under typical operating conditions. Classified areas must be recertified if there are changes. Recertification must be done at least every 6 months. All certification and recertification records must be reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper standards and records must be maintained in accordance with the requirements in *Documentation*.	

4.		In facilities with ante-areas and buffer areas, the sink used for hand hygiene must not be placed in the buffer area. The sink should be placed in the ante-area to allow for hand washing before entering the buffer area. In a segregated compounding area, the sink must be located at least 1 meter from the PEC. 797 contains specific requirements for BSCs and RABS.	
5.		The compounding room must be maintained at a temperature of 20° or cooler and a humidity below 60% at all times. Temperature and humidity must be controlled through an efficient heating, ventilation, and air conditioning (HVAC) system	*SOP 123 states 18-22 Deg C in clean room/buffer room. NO humidity specifications exist.*
6.		If a pass-through is used, it must only be opened one door at a time; both doors must never be opened at the same time.	
7.		Do not use tacky mats in ISO-classified areas.	*There is a tacky mat in the Class 8 Ante room*
8.		The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in a classified area or in a segregated compounding area must be smooth, impervious, free from cracks and crevices, and non-shedding. Surfaces must be resistant to damage by disinfectants. Junctures between the ceiling and the walls must be coved or sealed to eliminate cracks and crevices where dirt can	*Walls in the clean rooms seem to be plain sheet rock with regular acrylic paint (not epoxy covered). The wall in the pass through from the unclassified area to the Ante Room has some damage with chipping paint, right next to the transfer carts that contain sanitized materials on them.* *Light cover in the Anteroom was partially ajar with locking lever in unlocked position.*

		accumulate. If ceilings consist of inlaid panels, the panels must be impregnated with a polymer to render them impervious and hydrophobic, and they must be sealed. Walls must be constructed of durable material (e.g., heavy-gauge polymer). Panels must be locked together and sealed. If gypsum board is used, it must be epoxy-coated. Floors must be overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Classified areas and segregated compounding areas must not contain dust-collecting overhangs, such as utility pipes, or ledges, such as windowsills. The exterior lens surface of ceiling light fixtures must be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls must be sealed. The buffer area or area inside the perimeter of a segregated compounding area cannot contain water sources (e.g., sinks) or floor drains. Work surfaces must be constructed of smooth, impervious materials, such as stainless steel or molded plastic.	

No.	Section 503B FDA cGMP Guidance *	USP 797 Requirement **	XYZ Compounding SOPs and Practices
	Category: C) Environmental and Personnel Monitoring		
1.	Personnel sanitation practices and gowning are required to be both acceptable and qualified for the operations they perform. Procedures for monitoring the environment and personnel for the presence of viable particles and non-	Sterile compounding facilities must develop and implement written environmental monitoring procedures. All environmental sampling and results must be documented,	• *Personnel training program on aseptic techniques, gowning and cleaning/sanitation will need to be*

	viable particles should be established and followed as described here. Environmental monitoring should consist of a well-defined program that evaluates the potential routes of microbial contamination of the human drug that could arise from the air, surfaces, process, operation, and personnel practices. The program should contain an appropriate detection component to verify state of control of the environment. In particular, the program should achieve the following: • Cover all production shifts and include monitoring during normal production conditions • Include at least daily monitoring of the ISO 5 zone during operations • Establish alert and action limits and appropriate responses to each • Describe use of sampling (e.g., contact plates, swabs, active air samplers), alert and action limits, and testing methods (e.g., media, plate exposure times, incubation times and temperatures) that are designed to detect environmental contaminants, including changes in microflora type and amount • Be supported by an evaluation of the choice of the sampling locations and sampling methods	and records must be maintained. Sterile compounding facilities must be qualified initially using environmental air and surface sampling as described below to establish a baseline level of environmental quality. After initial qualification, the environment in which sterile compounding activities are performed must be monitored regularly. Data collected from environmental sampling must be reviewed regularly to detect elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment. Data from air and surface sampling must be reviewed in conjunction with personnel data to assess the state of environmental control and to identify CSP contamination risks. Prompt corrective action in response to any adverse data is essential. Data must also be reviewed following corrective actions to confirm that the actions taken have been effective. Routine environmental sampling during compounding operations must be conducted to confirm that the environmental quality in ISO-classified areas is maintained. Sampling also must be performed in any of the following circumstances: • As part of the certification of new facilities and equipment • As part of recertification, following any servicing of facilities or equipment	*revised.* • *Policy SOP 456 contains some details for the development of an Environmental Monitoring Program but does not capture all required and important information for the establishment of a compliant and robust program (not well-defined/structured). The actual program needs to be re-structured to add missing requirements and information.* ***Walk through** - personnel entering different clean rooms without changing gowning or wearing double sterile gloves. Garbing not correctly placed or fit. Personnel with health problems (coughing) working inside clean room. Personnel not constantly sanitizing the work area during compounding process.* • *No formal data review required in SOP after corrective action following an excursion (per 503B).* • *The only routine EM performed during operations is settling plates.* *No clear description of sampling type to use along with alert/actions assigned per sampling, sampling method and handling of results per sampling were observed.*

		• In response to identified problems (e.g., sterility failures; a complaint of patient infection when the CSP is considered to be a potential source of the infection) • In response to identified trends (e.g., repeated positive fingertip sampling results or failed media fill simulations; repeated observations of air or surface contamination)	*Some information stated but not clearly defined or structured for proper flow and understanding.* *Requirement for the creation of an EM assessment to justify the selection of sampling locations and methods not stated within the policy. The policy talks about sites where microbial contamination most likely will have an adverse effect on product quality, heaviest microbial proliferation or most inaccessible but does not clearly defined or identify by means of an area map where the exact location should be and why the area was selected in order to have uniformity within the pharmacist's/ pharmacy technician.* *Studies for initial Environmental Monitoring Qualification of controlled areas not referenced or mentioned within the policy as well as evaluations of EM air and surface sampling data to establish a baseline level for routine monitoring.* *Requirements for data trending not stated within the policy. EM data trends are used to detect changes within the environment.* *Missing requirements for additional sampling during specific circumstances.*

2.		The sampling program must include: 1) nonviable airborne particulate sampling; 2) viable airborne particulate sampling; and 3) surface sampling, including but not limited to equipment, work surfaces, and room surfaces. Environmental air sampling (both viable and nonviable) must be conducted during periods of typical activity (i.e., when compounding is occurring). Total non-viable particle counts of all ISO-classified areas must be conducted during typical operations every 6 months. Viable active air sampling of all ISO-classified areas must be conducted during typical operating conditions at least monthly. Viable active air sampling is required in each ISO-classified area (e.g., PEC and ISO Class 7 and 8 areas). 797 includes additional requirements and details related to sampling for viable particulate, the agar, incubation, data evaluation, and action levels. Air sampling sites must be selected in all classified areas. Measurements of air cleanliness must be taken in each PEC, at locations where there is greatest risk to the exposed CSPs, containers, and closures. Measurements of air cleanliness in other classified areas, including the buffer area and ante-area, should be taken at representative locations that reflect the quality of air in the area. Surface sampling for microbial contamination must be performed in all ISO-classified areas. All sampling sites and procedures must be	*Missing information and requirements for equipment used and how these are cleaned, sampled and stored.* *Missing description/location of sampling sites.* *Missing culture media type required based on sampling method to use* . *A list of sampling locations containing sampling methods to be used, frequency, sample size, sampling time and alert/actions levels not clearly stated/organize within the policy.* *Calibration requirement and frequency for equipment used for EM not stated within the EM program policy. Equipment calibration policy not referenced within SOP 789.* ➢ *Requirements not clearly listed for how to proceed when levels are exceeded during Environmental Monitoring, this is for all monitoring perform within the areas.*

		described in the facility's SOP. Surface sampling must be performed at the conclusion of compounding activities, but before the area has been cleaned and disinfected. Media used for surface sampling must be supplemented with additives to neutralize the effects of any residual disinfecting agents (e.g., TSA with lecithin and polysorbate 80). Multiple locations must be sampled at least monthly within each ISO-classified area, including the following: • The interior of the PEC and equipment contained in it • Staging or work areas near the PEC. • Frequently touched surfaces • Pass-through chambers (797 includes additional requirements and details related to surface sampling, the agar, incubation, data evaluation, and action levels.) The sampling program must contain a listing of the sample locations, procedures for collecting samples, frequency of sampling, size of sample (e.g., surface area, volume of air), time of day sampled in relation to activities in the compounding area, and levels that will trigger corrective action. Sampling locations, frequencies, and timing must be clearly described in a facility's established Standard Operating Procedure (SOP). It is important to sample locations posing the most contamination risk to the CSP (i.e., the PEC).	

		Personnel must be trained in the proper operation of the air sampling equipment used. All air sampling devices must be serviced and calibrated at appropriate intervals (i.e., as recommended by the manufacturer). If levels measured during the nonviable air sampling program exceed the appropriate ISO classification levels of the area sampled when measured under typical operating conditions, an investigation of the cause must be conducted and corrective action must be taken to prevent future deviations. When nonviable air sampling results for an ISO Class 5 PEC are exceeded, all compounding activities must cease in that PEC and a corrective action plan must be implemented immediately. When nonviable air sampling results for ISO Class 7 or 8 areas are exceeded, a corrective action plan must be implemented immediately. In such a case, if compounding is continued, the BUDs for any CSPs compounded must not exceed the BUDs for Category 1 CSPs until the area is successfully recertified.	

3.	Personnel monitoring should consist of a well-defined program that does the following: • Includes a routine program for daily/shift monitoring of operators' gloves and an appropriate schedule for monitoring gowns during operations • Establishes limits that are based on the criticality of the operation relative to the contamination risk to the product • Calls for an investigation of results that exceed the established levels or demonstrate an adverse trend, a determination of the impact on the sterility assurance of finished products intended to be sterile, and the development and execution of appropriate corrective actions	(Note – 797 only requires initial qualification of personnel for aseptic processing and periodic requalification. As part of this, monitoring of glove fingertips is required. These requirements are included in the "Aseptic Drug Processing" section below.)	➢ *Training program for personnel on aseptic techniques, gowning and cleaning/sanitation needs to be revised to ensure consistency and compliance within all personnel entering the ISO 5, 7 and 8 areas.* ➢ *EM program does not include a description of personnel monitoring required (sites) including initial personnel qualification and periodic re-qualifications as well as limits and handling of results exceeding the limits or showing a trend and their impact.* ➢ *No gown monitoring is done.*
4.	Procedures should include establishing the validity of the microbiological media, including the preparation, sterilization, and growth potential of the media used in performing tests, including environmental and personnel monitoring.	(Note – Related requirements are included in the "Aseptic Drug Processing" section below.)	*Policy does not capture the requirements for shipping, storage, release (acceptance based on growth promotion test performed by manufacturer - C of A) and sterility assurance of already prepared media purchased from an outside vendor.*

No.	Section 503B FDA cGMP Guidance *	USP 797 Requirement **	XYZ Compounding SOPs and Practices
	Category: G) Release Testing		
1.	Finished drug products should be tested to determine whether they meet final product specifications before their release for distribution.		*Sterile outsourced products are tested for sterility only.*
2.	Appropriate specifications must be established for each		*Specifications for micro, BE and*

	drug product. Specifications must address those attributes necessary to ensure the quality of the finished drug product and should include at a minimum: • Identity and strength of the active ingredient • For drug products purporting to be sterile, a limit for visible particles • For drug products purporting to be sterile and/or non-pyrogenic, sterility and a limit for bacterial endotoxins		*analytical attributes for each drug product have not been established in policies and procedures.*
3.	Procedures for release must be established that ensure that each batch of a drug product is not released until the following have been completed: • Except as described below, an appropriate laboratory determination has been conducted to ensure that each batch of a drug product conforms to specifications. • Associated laboratory data and documentation have been reviewed by the quality control unit and demonstrate that the drug product meets specifications. • A designated qualified individual from the quality control unit has authorized final release.	At the completion of compounding, before release and dispensing, the CSP must be inspected to determine whether the physical appearance of the CSP is as it should be and to confirm that the CSP and its labeling match the prescription or medication order. The physical inspection described below must be performed on all CSPs before they are released. In addition, sterility and bacterial endotoxin testing must be performed in some cases. (see 797) All checks and inspections, and any other tests or checks necessary to ensure the quality of the CSP (e.g., assays), must be included in the facility's SOP. <u>Physical Inspection</u> After compounding, and as a condition of release, each individual CSP unit must be inspected to identify any apparent physical defect. Each individual injectable CSP unit must be inspected against a lighted white background and a black background for evidence of visible particulates or other foreign matter, or discoloration. Some CSPs also must be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). Pre-release	*There is no laboratory testing to confirm identity and strength of the active ingredient.* *There is no Quality Control individual to authorize final release.* *Current SOP on Release Checks SOP 246, is weak on description of cloudiness or turbidity of the CSP when performing physical inspection (only states "evidence of turbidity" with no description or definition of turbidity).*

		inspection also must include a visual inspection of container–closure integrity (e.g., checking for leakage, cracks in the container, or improper seals). CSPs with observed defects must be immediately discarded, or marked and segregated from acceptable units in a manner that prevents them from being released or dispensed. When a CSP will not be released or dispensed promptly after preparation, a prerelease inspection must be conducted immediately before it is released or dispensed to make sure that the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which may develop during storage. A CSP with such defects must be immediately discarded, or marked and segregated from acceptable units in a manner that prevents it from being released or dispensed.	
4.	The Agency does not intend to take action against an outsourcing facility regarding the release testing requirements described above, under the following conditions: • For testing to confirm identity, if specifications have been established and met for strength (potency). • For sterility testing, if the drug product is terminally sterilized and a validated sterilization cycle that uses bioindicators is employed. • For sterility testing, if it is initiated before batch release (see also Subsection I "Stability/Expiration Dating," below, for information on how to label products released without a completed sterility test) and o procedures have been established that specify that if the drug product fails to meet a criterion for	Beyond use dates (BUDs) for proprietary bag and vial systems must be assigned in accordance with the manufacturer's instructions provided in product labeling. (Note – BUD is included in the "Stability/Expiration Dating" section below.)	*For sterility testing that is initiated before batch release, procedures do not exist which describe the process to be followed if sterility testing subsequently fails.*

	sterility, all facilities that received the drug product will be immediately notified of the test results and provided with any appropriate information and recommendations to aid in the treatment of patients; ○ the notification will be documented; and ○ FDA will be notified in writing. • For sterility testing, if the batch consists of fewer than 10 dosage units compounded pursuant to a prescription for a single patient, and the unit(s) is labeled with a beyond use date (BUD), where the BUD provides reasonable assurance of chemical and physical stability based on literature or other scientific information, and is established according to the following: ○ not to exceed 24 hours at USP controlled room temperature; ○ not more than 3 days refrigerated; ○ not more than 45 days in a solid frozen state between -25 and -10 degrees		
5.	If the batch size is very small and does not meet the criteria above for eliminating the sterility test when compounding pursuant to a prescription for a single patient, standard sterility tests may require that additional units be produced to be able to conduct the sterility test. For example, USP <71> "Sterility Tests" is the principal source used for sterility testing methods, and requires that the number of samples for batches of parenteral drug products containing less than 100 containers be 10% or 4 containers, whichever is greater. However, the Agency does not intend to take action against an outsourcing facility regarding the number of units tested if 10% of the containers in the batch is less than 4, and the sterility test is conducted using a number of containers that equals 10% rounded up to the next whole number.		
6.	With regard to testing other than sterility testing, for		*Procedures do not address the number of*

	batches of less than 10 units, since complete release testing would require use of a significant proportion of the batch, the Agency does not intend to take action against an outsourcing facility regarding testing on every batch to demonstrate conformity with other specifications such as identity, strength, and particulate, if such testing is performed on samples from every other batch, or once at least 10 units of that drug product have been produced. For example, if the batch size is consistently 5 units, testing should be conducted on every second batch. As another example, if the first batch is 5 units, the second batch is 3 units, and the third batch is 3 units, testing should be performed on the third batch because the minimum of 10 units has been met.		*samples to test and frequency of tests for other than sterility.*
7.	For aqueous solutions, testing for identity and strength can be performed on the bulk solution just before filling the finished drug product containers.		

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* *Guidance for Industry - Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. July 2014*

** *Proposed <797> intended to be published in USP 39 <797>*

BYLAWS OF THE VIRGINIA BOARD OF PHARMACY

ARTICLE I: GENERAL

The organizational year for the Board shall be from July 1st through June 30th. At the last meeting before July 1, the Board shall elect from its members, a chairman and a vice chairman. The term of office shall be one year and shall begin on July 1. A person shall not serve as chairman or vice chairman for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

A. The officers of the Board shall be the chairman and the vice chairman.

B. The chairman presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The chairman shall appoint all committees unless otherwise ordered by the Board.

C. The vice chairman shall act as chairman in the absence of the chairman.

D. In the absence, or inability to serve, of both the chairman and vice chairman, the chairman shall appoint another board member to preside at the meeting and/or formal administrative hearing.

E. The executive director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business shall be as follows:

1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.
2. Approval of Agenda
3. Public comment received
4. Approval of Minutes
5. The remainder of the agenda shall be established by the executive director in consultation with the chairman.

Adopted: July 1, 1997
Revised: ~~December 9, 2014~~
September 7, 2016

ARTICLE IV: COMMITTEES

A. There shall be the following standing committees:

Special Conference Committees
Inspection Special Conference Committee
Examination Committee
Item Review Committee
Regulation Committee
Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. A special conference committee may also review information regarding a non-routine applicant for whom there may be cause to deny or restrict and may issue a final Order to grant or deny the application or to issue a license, registration or permit with terms and conditions. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The chairman may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chairman shall appoint committees as needed to expedite the adjudication of cases.

2. Examination Administrator Selection Committee. This committee shall consist of three board members, the deputy executive director supervising the examination contracts, and the executive director. The Committee shall meet as required to review proposals and select the administrators of the ~~Drug Law Examination and the~~ Pharmacy Technician Examination.

3. Item Review Committee. This committee shall consist of at least six pharmacists, to include one board member and the executive director, holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of approving content to assemble the Virginia Multistate Pharmacy Jurisprudence (MPJE) form(s) which shall be accomplished through writing, reviewing, and selecting items for the VA MPJE item pool. ~~writing new items for the Drug Law Examination item bank to maintain the integrity and defensibility of the examination. Additionally, the Board delegates to this Committee the approval of the Drug Law Examination for the purpose of licensure.~~

4. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board's Public Participation Guidelines and any Executive Order of the Governor, and any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

5. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and any matters related to such programs.

B. Ad Hoc Committees.

The chairman shall also name such other committees as may be deemed necessary.

C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

The Board delegates the following functions:

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.

2. The Board delegates to the executive director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.

3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.

4. The Board delegates to the Department of Health Professions' inspectors the authority to issue summaries of inspection deficiencies upon completion of an inspection, and the Board delegates to the executive director the authority to issue letters regarding reported deficiencies to the facilities or licensee.

5. The Board delegates to the executive director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

6. The Board delegates to the executive director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

7. The Board delegates to the executive director, in consultation with the chairman, the review and approval of applications for special or limited use pharmacy permits. If the executive director and chairman do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.

8. The Board delegates to the executive director, in consultation with the chairman, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the executive director and the chairman not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.

9. The Board delegates to the executive director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the chairman. Should the executive director and chairman not reach agreement, the matter shall be referred to a special conference committee.

10. The Board delegates to the chairman, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.

11. The Board delegates the approval of continuing education programs to the executive director in consultation with one member of the Board.

12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with § 54.1-2408.1, to the executive director or deputy executive director. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with § 54.1-2400 (13), to the executive director or deputy executive director. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the executive director or deputy executive director.

13. The Board delegates to the chairman, or the vice chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with § 54.1-3307.3.

14. The Board delegates to the executive director, in accordance with § 54.1-3434.1(A)(2), the authority to accept an inspection report or other documentation for a non-resident pharmacy from an entity that may not be listed on the Board's guidance document, or to request an inspection by an agent of the Board.

15. The Board delegates to the executive director the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

16. The Board delegates to the executive director, in consultation with the chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses. A waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

ARTICLE VI: AMENDMENTS

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date: July 1, 1997
Latest revision: ~~December 9, 2014~~ September 7, 2016

Agenda Item: FDA Comment Period for Draft Guidance regarding Insanitary Conditions at Compounding Facilities

Staff Note:

Comment period open until October 3, 2016.

Included in your packet:

Draft guidance from FDA

Proposed comment from Board

Possible Board Action:

Adopt proposed comment and direct staff to submit to FDA on board's behalf.

Amend proposed comment and direct staff to submit to FDA on board's behalf.

Submit no comment to FDA by taking no action

Insanitary Conditions at Compounding Facilities

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

August 2016
Compounding and Related Documents

Insanitary Conditions at Compounding Facilities

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

August 2016
Compounding and Related Documents

Contains Nonbinding Recommendations

Draft — Not for Implementation

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Guidance for Industry[1]

Insanitary Conditions at Compounding Facilities

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."[2] Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act, compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section 503A nor section 503B provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs prepared, packed, or held (hereinafter referred to as "produced") under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the Act.[3] Any drug that is produced under insanitary conditions is adulterated under the Act, including compounded human and animal drugs; repackaged drug products; compounded or repackaged radiopharmaceuticals; and mixed, diluted, or repackaged biological products. The policies described in this guidance document specifically address pharmacies, Federal facilities, physicians' offices (including veterinarians' offices), and outsourcing facilities that compound or repackage human or animal drugs (including radiopharmaceuticals); or that mix, dilute, or repackage biological products. For purposes of this guidance, we refer to such entities as "compounding facilities."

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs and the Center for Veterinary Medicine at the Food and Drug Administration.

[2] Insanitary conditions are conditions that could cause a drug to become contaminated with filth or rendered injurious to health; the drug need not be actually contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substance is deemed to be adulterated under section 501(a)(1) of the FD&C Act.

FDA is issuing this guidance to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions. This guidance is also intended to assist State regulatory agencies in understanding some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Public Health Risk of Insanitary Conditions

FDA has investigated numerous outbreaks of infections and deaths found to be the result of drug products that were contaminated because they were produced under insanitary conditions. Most notably, in 2012, injectable drug products produced by a compounding facility and shipped across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection. FDA has investigated numerous other serious adverse events, including deaths, associated with contaminated drug products produced by compounding facilities, and it is likely that such adverse events are underreported.

Since the 2012 fungal meningitis outbreak, FDA has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations as a result of those findings. However, FDA does not inspect the vast majority of compounding facilities in the United States because they generally do not register with FDA unless they elect to become outsourcing facilities.[4] Therefore, FDA is often not aware of these facilities and potential problems with their drug products, or conditions and practices, unless it receives a complaint, such as a report of a serious adverse event or visible contamination. It is critical that compounding facilities avoid the presence of insanitary conditions and identify and remediate any insanitary conditions at their facilities before the conditions result in drug contamination and patient injury.

In addition, to protect the public health, it is critical that both FDA and State regulatory agencies take appropriate action when compounders produce drugs under insanitary conditions. Based on its inspections, FDA determines whether compounding facilities produce drugs under insanitary conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may initiate regulatory action. However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the States and, as explained above, generally are not routinely inspected by FDA. Therefore, FDA encourages State regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices,

[4] *See* section 503B of the FD&C Act.

including those described below, and if so, to take action, as appropriate, consistent with State laws and regulations, and to contact FDA.

III. POLICY

Section III.A of this guidance describes examples of conditions that would be considered insanitary conditions under section 501(a)(2)(A) of the FD&C Act. FDA has observed each of these conditions in one or more of the compounding facilities it has inspected. **These are only examples and are not an exhaustive list. Other conditions not described in this guidance may be considered insanitary.**

Section III.B of this guidance describes procedures that compounding facilities should employ to ensure that they do not have insanitary conditions and that they are capable of producing sterile drug products, and section III.C describes actions that compounding facilities should take if they identify insanitary conditions at their facilities. Finally, section III.D of this guidance describes potential FDA regulatory actions if insanitary conditions are not adequately corrected.

FDA intends to consider the entire set of conditions at the facility, including whether the facility engages in the procedures described in section III.B, when prioritizing regulatory action against a compounding facility for producing drugs under insanitary conditions.

A. Examples of Insanitary Conditions[5]

1. Insanitary Conditions Applicable to the Production of Sterile and/or Non-Sterile Drugs

Although maintaining sterility is not a requirement for non-sterile drugs, non-sterile drugs can become contaminated with microorganisms of a type or at a level that can cause patient harm. Non-sterile aqueous solutions are particularly susceptible to microbial growth if contaminated. Contamination may also include non-viable filth and the presence of unintended drug components. The following are examples of insanitary conditions that are applicable to both sterile and non-sterile drug production.

- Vermin (e.g., insects, rodents) observed in production areas or areas immediately adjacent to production.
- Visible microbial contamination (e.g., bacteria, mold) in the production area.
- Non-microbial contamination in the production area (e.g., rust, glass shavings, hairs).
- Handling beta-lactam, hazardous, or highly potent drugs (e.g., hormones) without providing adequate containment, segregation, and cleaning of work surfaces, utensils, and personnel to prevent cross-contamination.
- Production of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

[5] For definitions of some of the terms used in this section, refer to United States Pharmacopeia (USP) Chapter <797>.

2. *Insanitary Conditions in a Sterile Operation*

a. Aseptic Practices

- Putting on gowning apparel improperly, in a way that may cause the gowning apparel to become contaminated. This includes, for example, gowning in non-classified areas, gowning apparel touching the floor, or putting on sterile gloves improperly (e.g., touching the outside of a glove with bare hands).
- Failing to disinfect or change gloves frequently enough given the nature of the operations to prevent contamination.
- Engaging in aseptic processing wearing non-sterile gloves. This could contaminate the critical area.[6]
- Engaging in aseptic manipulations with exposed hands, wrists, legs, hair, or mouth, for example.
- Performing aseptic manipulations outside of an International Organization for Standardization Class 5 (ISO 5) area.
- Exposing unprotected sterile product, including stock solutions, to lower than ISO 5 quality air (e.g., removing it from the ISO 5 area without a robust and intact container closure system).
- Engaging in aseptic processing after leaving the cleanroom and re-entering from a non-classified area without first replacing gowning apparel (e.g., sterile gloves, gowns, mask, foot covers). Movement of personnel in and out of the cleanroom without regowning may bring contaminants from the non-classified areas into the cleanroom.
- Moving quickly in the vicinity of open containers or instruments (e.g., needles). While conducting aseptic manipulations, ISO 5 airflow must be unidirectional to protect the product from contaminating particles. Quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.
- Conducting aseptic manipulations or placing equipment/supplies in an area that blocks the movement of first pass air around an open container, whether before or after it is filled with sterile product. If unidirectional air over the critical surface is blocked, the area is no longer protected. If it is blocked by personnel conducting aseptic manipulations, contamination on personnel, particularly on exposed skin, could be introduced to the critical area.
- Using a non-sterile tool or manually contacting the inner surface of the container or closure. For example, during manual stoppering (e.g., hand stoppering), personnel touching the top of open containers, or the lower side or bottom of closures. This could contaminate the drug in the vials.
- Touching equipment or other surfaces (e.g., walls, telephone, floors) located outside of the ISO 5 area with gloved hands and then proceeding with aseptic manipulations without changing or sanitizing gloves.

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[6] A *critical area* is an area designed to maintain sterility of sterilized materials. Sterilized product, containers or closures, and equipment may be exposed in critical areas. The ISO 5 area is the critical area, and the terms are used interchangeably throughout this guidance.

- Storing open sterile vials within the critical area without protective cover longer than needed for the process of filling drug product. The longer a vial is open to the environment, the greater the risk of contamination.
- Failure to disinfect container closure systems of sterile drug components immediately prior to opening for use.

b. Equipment/ Facilities

- Actionable microbial contamination of the ISO 5 area or in adjacent areas.
- Cleanroom with unsealed, loose ceiling tiles.
- ISO classified areas with difficult to clean (e.g., porous), particle-generating, or visibly dirty (e.g., rusty) equipment or surfaces such as shelving, floors, walls, doors, window sills, and ceilings. For example, wood is both difficult to clean and particle-generating.
- Classified areas and segregated production areas surrounding the ISO 5 area that contain dust-collecting overhangs (e.g., utility pipes or ledges, such as windowsills).
- ISO 5 area open to the surrounding cleanroom with minimal or no physical barriers separating it from non-aseptic activities (e.g., non-aseptic weighing materials, gowning, container labeling).
- ISO 5 area open to non-classified rooms (segregated production area). Lower quality air from the surrounding room entering the ISO 5 area increases the risk of introducing microbial contamination into drug products being manipulated.
- A facility designed and/or operated in a way that permits poor flow of personnel or materials, or allows the influx of poor quality air into a higher classified area. Examples include:
  - materials flow into the ISO 7 area directly from an unclassified area;
  - air return located next to the high efficiency particulate arrestance (HEPA) filter rather than near the floor;
  - an air vent between classified and unclassified areas;
  - a door opened between the unclassified area and the ISO 8 anteroom while the door between the ISO 7 and ISO 8 areas is also open;
  - inadequate pressure differentials between areas of higher quality air and lower quality air.
- A lack of HEPA-filtered air, or inadequate HEPA filter coverage or airflow, over the area to which sterile product is exposed.
- HEPA filters that are not sealed around each perimeter to the support frame. The air entering the cleanroom must be HEPA filtered to remove airborne particles. If HEPA filters are not sealed, air that is not HEPA filtered could enter the cleanroom.
- The presence of sinks or drains in the cleanroom where the ISO 5 area is located. Sinks and drains are sources of microbial contamination.
- Use of non-sterilized or non-depyrogenated equipment (e.g., transfer tubing, temporary bulk containers). Use of such equipment can introduce or increase bioburden and endotoxins.
- Use of non-sterilized or non-depyrogenated final containers/closures. Use of such container/closures could contaminate the drug product after it has been sterilized.

c. Sterilization

- The "sterilizing filter" is not adequate to accomplish sterilization and is not pharmaceutical grade.
- Temperature and time conditions used for heat sterilization are not lethal to heat-resistant microorganisms.

d. Cleaning and Disinfecting

- Non-sterile disinfecting agents and cleaning pads or wipes are used in the aseptic processing areas, especially the ISO 5 area. Non-sterile cleaning and disinfecting items could spread microbial spores.
- No, improper, or infrequent, use of a sporicidal agent in the facility's cleanrooms and ISO 5 area.
- No disinfection of equipment and/or supplies entering the aseptic processing areas. Disinfection should occur at each transition from areas of lower quality air to areas of higher quality (e.g., from non-classified to first classified room, from anteroom to buffer room, from buffer room to ISO 5 area).
- Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected are insufficient to achieve adequate levels of disinfection. The use, including contact time, of commercially-obtained disinfectants should follow the manufacturer's instructions.

B. Identifying Insanitary Conditions

Certain procedures are critical to ensuring that compounding facilities do not have insanitary conditions that could compromise drug sterility and that they are capable of producing sterile drug products. FDA recommends that compounding facilities that produce drugs that are intended to be sterile routinely employ these procedures to help ensure that they can produce sterile products. A non-exhaustive list of such procedures follows.

1. Conduct routine[7] environmental monitoring, including a) nonviable airborne particulate sampling; b) viable airborne particulate sampling; c) personnel sampling (including glove fingertip sampling); and d) surface sampling, including but not limited to equipment, work surfaces, and room surfaces. Environmental monitoring provides information on the quality of the aseptic processing environment and, if problematic, the compounding

[7] For compounding facilities that are not registered with FDA as outsourcing facilities, see USP Chapter <797>. For outsourcing facilities, see FDA's draft guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* ("interim CGMP draft guidance"). Once final, this guidance will represent FDA's current thinking regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until FDA promulgates CGMP regulations that are more specific to outsourcing facilities.

This interim CGMP draft guidance states that outsourcing facilities should conduct environmental monitoring of the ISO 5 area at least daily. FDA recommends that compounding facilities that are not registered as outsourcing facilities also conduct daily environmental monoitoring during operations.

facility should promptly identify potential routes of contamination and perform corrective actions.

2. Certify the ISO 5 area every six months. If the ISO 5 area is not certified every six months or does not pass all certification requirements, there is no assurance that the ISO 5 area is working properly (e.g., generating unidirectional ISO 5 airflow). Smoke studies should be conducted as part of the certification to assess the airflow patterns necessary to maintain unidirectional flow from areas of higher air quality (e.g., ISO 5) to areas of lower air quality (e.g., ISO 7) to prevent microbial contamination of the sterile drug products during processing. Conducting smoke studies under dynamic conditions helps to ensure that unidirectional airflow is maintained while personnel are working in the ISO 5 area.

3. Measure pressure differentials during operations to help ensure proper airflow (i.e., from areas of higher quality air to adjacent areas with lower quality air).

4. Conduct media fill studies to closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

C. Corrective Actions

A compounding facility should immediately assess the impact of insanitary conditions on drug products produced, which should include an evaluation of how widespread the insanitary conditions are and over what period of time the conditions existed.

The compounding facility also should determine whether to cease production of drug products until the conditions have been corrected and initiate a recall of all potentially affected lots on the market.

For example, FDA considers the following insanitary conditions to be particularly serious, and if any one of these conditions exists, FDA strongly recommends that a compounding facility immediately initiate a recall of purportedly sterile drugs and cease sterile operations until the condition(s) have been corrected:

- Vermin (e.g., insects, rodents) observed in ISO 5 areas or in immediately adjacent areas.
- Visible microbial contamination (e.g., bacteria, mold) in the ISO 5 area or in immediately adjacent areas.
- Non-microbial contamination in the ISO 5 area (e.g., rust, glass shavings, hairs).
- Performing aseptic manipulations outside of the ISO 5 area.
- Exposing unprotected sterile product, including stock solutions, to lower than ISO 5 quality air (e.g., removing it from the ISO 5 area without a robust and intact container closure system).
- Cleanroom areas with unsealed, loose ceiling tiles.

- Production of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.
- Consistent and frequent pressure reversals from areas of less clean air to areas of higher cleanliness.
- The "sterilizing filter" is not adequate to accomplish sterilization and is not pharmaceutical grade.
- Temperature and time conditions used for heat sterilization are not lethal to heat-resistant microorganisms.

If a compounding facility decides to initiate a recall, it should notify its local FDA District recall coordinator as soon as the decision to recall is made.[8] The compounding facility should also notify the applicable State regulatory body in the State(s) to which the facility ships drugs, consistent with State laws and guidance.

In addition to the immediate actions recommended above, if a compounding facility has insanitary conditions, it should undertake a comprehensive assessment of its operations, including, as applicable, facility design, procedures, personnel, processes, materials, and systems, and should consider consulting a third party with relevant drug production expertise to conduct this comprehensive evaluation and to assist in implementing appropriate corrective actions.

Compounding facilities producing purportedly sterile drug products under insanitary conditions should not rely on a passing sterility test as an indication of sterility assurance because microbial contamination, when present, is not uniformly distributed within a batch and may not be identified by a sterility test. Furthermore, compounding facilities must correct all insanitary conditions at their facility,[9] regardless of whether the drugs pass a sterility test.[10]

D. Regulatory Action

If a compounding facility produces drugs under insanitary conditions, the facility and responsible individuals may be subject to Federal regulatory actions including, but not limited to, a warning letter, seizure of product, and/or injunction. FDA may also recommend that the facility initiate a recall of some or all of its drugs and cease operations until the insanitary conditions have been adequately addressed. In addition, the applicable State regulatory agency may pursue regulatory action against the facility under applicable State authorities.

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[8] *See* the FDA guidance, *Product Recalls, Including Removals and Corrections.*

[9] *See* section 501(a)(2)(A) of the FD&C Act.

[10] USP Chapter <71> concerning sterility testing states, "these Pharmacopeial procedures are not by themselves designed to ensure that a batch of product is sterile or has been sterilized. This is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures."

MEMORANDUM

TO: US Food and Drug Administration

FROM: Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

DATE: September 7, 2016

RE: Comment on Draft Guidance regarding Insanitary Conditions at Compounding Facilities

Docket No. FDA-2016-D-2268

At its meeting on September 7, 2016, the Virginia Board of Pharmacy voted to support the adoption of guidance to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions. Additionally, the board agrees that the guidance will assist State regulatory agencies in understanding some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health.

Possible Options for 2017 Meeting Dates

Board Meetings

March
March 14th Board Room 2
March 21st Board Room 4
March 28th Board Room 2
March 29th Board Room 2

June
June 6th Board Room 2
June 20th Board Room 4
June 27th Board Room 2
June 28th-Board Room 2

September
September 12th Board Room 2
September 26th Board Room 4
September 27th Board Room 2
September 28th Board Room 2

December
December 5th Board Room 2
December 7th Board Room 2
December 11th Board Room 4
December 20th Board Room 2
December 21st Board Room 2

Regulation Committee

May
May 2nd Board Room 4
May 9th Board Room 2
May 10th Board Room 2
May 30th Board Room 2
May 31st Board Room 4

November
November 2nd Board Room 2
November 7th Board Room 2
November 9th Board Room 2
November 28th Board Room 2
November 6th Board Room 2