# COMMONWEALTH OF VIRGINIA
# Meeting of the Board of Pharmacy

**Perimeter Center, 9960 Mayland Drive, Second Floor** **(804) 367-4456 (Tel)**
**Henrico, Virginia 23233** **(804) 527-4472(Fax)**


## Tentative Agenda of Public Hearings and Full Board Meeting
***September 26, 2017***
**9:00AM**

| TOPIC | PAGES |
|---|---|
| **Call to Order of Public Hearing for Scheduling Certain Substances, Dispensing Schedule VI Drugs in Excess, and Use of Automated Dispensing Devices:** Ryan Logan, Chairman | |
| • Welcome & Introductions | |
| • Reading of Emergency Evacuation Script | |
| **Call for Public Comment:** | 1-2 |
| • Possible Scheduling of the Certain Chemicals in Schedule I of the Drug Control Act | 3-12 |
| • Proposed Regulations for Dispensing Schedule VI Drugs in Excess and Use of Automated Dispensing Devices | |
| **Adjournment of Public Hearings** | |
| **Call to Order of Full Board Meeting:** Ryan Logan, Chairman | |
| • Approval of Agenda | |
| • Approval of Previous Board Meeting Minutes: | |
| o June 26, 2017, Pilot Program Informal Conference Committee | 13-16 |
| o June 27, 2017, Full Board Meeting | 17-25 |
| o June 27, 2017, Public Hearing for Scheduling Certain Chemicals | 26-27 |
| o June 27, 2017, Formal Hearing | 28-29 |
| o June 28, 2017, Special Conference Committee | 30-41 |
| o July 17, 2017, Special Conference Committee | 42-43 |
| o July 31, 2017, Formal Hearings | 44-46 |
| o August 31, 2017, Formal Hearings | Handout |
| o August 31, 2017, Special Conference Committee | Handout |
| **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/Guidance:** | |
| • Regulatory Update – Elaine Yeatts | 47 |
| • Report from Ad Hoc Committee Meeting on 9/18/17 and Possible Action - Ellen Shinaberry/Elaine Yeatts | |
| o Delivery of Prescription Drug Orders (HB1956) | 48-67 |
| o Guidance for Complying with USP Chapter <800> | 68-87 |
| o Guidelines for Counseling on Drug Disposal (HB2046) | 88-93 |
| • Adoption of Regulation to Schedule Certain Chemicals in Schedule I – Elaine Yeatts | 94-99 |

- Adoption of Proposed Regulations for Controlled Substances Registration for Entities that Dispense Naloxone or for Telemedicine – Elaine Yeatts 100-110
- Amend Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities* – Elaine Yeatts/Caroline Juran 111-114
- Exempt Regulatory Action to Conform Definition of "Electronic Prescription" and Amend Guidance Document 110-35, *Guidance on Virginia Prescription Requirements* – Elaine Yeatts 115-135
- Repeal Guidance Document 110-26, *Re-dispensing Drugs Previously Dispensed in Compliance Packaging*, based on FDA Repackaging Guidance – Caroline Juran 136-151
- Amend Guidance Document 110-12, *Bylaws of the Virginia Board of Pharmacy* 152-155
- Revenue and Budget Analysis 156A-156

**New Business:**

- Conflict of Interests – Jim Rutkowski
- Scheduling Meeting Dates in 2018 157

**Reports:**

- Chairman's Report – Ryan Logan
- Report on Board of Health Professions – Ryan Logan 158-166
- 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 & summary suspension, if any**

**Adjourn**

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

****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 26, 2017** 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 13, 2017 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

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

1. **5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
2. **5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MIPT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
3. **5-methoxy-N-ethyl-N-isopropyltryptamine (5-MeO-EIPT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
4. **4-hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
5. **(N-methyl aminopropyl)-2,3-dihydrobenzofuran (MAPDB)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
6. **3,4-tetramethylene-alpha-pyrrolidinovalerophenone (TH-PVP)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.
7. **4-chloro-alpha-methylamino-valerophenone (4-chloropentedrone)**, its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

**The following compounds are powerful synthetic opioids. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.**

8. **2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (Methoxyacetyl fentanyl),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.
9. **N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropyl fentanyl),** its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

**The following compound is classified as a cannabimimetic agent. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.**

10. **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (5-fluoro-ADB-PINACA)**, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

# Proposed Regulations

## Public Hearing September 26, 1027

**Response to petitions for rulemaking**

**18VAC110-20-320. Refilling of ~~Schedule~~ Schedules III through VI prescriptions.**

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with § 54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

2. The partial dispensing of a prescription for a drug listed in Schedule III, IV, or V is permissible, provided that:

a. Each partial dispensing is recorded in the same manner as a refilling;

b. The total quantity of drug dispensed in all partial dispensing does not exceed the total quantity prescribed; and

c. No dispensing occurs after six months after the date on which the prescription order was issued.

B. A prescription for a drug listed in Schedule VI ~~shall~~ may be refilled ~~only~~ as ~~expressly~~ authorized by the practitioner. If no such authorization is given, the prescription shall not be refilled, except as provided in § 54.1-3410 C or subdivision 4 of § 54.1-3411 of the Code of

Virginia. Except for drugs classified by the American Hospital Formulary Service as psychotherapeutic agents, anxiolytics, sedatives, or hypnotics or for drugs of concern as defined in § 54.1-2519 of the Code of Virginia, a pharmacist, using professional judgment and upon request by the patient, may refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration.

A prescription for a Schedule VI drug or device shall not be dispensed or refilled more than one year after the date on which it was issued unless the prescriber specifically authorizes dispensing or refilling for a longer period of time not to exceed two years.

C. As an alternative to all manual recordkeeping requirements provided for in subsections A and B of this section, an automated data processing system as provided in 18VAC110-20-250 may be used for the storage and retrieval of all or part of dispensing information for prescription drugs dispensed.

D. The timing of dispensing an authorized refill of a prescription shall be within reasonable conformity with the directions for use as indicated by the practitioner; if directions have not been provided, then any authorized refills may only be dispensed in reasonable conformity with the recommended dosage and with the exercise of sound professional judgment. An authorized refill may be dispensed early provided the pharmacist documents a valid reason for the necessity of the early refill.

**18VAC110-20-540. Emergency drug kit.**

A. 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 or an automated drug dispensing system, as provided in subsection B of this section, 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 and diazepam rectal gel 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, resealing, or both. 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 items 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.

B. Drugs that would be stocked in an emergency kit, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555.

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

A. 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 or resealing, or both. 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)~~ items 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~~ Schedules 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-drug 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.

B. Drugs that would be stocked in a stat-drug box, pursuant to this section, may be stocked in an automated drug dispensing system in a nursing home in accordance with 18VAC110-20-555, except that the quantity of drugs in Schedules II through V stocked in the system shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the nursing home.

**18VAC110-20-555. Use of automated dispensing devices.**

Nursing homes licensed pursuant to Chapter 5 (§ 32.1-123 et seq.) of Title 32.1 of the Code of Virginia may use automated drug dispensing systems, as defined in § 54.1-3401 of the Code of Virginia, upon meeting the following conditions:

1. Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have ~~on-line~~ online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy.

2. A nursing home without an in-house pharmacy shall obtain a controlled substances registration prior to using an automated dispensing system, unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration.

3. For facilities not required to obtain a controlled substance registration, access to the automated dispensing device shall be restricted to a licensed nurse, pharmacist, or prescriber, or a registered pharmacy technician for the purpose of stocking or reloading.

4. Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:

a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.

b. The PIC of the provider pharmacy shall ensure that a pharmacist who has ~~on-line~~ online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed.

c. Drugs that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540 may be accessed prior to receiving electronic authorization from the pharmacist provided that the absence of the drugs would threaten the survival of the patients.

d. Automated dispensing devices shall be capable of producing a hard-copy record of distribution that shall show patient name, drug name and strength, dose withdrawn, dose to be administered, date and time of withdrawal from the device, and identity of person withdrawing the drug.

~~4.~~ 5. Drugs placed in automated dispensing devices shall be in the manufacturer's sealed original unit dose or unit-of-use packaging or in repackaged unit-dose containers in compliance with the requirements of 18VAC110-20-355 relating to repackaging, labeling, and records.

~~5.~~ 6. Prior to the removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device, which shall include the date; drug name, dosage form, and strength; quantity; nursing home; a unique identifier for the specific device receiving drugs; and initials of the pharmacist checking the order of drugs to be removed from the pharmacy and the records of distribution for accuracy.

~~6.~~ 7. At the direction of the PIC, drugs may be loaded in the device by a pharmacist or a pharmacy technician adequately trained in the proper loading of the system.

~~7.~~ 8. At the time of loading, the delivery record for all ~~Schedule~~ Schedules II through VI drugs shall be signed by a nurse or other person authorized to administer drugs from that specific device, and the record returned to the pharmacy.

~~8.~~ 9. At the time of loading any ~~Schedule~~ Schedules II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the PIC, who shall be responsible for reconciliation of the discrepancy or the proper reporting of a loss.

~~9.~~ 10. The PIC of the provider pharmacy or his designee shall conduct at least a monthly audit to review distribution and administration of ~~Schedule~~ Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of ~~Schedule~~ Schedules II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review of a sample of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all ~~Schedule~~ Schedules II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.

e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.

f. The hard copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

~~10.~~ 11. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes.

~~11.~~ 12. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device.

~~12.~~ 13. The PIC of the pharmacy providing services to the nursing home shall establish, maintain, and assure compliance with written policy and procedure for the accurate stocking and proper storage of drugs in the automated drug dispensing system, accountability for and security of all drugs maintained in the automated drug dispensing system, preventing unauthorized access to the system, tracking access to the system, complying with federal and state regulations related to the storage and dispensing of controlled substances, maintaining patient confidentiality, maintaining required records, and assuring compliance with the requirements of this chapter. The manual shall be capable of being accessed at both the pharmacy and the nursing home.

~~13.~~ 14. All records required by this section shall be filed in chronological order from date of issue and maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the nursing home except:

a. Manual Schedule VI distribution records may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

b. Distribution and delivery records and required signatures may be generated or maintained electronically provided:

(1) The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

(2) The records are maintained in a read-only format that cannot be altered after the information is recorded.

(3) The system used is capable of producing a hard-copy printout of the records upon request.

c. ~~Schedule II-V~~ Schedules II through V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 13 a and 13 b of this section if authorized by DEA or in federal law or regulation.

d. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained ~~off site~~ offsite or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Monday, June 26, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: The meeting was called to order at 2:00 p.m.

PRESIDING: Rafael Saenz, Committee Chairperson

MEMBERS PRESENT: Melvin Boone, Sr.

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Mykl D. Egan, Administrative Proceedings Division
Alina Kilpatrick, Administrative Proceedings Division
Sylvia Tamayo-Suijk, Executive Assistant

Ridgeline Physician Services and InstyMeds Medication Adherence System

The purpose of the informal conference was to act upon the Application of Ridgeline Physician Services and InstyMeds Medication Adherence System for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-30-40 (B) (2) and 18VAC110-30-240 (B) and (C). Present for the meeting from Ridgeline Physician Services was Brad Schraut, CEO of InstyMeds Corporation, Michael Burns, pharmacist and Vice President of pharmacy services at InstyMeds Corporation, and Charity Wolfe, Director at Wellspring Family Practice.

Ridgeline Physician Services requested a waiver of 18 VAC 110-30-40 (B) (2) that requires the visual inspection of the dispensed product before being delivered to the patient. Additionally, a waiver was requested of 18 VAC 110-30-240 (B) and (C) since all drugs dispensed will be sold in special packaging.

Mr. Schraut provided a background on the InstyMeds Medication Adherance System and the patient adherence model used by InstyMeds. An update to the program is a report that physicians may run to identify which patients did not fill the orders the physicians had given them and allow for a follow up call to determine why the patient has not filled the prescription. Mr. Schraut

and Mr. Burns reviewed the security of the dispensing machine which includes biometrics and alarm codes for the machine itself as well as the alarm for the office building.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for Ridgeline Physician Services. Additionally, he moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Mykl D. Egan, Alina Kilpatrick and Sylvia Tamayo-Suijk attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

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

1. An application shall be submitted for a practitioner of the healing arts to sell controlled substances license from each physician requesting the ability to dispense drugs to his own patients.
2. An application for a limited-use facility permit for Ridgeline Physician Services shall be submitted, designating one physician responsible for the drug stock, required inventories, the records of receipt and destruction, safeguards against diversion and compliance with laws and regulations.
3. Dispensing device shall have a monitored alarm within the device, separate from the facility alarm, with the alarm code restricted to the

dispensing physicians that will notify the monitoring entity and appropriate law enforcement in the event of a breach. The device shall require both a biometric as well as code access and be limited to the physician licensed to dispensed.

4. Access to the code or key for opening and loading the device shall be restricted to only times when a dispensing license is on-site and shall only be given to a registered pharmacy technician, nurse or physician assistant with training in compliance with 18 VAC 110-30-40 of the Regulations
5. A visual inspection to verify accuracy of the final dispensed drug prior to delivery as performed in the process of verifying the accuracy of the dispensed drug in its entirety as required in 18 VAC 110-30-40 of the Regulations will be waived, as well as certain provisions of 18 VAC 110-30-240 (B) and (C) of the Regulation, based on the presented information regarding the device's automation and bar-code technology and provided all drugs are dispensed in special packaging.
6. Drugs delivered for loading into the device shall be immediately placed in the device upon receipt to prevent possible diversion.
7. Ridgeline Physician Services shall be subject to two random inspections by the Board or its designated representative within a three year period, the first of which shall be conducted within 12 months of the entry of the order. Ridgeline Physician Services shall be solely responsible for the payment of the inspection fee.
8. Prior to stocking Schedule II through V drugs in the device, Ridgeline Physician Services shall provide the operating procedures for security and monitoring of the drugs to the Board for review and approval
9. All drugs that must be reconstituted shall be mixed by the dispensing physician, registered pharmacy technician, nurse, or physician assistant with training in accordance with 18 VAC 110-30-40 of the Regulations and visually inspected by the dispensing physician prior to delivery.
10. All prescription errors as well as loss or theft must be immediately reported to the Board and other authorities as necessary

11. Counseling shall be provided by the licensed physician at the facility or by a Virginia licensed pharmacist.
12. The dispensing physician shall comply with all laws and regulations regarding the dispensing of controlled substances.
13. Any operational changes or modifications to the pilot program must be reported to and approved by the Board prior to implementation.

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

Rafael Saenz, Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY**
**DRAFT/ MINUTES OF BOARD MEETING**

June 27, 2017
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:12AM.

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Sheila K. W. Elliott (arrived at 11:10)
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
Ryan Logan
Ellen B. Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
David Brown, Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Sylvia Tamayo-Suijk, Executive Assistant

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

APPROVAL OF AGENDA: An amended agenda was provided to the board which included an additional topic - amendment of Guidance Documents 110-44 and 110-45 regarding naloxone protocols.

**Motion:** **The Board voted unanimously to approve the amended agenda that included amending Guidance Documents 110-44 and 110-45 (naloxone protocols) as presented (motion by Saenz, second by Cathcart)**

APPROVAL OF MINUTES: The following minutes were considered for approval:

- March 21, 2017, Public Hearing of Scheduling Certain Chemicals
- March 21, 2017, Full Board Meeting
- March 22, 2017, Special Conference Committee
- April 4, 2017, Possible Summary Suspension
- April 4, 2017, Formal Hearings
- April 25, 2017 Special Conference Committee

- May 10, 2017, Regulation Committee
- May 30, 2017, Special Conference Committee
- June 8, 2017, Special Conference Committee

**Motion:**

**The Board voted unanimously to adopt the minutes from March 21, 2017 through June 8, 2017 as presented. (motion by Warriner, second by Boone)**

PUBLIC COMMENTS:

Patrick Wiggins, Health Systems Interventions Coordinator with the Virginia Department of Health, provided comment with regard to pharmacists and their role in collaborative practice agreements. Mr. Wiggins is partnering with the four pharmacy schools in Virginia to ascertain the scope a pharmacist may have within a collaborative practice and hopes the Board would assist in collecting this information. Mr. Wiggins requested the Board consider adding four questions to the annual pharmacist healthcare workforce survey given to all licensees upon renewal. The questions are as follows:

- Does your pharmacy have collaborative practice agreement?
- If yes, what type of collaborative practice agreement?
- How many licensed pharmacists in your pharmacy participate in the collaborative practice agreement?
- Does your pharmacy plan to implement a collaborative practice within the next year?

Michael Thomas and Michelle Sutherland, consultants representing Temp Time, provided support for the ad-hoc committee created by HB1956 to discuss a possible by which a consumer may be able to determine if there were any issues with temperature during the shipping of their temperature-sensitive medications. Mr. Thomas provided a letter from Mike Rush, Executive Director for Temp Time, to the Board also in support of such ad-hoc committee.

Kristen Russo, patient advocate for people living with arthritis, discussed her own personal experiences with temperature-sensitive medications such as biologics arriving via mail order with issues regarding temperature control.

Chloe Shaffer, PGY1 community based resident for Kroger, appeared on behalf of David Flammia with Kroger to discuss their opposition to the pending regulatory change to require a minimum of two years of experience for a pharmacist prior to being deemed eligible to be a pharmacist-in-charge. Ms. Shaffer believes the determination for a pharmacist-in-charge should be based on the individual and not simply on the number of years of practice. Ms. Juran thanked Ms. Shaffer for her comments but also reminded her that her comments may not be considered by the Board at this meeting and encouraged her to comment on this action once the public comment period has begun for this regulatory change.

Jeenu Philip, Senior Manager for Pharmacy Affairs with Walgreens, echoed the comments of Ms. Shaffer. Mr. Philip also commented on the pending regulatory change requiring a manual signature on prescriptions and made a recommendation to forgo this requirement.

Joseph Domino, representing a medical marijuana company located out-of-state provided comment on SB1027 allowing the Board to issue pharmaceutical processor permits. Mr. Domino had several questions regarding the cost, application and process for applying for such permit. Ms. Juran provided information with regard to the emergency regulations that were awaiting signature by the Governor.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, introduced and welcomed Ms. Michele Schmitz, the new Executive Director for Enforcement. Ms. Schmitz also provided a brief introduction and her hopes to provide the boards with more comprehensive detailed investigative reports in a timely manner. Dr. Brown discussed the changes in policy on how informal conferences will be conducted. He reported that as of July 1st, adjudication specialists will not be in attendance at closed hearings. However, special requests to have an adjudication specialist present can be made. Dr. Brown stated the final numbers for 2016 are in and there was a 40% increase in deaths due to opioid overdose in comparison with 2015. Dr. Brown reviewed the new Board of Medicine Regulations regarding opioid prescribing and encouraged pharmacists with any concerns to offer comments during the comment periods for the promulgation of permanent regulations. He stated that the Secretary of Health will convene two workgroups on electronic prescribing of opioids and developing some core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts briefly reviewed the chart of regulatory actions provided in the agenda, offering updates on pending regulatory actions voted on by the Board and providing the status of several pending actions.

- Adoption of regulations to schedule certain chemicals in Schedule I

There was a public hearing conducted at 9:10 a.m. this morning pursuant to requirements of §54.1-3443 of the Drug Control Act where no public comment was offered.

**MOTION:**

**The Board voted unanimously to adopt an exempt action amendment of Regulation 18VAC110-20-322 as presented which places the following chemicals into Schedule I:**

**Classified as research chemicals:**

- **4-Bromo-2,5 dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (250-NBOH)**

**Classified as a cannabimimetic agent:**

- **Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA)**

**Classified as powerful synthetic opioids:**

- **N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran fentanyl)**

**(motion by Warriner, second by Boone)**

- NABP presentation

In the interest of travel arrangements, the board agreed to take an agenda item out of order to hear a presentation from Neal Watson, Member Relations and Government Affairs Liaison with the National Association of Boards of Pharmacy. Mr. Watson provided a presentation to the Board that gave background on what an e-profile ID number is and how it is used by NABP and may be useful to the Board. Most pharmacists, pharmacy technicians, and pharmacy interns already possess an e-profile ID since it is assigned anytime someone uses an NABP service, e.g., examination, CPE monitoring, licensure endorsement, etc.. Mr. Watson stated the board may wish to consider adopting a regulation to require an applicant to obtain an e-profile ID number prior to applying that may be utilized by the applicant and the board to track discipline, exam scores as well as continuing education. Advantages include decreased administrative burden with daily communications with NABP for licensure or examination information, and elimination of board's need to communicate sensitive identification information to NABP when verifying identify of applicant. Mr. Watson indicated 10 states already require applicants to obtain the number and there is no cost to obtain an e-profile ID number. NABP hopes to expand e-profile IDs to facilities in the near future.

**MOTION:**

**The Board voted unanimously to adopt a Notice of Intended Regulatory Action (NOIRA) to require an e-profile ID number on initial application for pharmacists, pharmacy technicians and pharmacy interns and upon renewal of such licenses and registrations. (motion by Saenz, second by M. Elliott)**

- Periodic Regulatory Review, Adoption of amendments Chapter 20, *Regulations Governing Practice of Pharmacy,* Parts VI-VIII, X-XII and Chapter 50, *Regulations Governing Wholesale Distributors, Manufacturers, and Warehouses,* Parts I-II

Ms. Yeatts reminded the board of actions taken thus far during the periodic regulatory review process: a Notice of Periodic Review was published with 2 comments received; a Notice of Intended Regulatory Review Action was published with comment from 7/11/16 to 8/10/16; the Regulation Committee reviewed regulatory sections on 11/26/16, 2/28/17, and 5/10/17 with Board adoption of those amendments on 12/12/16 and 3/21/17. The remaining amendments must be adopted by the Board today. She then reviewed the proposed regulatory amendments in Chapters 20 and 50 as recommended by the Regulation Committee. In addition, she highlighted written comment provided by Ms. Shinaberry who could not attend the full board meeting. The Board then considered the recommended amendments and offered amendments as necessary.

Ms. Yeatts indicated the suggested 18VAC110-20-112 is not new language, but simply moved to the general provisions section.

**MOTION:** **The Board voted unanimously to amend the recommended regulatory amendments to Regulation 18VAC110-20-240 by inserting in subsection (A)(2) "the count of drugs" in the second sentence after "estimating". (motion by Warriner, second by Boone)**

**MOTION:** **The Board voted unanimously to insert in 18VAC110-20-425(A)(4) "complied with, and" following "maintained and", and to insert in 18VAC110-20-425(A)(4)(a) "and assigned bar codes" following "chapter" as presented in the agenda packet. (motion by Warriner, second by Saenz)**

**MOTION:** **The Board voted unanimously to adopt an amendment of Regulation 18VAC110-20-490 (B)(1) using Ms. Shinaberry's recommended language. (motion M. Elliott, second by Warriner)**

**MOTION:** **The Board voted unanimously to adopt the proposed regulatory amendments to Chapter 20, *Regulations Governing the Practice of Pharmacy,* Parts VII-VIII, X-XII as presented and amended. (motion by Warriner, second by Saenz)**

**MOTION:** **The Board voted unanimously to adopt the proposed regulatory amendments to Chapter 50 of the *Regulations Governing Wholesale Distributors, Manufacturers, and Warehouses,* Parts I-II as presented. (motion by Cathcart, second by M. Elliott)**

**MOTION:** **The Board voted unanimously to adopt Chapter 16, *Regulations Governing Delegation of Informal Fact-Finding Proceedings to an Agency Subordinate,* by relocating existing Regulation 18VAC110-20-15 into this new chapter. (motion by Boone, second by Warriner)**

2018 LEGISLATIVE PROPOSALS:

- Require reporting of Schedule V drugs and naloxone to PMP

Ms. Yeatts indicated the Prescription Monitoring Program (PMP) Advisory Panel had recently adopted a legislative proposal to require the dispensing of Schedule V drugs and naloxone to be reported to the PMP.

**MOTION:** **The Board voted unanimously to support the legislative proposal to require the dispensing of Schedule V drugs and naloxone to be reported to the PMP. (motion by Cathcart, second by Warriner)**

- Proposal to report information relating to persons picking up

Ms. Yeatts reported that the PMP received a request to consider requiring information relating to the person picking up the controlled substance to be reported to the PMP. The PMP Advisory Panel referred the matter to

| | |
|---|---|
| controlled substance to PMP | the Board of Pharmacy for future consideration as it would directly impact pharmacies and dispensing physicians licensed by the Board and require an amendment to the Drug Control Act which is administered by the Board of Pharmacy. |
| **MOTION:** | **The Board voted unanimously to refer to the Regulation Committee the request to require information relating to persons picking up controlled substance to the PMP for further consideration. (motion by S. Elliott, second by Boone)** |
| • Non-resident third-party logistics provider and non-resident warehouser | Ms. Juran explained there are gaps in the law regarding oversight for non-resident third party logistics providers, a new licensing category created by the passage of the federal Drug Quality and Security Act, and non-resident warehousers. Currently, the law does not authorize these entities to ship drugs or devices into the Commonwealth. Because the Drug Control Act is viewed as a permissive act, these entities cannot legally ship into Virginia without the law expressly authorizing the activity. In the interest of patient access and safety, it is necessary to amend the law to authorize these entities to ship into Virginia after obtaining appropriate registration with the Board. Ms. Juran stated a few corrections were needed to the legislative proposal as presented in the agenda packet. On page 103, the term "non-resident warehouser" in 54.1-3435.1 should be underlined and the term "registration" in 54.1-3435.4:2(B) should be changed to "license". |
| **MOTION:** | **The Board voted unanimously to adopt the legislative proposal to authorize registration of non-resident third-party logistics providers and non-resident warehousers as presented and amended by changing the term "registration" in 54.1-3435.4:2(B) to "license". (motion by Warriner, second by M. Elliott)** |
| • Adoption of amendments to Guidance Document 110-1, Categories of Facility Licensure | Amendments are necessary to reflect recent changes in the issuance of a facility permits for distribution of medical gases and controlled substance registrations following legislation passed in the 2017 General Assembly. |
| **MOTION:** | **The Board voted unanimously to adopt the amendments to Guidance Document 110-1, Categories of Facility Licensure, as presented. (motion by S. Elliott, second by Boone)** |
| • Formation of ad hoc committee to address HB1956, HB 2046, and develop guidance on USP Chapter <800> | Ms. Warriner, Ms. Elliott, Ms. Shinaberry and Mr. Saenz volunteered to be on the Committee. Ms. Juran will send an email to the full board for further solicitation. |

- Adoption of amendments to Guidance Documents 110-44 and 110-45 regarding Naloxone

Ms. Juran explained that she had received comment that the current language for the directions in the standing order within the board-adopted protocol might suggest that naloxone may only be administered one additional time, if unresponsive. Because multiple administrations of naloxone may be necessary to counteract a very potent fentanyl overdose, the individual was concerned that the person may not administer a sufficient amount of naloxone if on-hand.

**MOTION:**

**The Board voted unanimously to amend the directions for the standing order within Guidance Documents 110-44 and 110-45 as presented. (motion by M. Elliott, second by Saenz)**

NEW BUSINESS:

- Request to amend the pharmacist healthcare workforce survey regarding collaborative practice agreements

While the Board heard comment earlier in the meeting requesting an amendment to the survey regarding collaborative practice agreements, Ms. Juran explained that she had already received a request from a VCU School of Pharmacy professor to include a couple of questions on the survey to more appropriately assess pharmacist involvement with collaborative practice agreements. Ms. Juran worked with Elizabeth Carter, PhD, Executive Director, Healthcare Workforce Data Center to develop the questions which were presented to the Board on the handout.

**MOTION:**

**To better assess pharmacist involvement in collaborative practice agreements, the Board voted unanimously to amend question #22 within the pharmacist healthcare workforce survey to read "Do you provide any of the following services at this location? Check all that apply. Central filling, compounding, comprehensive medication reviews, remote consulting, remote order processing, immunization administration, medication synchronization, point-of-care testing" and to insert a new #23 to read "If you participate in a collaborative practice agreement for disease state management, which disease states are being managed? Check all that apply. Hypertension, hypercholesterolemia, asthma, tobacco cessation, travel medications, anticoagulation, diabetes, pain management". (motion by Cathcart, second by Saenz)**

- Select Standard for the Admissibility of Expert Testimony

James Rutkowski, Assistant Attorney General, discussed a Virginia Supreme Court decision regarding the Standard for the Admissibility of Expert Testimony. The Office of the Attorney General recommends using the traditional Virginia Standard to identify expert witnesses.

**MOTION:**

**The Board voted unanimously to adopt the traditional Virginia Standard for the Admissibility of Expert Testimony which states: "To qualify to serve as an expert witness, an individual: must possess sufficient knowledge, skill, or experience regarding the subject matter of the testimony to assist the trier of fact in the search for the truth. Generally, a witness possesses sufficient expertise when, through experience, study or observation the witness acquires**

**knowledge of a subject beyond that of persons of common intelligence and ordinary experience.". (motion by Warriner, second by Saenz).**

- Election of Chairman and Vice-Chairman

**MOTION:** **The Board voted unanimously to elect Ryan Logan as Board Chairman for the term July 1, 2017 through June 30, 2018. (motion by Warriner, second by Thornbury)**

**MOTION:** **The Board voted unanimously to elect Michael Elliott for the office of Vice-Chairman for the term July 1, 2017 through June 30, 2018. (motion by Saenz, second by Warriner)**

REPORTS:

Chairman's Report — Ms. Thornbury thanked the Board for the opportunity to serve as Chairman. She thanked Mr. Logan for stepping in during her absence.

Report on Board Of Health Professions — There was no report.

Report on Licensure Program — Mr. Johnson reported that the board issued 998 licenses for the period of March 1 through May 31, 2017 including 166 pharmacist licenses and 513 technician registrations. There were a total of 281 pharmacy inspections of which 184 were routine inspections.

Report on Disciplinary Program — Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of June 22, 2017. She noted that the report has a new format and that these specific status numbers for both patient care and non-patient care cases can be compared with the previous March 9, 2017, numbers. The report indicates that the Board had 310 open cases as of that date with 124 being patient care cases and 186 being non-patient care cases.

Executive Director's Report: — Ms. Juran provided a handout summarizing recent or ongoing projects, recent or upcoming presentations and meetings, and staffing issues. Projects included: implementation of oversight for pharmaceutical processors and development of Request for Proposal for needed computer software; preparations for E-prescribing workgroup to meet August 2nd and 29th, if necessary, which resulted from HB2165; assisting with response to Congressional inquiry regarding high cost of topical compounded drugs charged to Workers' Compensation; responding to inquiries for Joint Commission on Healthcare studies. Ms. Juran stated Sylvia Tamayo-Suijk began June 25th as the new executive assistant, Maria Damico was recently hired by Enforcement as a part-time pharmacist inspector, and Michelle Schmitz recently began as the new

Enforcement Director.

ADJOURN: With all business concluded, the meeting adjourned at approximately 12:50pm.

Rebecca Thornbury, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY

## PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

June 27, 2017
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 9:10AM.

PRESIDING: Rebecca Thornbury, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott
Rafael Saenz
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
Ryan Logan
Ellen B. Shinaberry

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
David Brown, Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Sylvia Tamayo-Suijk, Executive Assistant

PUBLIC HEARING FOR SCHEDULING OF CERTAIN CHEMICALS

Ms. Thornbury called for comment to consider placement of the following chemical substances into Schedule I:

Classified as research chemicals:

- 4-Bromo-2,5 dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (250-NBOH)

Classified as a cannabimimetic agent:

- Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA)

Classified as powerful synthetic opioids:

- N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran fentanyl)

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the 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.

PULIC COMMENT: No comment was offered.

ADJOURN: The public hearing adjourned at 9:12AM.

Rebecca Thornbury, Chairman

Caroline D. Juran, Executive Director

Date

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## MINUTES OF A PANEL OF THE BOARD

June 27, 2017
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 1:35 p.m.

PRESIDING: Rebecca Thornbury, Chair

MEMBERS PRESENT:
Melvin Boone
Freeda Cathcart
Michael Elliott
Sheila Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
Wayne Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Sylvia Tamayo-Suijk, Executive Assistant

QUORUM: With five members of the Board present, a quorum was established.

REBECCA COOK
Registration No. 0230-027504

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

Wayne Halbleib, Senior Assistant Attorney General presented the.

Ms. Cook was not present.

Ann Hardy, DHP Investigator; Rodney Stiltner, VCU Health Systems, Pharmacy Director; and Ed Owens, VCU Health Systems, Employee Relations Manager testified in person on behalf of the Commonwealth.

| | |
|---|---|
| CLOSED MEETING: | Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Rebecca Cook. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler, Jim Rutkowski and Sylvia Tamayo-Suijk attend the closed meeting. |
| RECONVENE: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the quorum re-convened an open meeting and announced the decision. |
| DECISION: | Upon a motion by Mr. Boone, and duly seconded by Mr. Elliott, the panel voted 5-0 to indefinitely suspend Ms. Cook's pharmacy technician registration for not less than two years. |
| ADJOURN: | With all business concluded, the meeting adjourned at 2:50 p.m. |

Rebecca Thornbury, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, June 28, 2017
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:10 a.m.

PRESIDING: Rafael Saenz, Committee Chair

MEMBERS PRESENT: Sheila K.W. Elliott, Committee Member

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

CRYSTAL ANDERSON
Pharmacy technician registration
#0230013262

Crystal Anderson, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision: Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Crystal Anderson in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of their pharmacy technician registration.

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

SABRINA COLLINS
Pharmacy technician registration
#0230007660

Sabrina Collins, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Sabrina Collins in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of their pharmacy technician registration.

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

BENITA EDISON
Pharmacy Technician registration
#0230021311

Benita Edison, 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 26, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Benita Edison. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, Alina Kilpatrick and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in

its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found that no violation had occurred.

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

JENNIFER HOLMES
Pharmacy Technician registration
#0230022261

Jennifer Holmes, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Jennifer Holmes. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, Alina Kilpatrick and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of

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

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Jennifer L. Holmes in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order with no further action.

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

PORSHA MOON
Pharmacy Technician registration
#0230012490

Porsha Moon, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Porsha Moon in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of their pharmacy technician registration.

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

SOBIA NAUREEN
Pharmacy Technician registration
#0230017939

Sobia Naureen, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Sobia Naureen in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of their pharmacy technician registration.

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

SAMONNE LA'TREECE PORTER
Pharmacy Technician registration
#023023404

Samonne La'Treece Porter, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Samonne La'Treece Porter in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an

Order that imposes a reprimand of their pharmacy technician registration.

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

TAMMIE L. WILLIAMS
Pharmacy Technician registration
#0230005857

Tammie L. Williams, pharmacy technician, did not attend to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Tammie Williams in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of their pharmacy technician registration.

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

| | |
|---|---|
| QUANGLONG N. TRUONG<br>Pharmacist License #0202213338 | Quanglong N. Truong, pharmacist, did not attend to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 26, 2017 Notice. |
| Closed Meeting: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Quanglong N. Truong. Additionally, he moved that Mykl D. Egan, Alina Kilpatrick and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Quanglong N. Truong in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a $250 monetary penalty and no additional continuing education requirement.<br><br>As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Quanglong N. Truong, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Quanglong N. Truong within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.<br><br>Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated. |

| | |
|---|---|
| INOVA LOUDON HOSPITAL PHARMACY<br>Permit# 0201000992 | Debbie Lynn Wagner, Pharmacist-In-Charge, and Cathleen Cowden, Director of Pharmacy, attended the meeting to discuss allegations that Inova Loudon Hospital Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 26, 2017 Notice. |
| Closed Meeting: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Inova Loudon Hospital Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, Alina Kilpatrick and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that found the pharmacy violated certain laws and regulations and required a $6000 monetary penalty.<br><br>As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Inova Loudon Hospital Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Inova Loudon Hospital Pharmacy within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.<br><br>Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated. |

| | |
|---|---|
| OPTION CARE<br>Permit #0201003388 | Loretta Lombardo, Pharmacist-In-Charge, Nikia L. Gray, attorney with Quarles & Brady LLP, and Edward D. Rickert, Quarles & Brady LLP, attended the meeting to discuss allegations that Option Care may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 26, 2017 Notice. |
| Closed Meeting: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Option Care. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, Alina Kilpatrick and Beth L. O'Halloran attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, the Committee made certain Findings of Facts and Conclusions of Law and found Option Care in violation of certain laws and regulations of the Board of Pharmacy and unanimously voted to enter an Order that imposes a $5500 monetary penalty.<br><br>As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Option Care, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Option Care within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.<br><br>Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated. |

ANNANDALE PHARMACY
Permit #0201004585

Mr. Bo Yeon Kim, Pharmacist-In-Charge, attended the meeting to discuss allegations that Annandale Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 26, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Annandale Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, and Alina Kilpatrick 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. Elliott, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $1000 monetary penalty.

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

HANARO PHARMACY
Permit #0201004377

Mr. Bo Yeon Kim, Pharmacist-In-Charge, attended the meeting to discuss allegations that Hanaro Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the May 26, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Mr. Saenz, 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 Hanaro Pharmacy. Additionally, he moved that J. Samuel Johnson, Mykl D. Egan, and Alina Kilpatrick 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. Elliott, and duly seconded by Mr. Saenz, the Committee accepts certain allegations as Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that imposes a $1000 monetary penalty.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Hanaro Pharmacy, unless a written request is made to the Board requesting a formal hearing on the allegations made against it is received from Hanaro 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 2:00pm.

Rafael Saenz, Chair

Date

J. Samuel Johnson, Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

| | |
|---|---|
| Monday, July 17, 2017 | Department of Health Professions |
| Commonwealth Conference Center | Perimeter Center |
| Second Floor | 9960 Mayland Drive |
| Board Room 1 | Henrico, Virginia 23233 |

| | |
|---|---|
| CALL TO ORDER: | A meeting of the Special Conference Committee of the Board of Pharmacy was called to order at 10:30 a.m. |
| PRESIDING: | Michael Elliott, Committee Chair |
| MEMBERS PRESENT: | Jody Allen, Committee Member |
| STAFF PRESENT: | Cathy Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist |
| JAMES L. SURRATT, JR.<br>License No. 0202-205254 | James Surratt appeared with Johnny Moore, VAPAPP, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the Junes 13, 2017 Notice. |
| Closed Meeting: | Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of James L. Surratt, Jr. Additionally, she moved that Cathy Reiniers-Day attend the closed meeting because her 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 Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Allen and duly seconded by Mr. Elliott, the Committee unanimously voted to enter an Order that Mr. Surratt continue his participation with HPMP. |
| AMANDA LANE ASHDOWN<br>Registration No. 0230-021067 | Amanda Lane Ashdown did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the June 13, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Ashdown's legal address of record. |

| | |
|---|---|
| Closed Meeting: | Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Amanda Lane Ashdown. Additionally, she moved that Cathy Reiniers-Day attend the closed meeting because her 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 Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Allen and duly seconded Mr. Elliott, the Committee unanimously voted to offer Ms. Ashdown a Consent Order for the indefinite suspension of her right to renew her pharmacy technician registration. |
| Adjourn: | With all business concluded, the meeting adjourned at 3:00 p.m. |

_____
Michael Elliott, Chair

_____
Date

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

# (DRAFT/UNAPPROVED)
## VIRGINIA BOARD OF PHARMACY
## MINUTES OF A PANEL OF THE BOARD

Monday, July 31, 2017
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:55 a.m.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Michael Elliott (departed at 11:20 a.m.)
Sheila Elliott
Rafael Saenz
Ellen Shinaberry
Cynthia Warriner (arrived at 10:50 a.m.)

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
Wayne Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With five (5) members of the Board present, a panel of the board was established.

SHAWANDA GILLIAM
Registration No. 0230-009351

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

Wayne Halbeib, Senior Assistant Attorney General, presented the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Ms. Gilliam was not present.

Cristina Bargdill, DHP Enforcement Supervisor and Rebecca Aycock-Brown, Nelson Family Medicine, PhD LCP testified on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Mr. Elliott, and duly seconded by Ms. Shinaberry, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Shawanda Gilliam. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler and Jim Rutkowski attend the closed meeting.

| | |
|---|---|
| RECONVENE: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. |
| DECISION: | Upon a motion by Mr. Saenz, and duly seconded by Ms. Elliott, the panel voted 5-0 to accept the Findings and Facts of Law proposed by Mr. Halbleib and amended by the board.<br><br>Upon a motion by Mr. Saenz, and duly seconded by Ms. Elliott, the panel voted 5-0 to indefinitely suspend Ms. Gilliam's right to renew her pharmacy technician registration.<br><br>Cynthia Warriner arrived. |
| Quorum: | With six (6) board members present, a quorum of the board was established. |
| POSSIBLE SUMMARY SUSPENSION: | 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. |
| DECISION: | Upon a motion by Mr. Elliott and duly seconded by Mr. Saenz, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by Corinthians Hughey poses a substantial danger to the public; and therefore, the license of Mr. Hughey shall be summarily suspended.<br><br>Further, upon a motion by Mr. Elliott and duly seconded by Ms. Shinaberry, the Board unanimously voted that a Consent Order shall be offered to Mr. Hughey for the indefinite suspension of his license to practice as a pharmacist for not less than two years, in lieu of a formal administrative hearing.<br><br>Michael Elliott departed. |
| Quorum: | With five (5) board members present, a panel of the board was established. |
| DALE A. MOORE<br>License No. 0202-210861 | A formal hearing was held in the matter of Dale Moore to discuss his request for the reinstatement of his pharmacist license and allegations that he may have violated certain laws and regulations governing the practice of pharmacy in Virginia. |

Wayne Halbeib, Senior Assistant Attorney General, presented the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Mr. Moore was not present.

Joyce Johnson, DHP Senior Investigator, testified on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Warriner, and duly seconded by Ms. Elliott, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Dale Moore. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Kennia Butler and Jim Rutkowski attend the closed meeting.

RECONVENE:

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

DECISION:

Upon a motion by Mr. Saenz, and duly seconded by Ms. Elliott, the panel voted 5-0 to accept the Findings and Facts of Law proposed by Mr. Halbleib and amended by the board.

Further, upon a motion by Mr. Saenz, and duly seconded by Ms. Elliott, the panel voted 5-0 to deny Mr. Moore's application for reinstatement of his pharmacist's license.

ADJOURN:

With all business concluded, the meeting adjourned at 12:40 p.m.

Ryan Logan, Chair

Cathy Reiniers-Day
Deputy Executive Director

Date

# Board of Pharmacy

## Chart of Regulatory Actions as of September 8, 2017

**Board** **Board of Pharmacy**

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Controlled substances registration for nalozone and teleprescribing [Action 4789]<br>Emergency/NOIRA - *Register Date: 5/29/17*<br>*Board to adopt proposed regulations 9/26/17* |
| [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]<br>NOIRA - *Register Date: 7/11/16*<br>*Board adopted proposed regulations 6/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Response to petitions for rulemaking [Action 4694]<br>Proposed - *Register Date: 9/4/17*<br>*Comment period ends: 11/3/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Drug destruction in correctional facilities [Action 4788]<br>Fast-Track - *Register Date: 7/24/17*<br>*Effective: 9/7/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Partial fill of Schedule II drugs [Action 4790]<br>Fast-Track - *Register Date: 7/24/17*<br>*Effective: 9/7/17* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>Final - *At Governor's Office* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | (E)<br>Scheduling of chemicals [Action 4853]<br>Final - *Register Date: 9/4/17*<br>*Effective: 10/4/17* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors [Under development] | New regulations [Action 4695]<br>Emergency/NOIRA - *Register Date: 8/7/17*<br>*Emergency effective: 8/7/17 to 2/6/19* |

**HB 1956 Prescription drug order; requirements for shipping Schedule VI controlled substances.**

another bill? go

**Gordon C. Helsel, Jr. | all patrons ... notes | add to my profiles**

*Summary as introduced:*

**Delivery of prescription drug order; shipping Schedule VI controlled substances.** Clarifies requirements related to delivery of prescription drug orders, including delivery of such orders by mail, common carrier, or delivery service, and requires the Board of Pharmacy to adopt regulations for the delivery of prescription orders by mail, common carrier, or delivery service.

*Full text:*

01/10/17 House: Prefiled and ordered printed; offered 01/11/17 17102125D **pdf | impact statement**

*Status:*

01/10/17 House: Prefiled and ordered printed; offered 01/11/17 17102125D
01/10/17 House: Referred to Committee on Health, Welfare and Institutions
01/17/17 House: Assigned HWI sub: Subcommittee #1
01/31/17 House: Subcommittee recommends laying on the table by voice vote
02/07/17 House: Left in Health, Welfare and Institutions

17102125D

# HOUSE BILL NO. 1956

Offered January 11, 2017

Prefiled January 10, 2017

*A BILL to amend and reenact § 54.1-3420.2 of the Code of Virginia, relating to delivery of prescription drug order; shipping Schedule VI controlled substances.*

Patrons—Helsel and Peace

Referred to Committee on Health, Welfare and Institutions

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

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

**§ 54.1-3420.2. Delivery of prescription drug order.**

A. *Prescription drug orders may be delivered (i) directly to the patient or his legally authorized representative at the pharmacy; (ii) to the home of the patient, by hand delivery or by mail, common carrier, or delivery service; or (iii) to another delivery location, by hand delivery or by mail, common carrier, or delivery service, provided such delivery to such delivery location is authorized by federal law and regulations of the Board. The Board shall adopt regulations governing the delivery of prescription orders by mail, common carrier, or delivery service to a patient's home or to another delivery location, which shall include requirements related to access, accuracy, security, required records, storage, and accountability. Such regulations shall also include temperature control standards and shall require, for any drug requiring temperature control, a method approved by the United States Pharmacopeia by which the patient can detect temperature variances that could cause degradation of the drugs.*

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

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

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

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

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

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

~~E.~~ *F.* Prescription drug orders dispensed to a patient and delivered to a program of all-inclusive care for the elderly (PACE) site licensed by the Department of Social Services pursuant to § 63.2-1701 and

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

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

ROBERT D. "BOBBY" ORROCK
POST OFFICE BOX 458
THORNBURG, VIRGINIA 22565

FIFTY-FOURTH DISTRICT

COMMITTEE ASSIGNMENTS:
HEALTH, WELFARE AND INSTITUTIONS (CHAIRMAN)
FINANCE
AGRICULTURE, CHESAPEAKE AND
NATURAL RESOURCES
RULES

February 17, 2017


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

Dear Mr. Brown.

The Virginia Health, Welfare and Institutions Subcommittee voted to lay HB1956 on the table with a letter requesting the Virginia Board of Pharmacy to consider the issue related to any variances that may exist between mail-order and hand-delivered prescription medications.

I would appreciate your consideration of this and please inform me of any recommendations by November 2017.

Sincerely,

Robert D. (Bobby) Orrock, Sr.

RDO/rh

DISTRICT: (540) 891-1322 • RICHMOND: (804) 698-1054 • E-MAIL: DELBORROCK@HOUSE.VIRGINIA.GOV

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND

CHRISTOPHER K. PEACE
POST OFFICE BOX 819
MECHANICSVILLE, VIRGINIA 23111

NINETY-SEVENTH DISTRICT

COMMITTEE ASSIGNMENTS:
GENERAL LAWS (VICE CHAIRMAN)
APPROPRIATIONS
HEALTH, WELFARE AND INSTITUTIONS

March 2, 2017



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

**RE: House Bill 1956 (Helsel): Delivery of prescription drugs orders**

Dear Dr. Brown,

On Tuesday, January 31, 2016, the Virginia Health, Welfare and Institutions Subcommittee voted to lay HB1956 on the table with a letter. I understand that the Chair has sent a letter asking the Board of Pharmacy to consider and provide recommendations regarding variances that may exist between mail-order and hand-delivered prescription medications.

As a member of the subcommittee which heard the bill, I heard conflicting claims about federal regulations related to the transportation of prescription drugs, including how the federal standards impact transit from the manufacturer to the pharmacy to the consumer. This matter is particularly important as more and more medications are delivered via mail-order or common carrier, including high-cost specialty pharmaceuticals such as biosimilars and biologics. I am interested in understanding how and whether mail-order shipment requirements have kept pace with changing pharmaceutical products, and whether Virginia's patients are obtaining the information they need to make informed decisions about their mail-order medications, especially those for which temperature control is vital to maintaining the efficacy of the drug.

As such, I would like to request that, as the Board studies the issues as requested by the Chair, that the Board consider specific questions that I, and other members have, regarding this matter. Information related to the following questions will be of great help as we consider this issue going forward:

1. What states have implemented rules, regulations or guidance regarding the shipment of prescription drugs directly to the consumer by mail or common carrier?

DISTRICT: (804) 730-3737 • RICHMOND: (804) 698-1097 • E-MAIL: DELCPEACE@HOUSE.VIRGINIA.GOV

2. Of the states that do have some form of regulation to govern shipping, which states require some form of notice or instruction to the consumer related to temperature? Do any states require a method by which consumers can detect temperature variation?

3. Which states collect data related to problems with the shipping of prescription drugs, either for all licensed pharmacies that ship drugs by mail or common carrier, or for any health plan that is overseen or implemented by the state (i.e. a state employee health plan, Medicaid, plan, etc.?) What kinds of data are collected?

4. What federal regulations or guidelines exist related to temperature controls of mail order prescription drugs? Is this really covered by "track and trace" as was claimed by some?

5. What part of the shipping process do the federal regulations control? (i.e. the oversight and monitoring of medications between the manufacturer and the pharmacy or between the pharmacy and the consumer?)

6. Does the Commonwealth track current losses related to fraud, waste and spoilage of mail order prescription drugs and if so, what are the associated costs to the Commonwealth?

7. What is the approximate number of Virginians (covered by commercial plans) who are required to obtain medication via mail-order?

I appreciate the work the Board of Pharmacy does to protect the public and I thank you for your consideration of this request.

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

Sincerely,

Christopher K. Peace

CHRISTOPHER T. HEAD
POST OFFICE BOX 19130
ROANOKE, VIRGINIA 24019

SEVENTEENTH DISTRICT

COMMONWEALTH OF VIRGINIA
HOUSE OF DELEGATES
RICHMOND



COMMITTEE ASSIGNMENTS:
FINANCE
HEALTH, WELFARE AND INSTITUTIONS
MILITIA, POLICE AND PUBLIC SAFETY



May 22, 2017

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

**RE: House Bill 1956 (Helsel): Delivery of prescription drugs orders**

Dear Dr. Brown,

I understand that the Chair of the Health, Welfare and Institutions Committee has sent a letter asking the Board of Pharmacy to consider and provide recommendations regarding variances that may exist between mail-order and hand-delivered prescription medications.

This came as a result of a motion I made to Table HB 1959 with a letter. During the subcommittee meeting that heard the bill, a number of concerning points were made. One speaker even indicated that if members are concerned about temperature excursions with certain drugs shipped from a pharmacy through mail order, there should be just as much concern over the shipment of drugs on the way to the pharmacy from a manufacturer or distributor. We need the Board's expertise to help clarify this and other questions. As such, I would like to request that, as the Board studies the issue as requested by the Chair, the Board consider a few specific questions which I have outlined below:

1. §54.1-3420.2 requires that all medications shipped by mail order include a written notice "alerting the consumer that under certain circumstances chemical degradation of drugs may occur." Is this notice specific to the drug(s) being shipped? What guidelines does the Board have in place for the content of these notices?

2. How does the Board track compliance with the law requiring this notice?

3. How does a consumer know if his or her medicine has been subjected to circumstances that can affect the drug's efficacy?

4. Conflicting information was presented to the subcommittee as to whether or not the federal government already has regulations or guidelines in place regarding temperature variations of drugs shipped by mail or common carrier. Are such regulations or guidelines in place, and do the guidelines cover all aspects of medication shipments,

DISTRICT: (540) 283-2839 • RICHMOND: (804) 698-1017 • E-MAIL: DELCHEAD@HOUSE.VIRGINIA.GOV

including transit from the manufacturer/wholesaler to the pharmacy, as well as shipment from the pharmacy to the consumer?

5. What is the current process used by pharmacies to determine whether the drugs received by the pharmacy have been exposed to conditions that could compromise the efficacy of the drug(s)? Does Virginia have guidelines specific to this shipping scenario, or do the manufacturers/wholesalers rely on federal regulations or guidelines when shipping to a pharmacy?

6. If there are no state or federal guidelines that cover shipment from the manufacturer/wholesaler to the pharmacy or pharmacy to consumer, is this something Virginia can address?

I appreciate your consideration of this request. If you have any questions, please do not hesitate to contact me.

Sincerely,

Christopher T. Head
Virginia House of Delegates

**McGuireWoods Consulting LLC**
Gateway Plaza
800 East Canal Street
Richmond, VA 23219
Tel 804.775.1900
Fax 804.775.1061
www.mwcllc.com

**Michele L. Satterlund**
Direct: 804.775.1911.

McGUIREWOODS CONSULTING
Public Affairs Solutions

msatterlund@mwcllc.com

September 6, 2017

*By Email: caroline.juran@dhp.virginia.gov*
Ms. Caroline Juran
Virginia Board of Pharmacy
9960 Mayland Drive
Richmond, VA 23233-1463

**RE: House Bill 1956 / Ad-Hoc Study on Mail Order Delivery of Prescription Medications**

Dear Ms. Juran,

I am writing on behalf of Temptime to provide comment on the ad-hoc committee's study related to the variances that exist between mail-order and hand-delivered prescription medications.

Temptime works to improve global public health and better patient outcomes by manufacturing temperature monitoring devices used in the shipment of medications. Temptime is one of many companies that manufacture a variety of temperature devices for this purpose.

**Protecting Patients**

Few issues are more important to public health than the proper storage and handling of medications. To properly maintain a medication's stability, many medications must be stored in a refrigerator or freezer. Excessive heat or cold—even a single exposure in some instances—can reduce a medication's potency and result in significant health risks to the patient.

Given the seriousness of temperature control as it relates to the efficacy of medication, it is critical that Virginia ensure that all medication, regardless of how it is delivered, is subject to the same temperature control standards and that patients, regardless of how they take receipt of their medications, have the information they need to ensure the medication's stability.

As more and more patients receive complex temperature sensitive medications by mail-order, the last mile of delivery (from the mail-order pharmacy to the patient) has generated greater attention. In 2015, the American Academy of Pediatrics, recognizing the importance of this issue, passed a resolution

advocating for improved safety of all mail-order medication.[1] The resolution advocated for, among other things, the use of visual temperature indicators on each box or vial of medication shipped in the mail. The Academy passed the resolution after a 2012 Yale University study related to the temperature of vaccines found that the temperature variances between refrigeration units placed vaccines at risk of reduced potency (and children at risk for ineffective protection) and that freeze indicators affixed to boxes of vaccines provided an early warning related to the risks of compromised medication.[2]

Additionally, in the last several years, separate classes of patients in California have filed two class actions alleging that, among other things, refrigerated specialty drugs (Enbrel) shipped to consumers are not being stored and maintained between a temperature of 36-46 degrees and that the shipper "has never provided or included a means by which Plaintiff or the Class could monitor or verify the temperature of the Enbrel or other Specialty Drugs after it left Caremark's pharmacy."[3]

As the use of complex drugs such as biologics and biosimilars continues to increase, it is critical that patients have access to information that indicates whether the medication has been subjected to conditions that cause degradation. Biosimilars and biologics are often both expensive and highly sensitive to temperature variances, and some patients indicate they have lost thousands of dollars in an effort to protect themselves from heat and freeze damaged medications.

Further, for those patients who are required to utilize mail-order services as part of a health plan's benefits, the issue is extremely important, as they may not have the resources to utilize a local brick and mortar pharmacy ("local pharmacy"). In these situations, the patient, who likely has no medical or chemical composition training, must "guess" whether his or her medication has been compromised.

Giving patients, at a minimum, a method by which to determine whether their medication may have been compromised by a temperature variance will create more uniformity between mail-order and local pharmacies and will help give patients the information they need to make informed decisions about their own health.

**Variances: Mail-order and hand-delivered medication**

Mail-order

Virginia code §54.1-3420.2 requires that drugs delivered by mail include a generic written notice "alerting the consumer that under certain circumstances chemical degradation of drugs may occur."

The consideration of temperature is important enough that Virginia law mandates this notice be provided to patients, yet the law does not require that the same patient who has received the notice (and, as a result, may be concerned whether his or her medication was left in the mailbox on a very hot or very cold

[1] Resolution #55 (15) – 2015 Annual Leadership Forum, American Academy of Pediatrics

[2] Angoff, R., Wood, J., Chernock, M. C., & Tipping, D. (2015). Visual Indicators on Vaccine Boxes as Early Warning Tools to Identify Potential Freeze Damage. *Infectious Diseases in Clinical Practice (Baltimore, Md.)*, *23*(4), 184–189.

[3] Boysen, Ryan. *CVS' Shoddy Shipping Ruined Arthritis Drug, Suit Says.* Law360. 3 February 2017.
Field, Emily. *Amgen, CVS Units Hit With Suit Over Arthritis Drug Shipping.* Law360. 20 October 2014.

day) have some means by which to determine whether the medication has been exposed to an extreme temperature event.

Virginia law also requires that medications delivered by mail include another written notice that provides "a toll-free or local consumer access telephone number which is designed to respond to consumer questions pertaining to chemical degradation of drugs." The law does not require that a physician or a pharmacist or an individual trained in chemical composition/degradation staff the consumer access telephone service, nor does the law require any sort of tracking related to the frequency or types of calls received by these services.

Consequently, the information a patient receives regarding chemical degradation could simply be "speculation" provided a telephone operator who can't visually inspect the medication or test it, and the operator, like the patient, can only make an educated guess as to whether the medication has been compromised.

Hand-delivery

In contrast to the handling of mail-order delivery medications, a local pharmacy that delivers medication by handing it directly to the patient is subject to a variety of very strict provisions related to the proper temperature control of drugs. These requirements provide patients with a level of confidence, knowing that the drugs have been in a monitored and controlled environment until the time they are handed to the patient.

The Virginia regulations covering pharmacies are very detailed in terms of the standards the pharmacy must meet, and so seriously does the Board take the issue, that the Regulation Committee recently recommended amendments to 18VAC110-20-150, which would require any pharmacy stocking cold temperature drugs to record the temperatures daily and to maintain the record for a period of two years.

It's difficult to imagine a local pharmacist filling a prescription for a temperature sensitive medication and then just walking away—leaving the drug on a counter, in a slot, or wherever room temperature drugs are stored while awaiting pickup for one, two, three or more days until the consumer arrives to get their medication.

Yet, this is exactly what happens daily with prescription drugs delivered through the mail. And, while most pharmacies take reasonable care in packaging the shipment of drugs, there are still days when the temperature is so high (or low) that the packaging may not be enough. This is further compounded if the patient is away for two or more days and cannot take immediate receipt of the medication, or if the system used for transport is not temperature controlled.

The Board's regulations for local pharmacies provide patients with confidence that, until the moment the medication is handed to the patient by the pharmacist, the medication has not been compromised in a way that could impact the medication's efficacy.

No similar protections exist in Virginia law for patients who receive their medications via mail-order and the goal of HB1956 was to give patients, at a minimum, the ability to determine whether the medication they receive by mail-order shipment may have been exposed to a heat or freeze event that could impact the efficacy of the drug, and subsequently, the patient's health.

Having access to temperature information will allow an informed conversation to take place between the patient, the patient's provider, and the pharmacy, and will give patients an important tool to protect their own health.

**States**

Virginia is not the first state to consider a requirement that mail-order shipments include a method by which the patient can determine whether the medication may have been subjected to a compromising heat or freeze event.

New Jersey's Board of Pharmacy recently finalized regulations that require all temperature sensitive medications shipped via mail-order to use adequate methods to ensure the temperature controlled conditions are maintained during delivery and requires the pharmacy to include instruction to the patient on how to detect temperature variance and how to report the variance (emphasis added):

> **New Jersey Administrative Code 13:39-5.11 Control and Monitoring of Temperature of Prescription Drugs and Chemicals**
> "2) A pharmacy that delivers a filled prescription drug or chemical to the patient, agent of the patient, or facility or healthcare provider providing care to the patient *by any method*, except when picked up directly from the pharmacy by the patient or his or her authorized agent, *shall*, in the professional judgment of the pharmacist, and in accordance with the pharmacy's policies and procedures as set forth in (d) below, use adequate methods to ensure temperature controlled conditions are maintained during facility storage, transportation, and delivery.
>
> i. To ensure that temperature control is maintained during delivery, the shipping processes may include the use of appropriate packaging material or devices according to information provided by the manufacturer, Chapter 1079 of USP, other learned treatises, or expert qualification analysis.
>
> ii. When packaging material or devices are used to maintain temperature control during delivery, *the contents of the package shall include instructions to the recipient how to easily detect improper storage or temperature variation, and instructions how to report the storage or temperature excursion to the pharmacy.*"

South Carolina recently began looking at the issue, as well. The Board of Health finalized regulations requiring that emergency medical services (EMS) responders control the temperature anywhere medications are stored to prevent drug adulteration, and to put in place requirements for the disposal of these medications in situations where a heat or freeze event occurred (emphasis added).

> **South Carolina Regulation 61-7 Section 601 Ambulance Design and Equipment**
> "5. Environmental Control and Medications: *The temperature in the patient compartment or anywhere medications are stored (QRVs, fire apparatus, rapid response vehicles, carry-in bags, and other) shall be monitored for temperature extremes to prevent drug adulteration.* Medications (excluding oxygen) and IV fluids will be removed and discarded if the temperatures reach or exceed one hundred (100) degrees Fahrenheit (thirty-eight (38) degrees Celsius). Medications and IV fluids shall also be removed and discarded if temperatures in the drug storage area drop below twenty (20) degrees Fahrenheit (negative seven (-7) degrees Celsius)."

Similarly, Iowa's Board of Pharmacy recently amended the Iowa Administrative Code (Chapter 11, Drugs in Emergency Medical Service Programs) to require that all Iowa Service Programs "...shall utilize a method

to provide continuous temperature control or monitoring, such as a temperature indicator, which at a minimum identifies when the drugs have been exposed to extreme temperatures. The service program shall regularly, but at least weekly, verify and document verification that the drugs have not been exposed to extreme temperatures."

Under Pennsylvania Code §27.18, prescription drugs that can deteriorate due to heat or cold, can be sent via mail-order "if it is shipped in a manner which would preserve the integrity of the drug, such as cold packs or other temperature control devices *and sensors that would alert the patient if the integrity of the drug was compromised.*"

In 2014, the Georgia Board of Pharmacy promulgated regulations mandating the inclusion of a temperature monitoring device in all temperature sensitive medications. The regulation was a result of legislation that successfully passed the Georgia General Assembly mandating the inclusion of a device in temperature sensitive medication sent by mail-order. Subsequently, legislation was passed changing "shall" to "may," and in February 2017 the Georgia Board of Pharmacy updated the regulations to reflect the code language.

In Washington State, SHB1765 was recently signed by the Governor. The legislation requires, among other things, that donated medications not equipped with a temperature indicator may only be released when the medication is accompanied by a donor form that attests that the donated medication has been stored in a manner and location that adheres to the condition established by the manufacturer and that the medication has not been adulterated.

**Mail-order medication loss costs**

Temptime is currently unaware of any mechanism by which to determine the numbers of patients in Virginia that receive medication by mail-order as compared to the numbers of patients that receive medication via hand-delivery. Our understanding is that this information is proprietary to the commercial health plans and mail-order pharmacies and it is not available publically. However, the anecdotal information we have collected indicates that waste related to temperature variance is likely high.

In 1997, a United States Pharmacopeia study found that about one quarter of packages delivered through the mail were exposed to "excessive heat which can diminish some medications' effectiveness. In the study, dummy packages with embedded temperature sensors were sent to 32 states. The study found that more than one in four mail-order prescription deliveries in the US were likely to be exposed to excessive heat during transit to the patient.[4]

In 2013, another study tested five packaging technologies commonly used by specialty pharmacies. The packages were subjected to real-world temperatures, and of the five systems tested, not one maintained the temperature range required for biologics. The study noted that the last mile of delivery is critical, given that medicines could be delayed or left exposed during this critical last stop in the cold chain.[5]

---

[4] Okeke, C. C., Bailey, L. C., Medwick, T., and Grady, L. T., "Temperature Fluctuations During Mail Order Shipment of Pharmaceutical Articles Using Mean Kinetic Temperature Approach," Pharmacopeial Forum, 23(3) May-June 1997, page 4155-4182.

[5] Modality Solutions. The Cold, Hard Facts: What You Need To Know About Thermal Shipping Technologies. 2013.

In another attempt to obtain an accurate comparison between the numbers of patients receiving medication by mail-order or hand-delivery in Virginia, we reviewed the number of individuals enrolled in Virginia's state employee health plan.

In a presentation dated January 19, 2017, the Virginia Department of Human Resources Management reported that in 2016, 195,095 individuals were enrolled in Virginia's state employee health insurance plan. Of the total claims made in 2016, $273.1M was spent on medication claims[6].

The presentation goes on to note that of the claimed expenses, high cost specialty drugs such as Humira, Enbrel and Harvoni (all of which are temperature sensitive medications) were part of the "top ten" claim expenses. Additionally, the report notes that state employees filled five times more specialty prescriptions in 2016 than they did in 2012, and in 2016, the state spent 2.5 times more in costs of specialty drugs than in 2012.

Given the growing usage of complex medications by state employees, it is likely that a portion of these medications are delivered by mail-order. Temptime is continuing to work on obtaining detailed information related to the number of state employees receiving mail-order specialty drugs and we hope to provide this information to the committee by the hearing date.

**Federal regulations**

While the Food and Drug Administration, Drug Enforcement Agency and Centers for Medicare & Medicaid Services all have various rules related to prescription medications, none of these agencies have promulgated cold-chain rules related specifically to the last mile of delivery.

Under 21 CFR 205.50(c) the regulation governing state licensing of wholesale prescription drug distributors, the following is required for the storage of all prescription drugs:

> "(c) Storage. All prescription drugs 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 in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
>
> (1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected."

Guidance for the last mile of delivery (pharmacy to patient) is provided by the United States Pharmacopeia (USP) and The National Formulary (USP-NF). The USP-NF guidance contains definitions, tests, and standards for chemical and biological drug substances. There are five general chapters that include information related to the temperature-sensitive supply chain.

- 1079: Good Storage and Shipping Practices
- 1083: Good Distribution Practices – Supply Chain Integrity

[6] http://hac.state.va.us/subcommittee/compensation_retirement/files/1-19-17/DHRM.pdf

- 1118: Monitoring Devices time, temperature and humidity
- 1077: Good Packaging Practices
- 1150: Pharmaceutical Stability

Specifically, USP-NF Chapter 1079 is intended to provide guidance on "good storage and distribution practices to ensure that medicine reaches the end user with quality intact." The end user is defined to include practitioners, patients and consumers.

The guidance provided by Chapter 1079 is clear that temperature control throughout the entire supply chain is critical, and notes that the guidance is intended to apply to all organizations and individuals involved in any aspect of the storage and distribution of a drug product, *including mail-order pharmacies.*

In a section devoted specifically to temperature monitoring, Chapter 1079 notes that:

> "when specific storage conditions are required and transportation qualification has not been performed, and in the absence of active or passive containers, environmental records or devices should be used to confirm that an acceptable range has been properly maintained during each stage in the supply chain."

Further, Chapter 1079 stresses the importance of temperature as it relates to medication stability, noting (emphasis added):

> *"Temperature is one of the most important conditions to control,* and requirements for each drug product should be based on stability data. Temperatures should be tracked using a monitoring systems.....*The monitoring devices should provide an alert mechanism if the preset ranges are breached...."*

Additionally, Chapter 1079 states that the following practices and controls are examples of appropriate measures that should be put in place to ensure environmental control along every step of the supply chain (emphasis added):

- "Temperature-monitoring equipment, a monitoring device, a temperature data logger, or other such device that is suitable for its intended purpose should be used.
- An appropriate number of temperature monitors or some other form of recordation or proof of temperature control. *Temperature monitor(s) should be used with every distribution process unless another process has been put in place to ensure specified temperature ranges.*
- Electronic temperature monitors should be calibrated to National Institute of Standards and Technology (NIST) or other suitable standard.
- Chemical temperature indicators may be used as appropriate.
- Predetermined temperature ranges should be set for all applicable areas, *as well as a plan of action in the event of an unacceptable excursion."*

The USP guidance is clear that temperature control is vital to the stability of medication throughout the entire supply chain, and whether medication is delivered via mail-order or by hand-delivery, the USP contemplates temperature monitors will be used at every step of the distribution process to ensure the end user has the information he or she needs to ensure the medication is safe to use.

Interestingly, we have heard some say that the Implementation of Track & Trace as part of the Drug Supply Chain Security Act (DSCSA) is all that is needed to address temperature control in mail-order. We respectfully disagree.

Track & Trace is primarily designed for the purpose of limiting and preventing diversion of medication. There is no temperature control requirement related to Track & Trace, nor does the 2D barcode associated with Track & Trace measure temperature variances, or provide a method by which the patient can determine whether a temperature variance has occurred.

**Shipment to pharmacies**

Virginia law takes the issue of temperature control very seriously and outlines strict temperature control requirements for the wholesale distributors, manufacturers, warehouses and pharmacies that store and maintain prescription drugs.

So it remains puzzling that during the last mile of delivery, when the medication is most vulnerable, the law is virtually silent regarding the need for temperature control and/or a mechanism by which the patient can determine if degradation of the medication may have occurred.

Under Virginia Administrative Code 18VAC110-50-10 et seq. wholesale distributors, manufacturers and warehouses that receive, store and transport prescription drugs are required to provide, among other things, adequate temperature conditions. Additionally, these regulated entities, upon receipt of drugs, are required to review the integrity of the drugs, taking into account "the total facts and circumstances surrounding the transactions and the wholesale distributors, nonresident wholesale distributor or third-party logistics provider involved."

Additionally, if a prescription drug is stored before it is shipped to the pharmacy, under 18VAC110-50-50, the drug must be stored at appropriate temperatures and under appropriate conditions in accordance with the requirements of USP-NF or the drug's labeling instructions. Further, the regulation requires that temperature/humidity recordings or logs are utilized to ensure the proper storage of the medications.

So seriously does the Board take the issue of temperature control that, as already noted above, 18 VAC 110-20-10 et seq. imposes strict requirements on pharmacies storing or maintaining prescription drugs, including daily monitoring of refrigerator or freezer storage, as well as compliance with USP-NF.

It is only in the last mile of delivery that Virginia law is silent regarding temperature control mechanisms—and it is this situation that has left patients feeling unsafe, trying to guess whether the medication left on their front porch while they were at work, is safe to take or whether it has been exposed to a degrading heat or freeze event.

**Conclusion**

Virginia's patients need assurance that, regardless of the method in which they receive their medication, whether by mail-order or hand-delivery, the medication is safe and has been in a temperature controlled environment up until the moment the medication is received by the patient.

Giving patients, at a minimum, a method by which to determine whether their medication may have been compromised by a temperature variance will create more uniformity between mail-order and local

pharmacies and will help give patients the information they need to make informed decisions about their own health.

We ask the Board to consider a requirement that all mail-order medication shipped to Virginia patients include a method that easily allows the patient to determine if their medication has been subjected to a temperature variance.

Thank you for your time and consideration of this request. We look forward to working with you on this important matter.

Sincerely,

Michele Satterlund
McGuireWoods Consulting

cc: Jody Allen, Board of Pharmacy
Ryan Logan, Board of Pharmacy
Ellen Shinaberry, Board of Pharmacy
Sheila Elliott, Board of Pharmacy
Melvin Boone, Board of Pharmacy
Michael Thomas, McGuireWoods Consulting
Mike Rush, Temptime Corp.

decided it will not require practical experience in two practice settings. There was also some concern expressed with the availability of ASHP-accredited pharmacy technician training programs. Information from PTCB indicating an increase in the number of training programs was provided in the agenda packet.

**MOTION:**

**The Committee voted unanimously to recommend to the full board that it adopt a legislative proposal requiring Pharmacy Technician Certification Board (PTCB) certification for initial pharmacy technician registration with a delayed effective date of July 1, 2018. (motion by Warriner, second by Boone)**

- Consider 2017 Legislative Proposal for Requiring Temperature Monitoring Devices

At the March 2016 full board meeting, Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider a legislative proposal requiring temperature sensitive medications shipped via mail to be accompanied with a device to monitor temperature during shipping. There was discussion regarding USP requirements which currently requires those shipping drugs to do so in an appropriate manner to ensure the drugs are stored at appropriate temperatures. Ms. Juran also stated that she was informed that the Georgia bill, HB132, referenced in the agenda packet was amended prior to Governor's signature and no longer requires shipments of drugs to include a temperature monitoring device.

**MOTION:**

**The Committee voted unanimously to recommend to the full board that it take no action at this time on a legislative proposal requiring shipment of drugs to include a temperature monitoring device. (motion by Shinaberry, second by Boone)**

- Consider 2017 Legislative Proposal for Addressing Compounding Best Practices

Ms. Juran highlighted certain best practices in Pew Charitable Trust's report summarizing Best Practices for State Oversight of Drug Compounding that it may wish to consider requiring in a legislative proposal. There was discussion regarding adverse event reporting for compounded drugs and ability for the Board to seize or quarantine a compounded product if there is a suspected cause for patient harm. Ms. Warriner expressed concern for the board possibly incurring costs associated with storing and possibly destroying seized drugs. She also concurred with the public comment provided that the board should not require adverse event reporting of compounded drugs without requiring adverse event reporting of all drugs. Ms. Shinaberry requested that Ms. Juran and Mr. Johnson comment on the best practice of inspecting sterile compounding pharmacies annually. Ms. Juran stated that current staffing levels would not allow sterile compounding pharmacies to be inspected annually if inspectors continue to inspect all non-compounding pharmacies every two years. She indicated they will continue to monitor inspection frequencies and may consider moving to a risk-based inspection schedule. The Board also discussed its current authority to embargo a drug product and its experience in requiring a recall through issuance of consent orders.

**(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

# Virginia Board of Pharmacy

## COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

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

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection. USP Chapter 800 describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. USP first published Chapter 800 in 2014. It was published as an official standard in February 2016 with a delayed implementation date of July 1, 2018. The Board expects those performing sterile and non-sterile compounding to comply with USP Chapter 800 as of July 1, 2018.

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

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

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

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

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

*Originally adopted: June 8, 2004*
*Revised: December 1, 2015, September 26, 2017*

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

Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.

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

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

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

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

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

5. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***

No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

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

   Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

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

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

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

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

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

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

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

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

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

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

- high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
- in multiple-dose vials (MDVs) for administration to multiple patients or
- CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing

process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Yes.

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

Yes.

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

USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations for the lungs, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

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

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

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

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

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at

https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

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

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

***39. May a microbiological method alternative to compendial methods be used?***

Regarding sterility testing, USP Chapter <797> states, "The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible." Additionally, USP General Chapter <1223> "provides guidance on the selection, evaluation, and use of microbiological methods as alternatives to compendial methods. To properly implement alternative methods, one must consider a number of important issues before selecting the analytical technology and qualifying that method with the actual product. These issues include, but are not limited to, identification of suitable alternative methodology, development of user specifications for equipment selection, demonstration of the applicability of the method as a replacement for a standard compendial method, and qualification of the method in the laboratory…..*General Notices and Requirements* in the *USP* states, "Alternative methods and/or procedures may be used if they provide advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability to automation or computerized data reduction, or in other special circumstances." General Chapter <1223> also makes reference to 21 CFR Part 211.194 stating, "This subsection of the regulations also recognizes the legal basis of *USP* and the *National Formulary (NF)* standards and makes it clear that it is the responsibility of the user to validate methods or procedures that differ from those standardized in the compendia." Refer to *USP* for additional guidance.

***40. What are the hazardous drugs (HD) that USP Chapter <800> oversees?***

Refer to the most current National Institute for Occupational Safety and Health (NIOSH) list at www.cdc.gov. Note: Chapter <800> defines HDs are those on the NIOSH list, not the EPA hazardous materials list. Some drugs on the Environmental Protection Agency (EPA) list may not be on the NIOSH list, e.g., epinephrine.

***41. In general, how are drugs grouped within the NIOSH list?***

Hazardous drugs are categorized into three tables:

- Antineoplastic drugs, e.g., cisplatin, methotrexate
- Non-antineoplastic drugs, e.g., carbamazepine, estrogen/progesterone combinations

- Non-antineoplastic drugs that have adverse reproductive effects, e.g., temazepam, warfarin

***42. What drugs MUST comply with all USP Chapter <800> containment requirements?***

Drugs on the NIOSH list that must follow the requirements in this chapter include:

- Any HD active pharmaceutical ingredient (API) on any of the three tables, and
- Any antineoplastic requiring manipulation other than counting or repackaging.

***43. What drugs do NOT have to comply with all the USP Chapter <800> containment requirements?***

Drugs on the NIOSH list that do not have to follow all the containment requirements of this chapter if an assessment of risk is performed and implemented include:

- Final dosage forms of compounded HD preparations and conventionally manufactured HD products, including antineoplastic dosage forms, that do not require any further manipulation other than counting or repackaging (unless required by the manufacturer)

***44. How should a pharmacist determine how to comply with 800?***

Pharmacists should ask themselves the following questions, at a minimum:

- What drugs do I receive, store, dispense that are deemed hazardous pursuant to the NIOSH list?
- Must those drugs comply with all containment requirements or do some qualify for performing an assessment of risk?
- What changes will I need to make to my facility in order to comply with Chapter <800>?
- What personnel training is needed to meet compliance?
- What cleaning processes must be implemented or changed to meet compliance?
- What activities do I perform with these hazardous drugs, e.g., compounding, administration, etc.?

***45. If it is determined that the pharmacy stocks HDs, what options exist for the pharmacy?***

The pharmacy may treat all dosage forms of all HDs the same and follow all containment requirements in Chapter <800> or it may perform an assessment of risk to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API.

***46. What hazardous drugs may be considered during an assessment of risk?***

- Antineoplastics that only need to be counted or packaged
- Non-antineoplastics
- Reproductive-only hazards

***47. What should be considered, at a minimum, during an assessment of risk?***

- Type of HD, dosage form, risk of exposure, packaging, manipulation to be performed
- Alternative containment strategies and/or work practices should be documented
- The assessment of risk shall be reviewed every 12 months and documented.

***48. What minimal questions and/or information will an inspector for the Board of Pharmacy be asking during an inspection? Note: Enforcement of Chapter <800> will not begin until after the July 1, 2018 effective date of the chapter.***

- Does the pharmacy perform sterile or non-sterile compounding?
- Does the pharmacy stock HDs? The list of HDs the pharmacy stocks must be provided for inspector review.
- Are all HDs contained in a manner consistent with USP Chapter <800> or was an assessment of risk performed to identify and use alternative containment strategies and/or work practices for specific dosage forms of HDs that are not antineoplastic agents or not API. The assessment of risk must be provided for inspector review.
- Who is the 'designated person' for the pharmacy who is responsible for the continuing to evaluate the fundamental practices and precautions for handling HDs?
- Documentation of required training.
- Appropriate personnel equipment.
- Appropriate engineering controls.
- Standard operating procedures for safe handling of HDs for all situations in which the HDs are used throughout the facility.

***49.*** What does USP Chapter <800> list as the general engineering control requirements for performing non-sterile HD compounding?

**Table 2. Engineering Controls for Nonsterile HD Compounding**

| Containment Primary Engineering Control (C-PEC) | Containment Secondary Engineering Control (C-SEC) |
|---|---|
| • Externally vented (preferred) or redundant-HEPA filtered in series<br>• Examples: CVE, Class I or II BSC, CACI | • Externally vented<br>• 12 ACPH<br>• Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas<br>• Fixed walls |

***50. What does USP Chapter <800> list as the general engineering control requirements for performing sterile HD compounding?***

**Table 3. Engineering Controls for Sterile HD Compounding**

| Configuration | C-PEC | C-SEC | Maximum BUD |
|---|---|---|---|
| ISO Class 7 buffer room with an ISO Class 7 ante-room | • Externally vented<br>• Examples: Class II BSC or CACI | • Externally vented<br>• 30 ACPH<br>• Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas | As described in ‹797› |
| Unclassified C-SCA | • Externally vented<br>• Examples: Class II BSC or CACI | • Externally vented<br>• 12 ACPH<br>• Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas | As described in ‹797› for CSPs prepared in a segregated compounding area |

***51. Where may a list of recommended personal protective equipment by type of drug formulation and engineering controls for working with HDs in a healthcare setting be found?***

Table 5 of the NIOSH list.

For more information regarding USP Chapter <800>, an extensive list of frequently asked questions published by USP may be accessed at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings.

Sept 7, 2017

Dear Members of the Virginia Board of Pharmacy Ad Hoc Committee:

We appreciate the opportunity to provide written comment regarding the committee's discussion of USP 800 implementation. It goes without saying that implementation of USP 800 standards in all settings that use hazardous substances is a huge undertaking! Over the past year there has been, and continues to be, more and more discussion about this implementation, its challenges and validities. We appreciate the Board considering all facets of this major change to practice sites across the state. At this point in time, we are not sure what items are on the agenda for the committee to discuss, but we were hoping to bring up the following concerns.

- **Decreased patient access to medications** – Many of our colleagues are expressing concern that they will not be able to continue to provide medications that contain hazardous substances because they cannot afford the required facility changes. As an example, approximately 50% of our business will be considered Hazardous once USP 800 goes into effect. Across the state that adds up to a lot of patients looking for a place to fill a lot of prescriptions.
- **Expenses cannot be absorbed in the normal course of business** – Compliance with USP 800 will drive prices up, potentially causing patients to abandon needed therapies. As an example, our remodel pricing is being quoted at over $400,000 and we're one small pharmacy. We cannot imagine what the larger hospitals and clinics are facing.
- **Employee and patient safety is always a top priority** – We already comply with NIOSH/OSHA guidelines to ensure our employees are not unduly exposed to hazardous substances. Additionally, there have been questions raised as to the science behind the USP guidelines and whether they would actually lead to reduced exposure and/or improved worker safety.
- **The status of adoption of USP 800 by other states is changing** – Some states are only partially implementing USP 800 or pushing the compliance date back to allow more time for pharmacies to make the necessary changes or further determine if these standards are necessary. See the attached NASPA USP 800 state chart.
- **Vendors may experience shortages and delays** – Because all facilities across the country need to be compliant on the same day, we are already hearing of shortages of supplies and delays in services related to USP 800 compliance.
- **Inspections standards not yet published** – There are different interpretations out there for meeting USP 800 standards. Before we can invest this much money we really need to know the Board's inspection standards as they relate to USP 800.

www.compoundingcenter.com

36-C Catoctin Circle, SE
Leesburg, VA 20175
(703) 779-3301

We appreciate the committee's consideration of our concerns and plan to be present at the meeting on September 18th to assist in any way we can.

Thank you,

Cheri Garvin, RPh, Jay Gill, PharmD, and Alexander Pytlarz, PharmD

| State | USP 800 Adopted | Notes |
|---|---|---|
| Alabama | No | Proposing regulations to require compliance with all current requirements of USP. |
| Alaska | No | No discussions, so far. BOP plans to make changes to compounding regulations in the near future. USP 800 may be discussed at the time. No specific timeframe given as to when regulation changes will be made. |
| Arizona | Yes | Requires that pharmacies follow USP compendium; therefore, USP 800 is automatically adopted by reference. |
| Arkansas | No | Will be discussed at September BOP mtg. |
| California | Yes | |
| Colorado | No | |
| Connecticut | Yes | |
| Delaware | No | Request made by one state department to have added to agenda for August BOP meeting. |
| District of Columbia | | |
| Florida | No | |
| Georgia | No | Under review. No timetable for action. |
| Hawaii | No | No plans at this time to adopt. |
| Idaho | No | Group of national pharmacy associations (APhA, NCPA, NACDS) asked BOP not to act until 2021. BOP indicated it has no plans to pursue addt'l rule changes related to USP 800 in the near future. |
| Illinois | No | BOP was asked for 5-year stay. |
| Indiana | No | It will be discussed in the coming months. |
| Iowa | Yes | |
| Kansas | No | BOP just recently acquired legislative authority to regulate compounding. BOP is currently in the process of promulgating rules and regulations with USP 795 & 797. Will take up USP 800 in early 2018. |

*Compiled by NASPA – current as of 8/9/2017. Support your state pharmacy association!*

| | | |
|---|---|---|
| Kentucky | No | BOP is assembling a task force to review. Believes there will be some form of USP 800 coming soon. |
| Louisiana | No | USP 800 is on the BOP's Aug. 25 meeting agenda for discussion. The board's general operating position is that all of the USP chapters numbered below 1000 are enforceable standards, and pharmacies are expected to comply with those standards, even though they may not be included formally in regulations (USP 795, 797 were adopted). |
| Maine | No | Will be discussed; but no plans for rulemaking at this time. |
| Maryland | No | Currently proposing legislation for compliance with all USP standards. |
| Massachusetts | Yes | State law requires all pharmacies to adhere to USP; therefore, it's adopted by reference. BOP in process of drafting addt'l hazardous compounding regs. Pharmacies need to comply with USP 800 by July 1, 2018 deadline. |
| Michigan | No | |
| Minnesota | No (though, it's enforceable in Minnesota; see notes) | BOP has not officially adopted USP 800 in Minnesota Rules Chapter 6800; however, the BOP considers USP to be enforceable even though it has not formally adopted. |
| Mississippi | No | BOP is discussing. |
| Missouri | No | BOP is watching. No discussion planned. |
| Montana | No | Will eventually adopt into pharmacy rules, but waiting to see what other states are doing. |
| Nebraska | No | BOP is discussing. |
| Nevada | No | Board discussed at its July meeting and directed staff to start the rulemaking process for changes for USB 800 by scheduling a workshop with the board. First workshop will be at the board's September meeting. |
| New Hampshire | No | No discussions planned at this time. |

*Compiled by NASPA – current as of 8/9/2017. Support your state pharmacy association!*

| | | |
|---|---|---|
| New Jersey | No | BOP is revising some regulations. There will be reference to USP 800, though it's not clear if the board will adopt it in total. More information may be available in the fall. |
| New Mexico | Yes | USP is the official compendium for New Mexico; therefore, USP 800 is automatically adopted by reference. |
| New York | No | Not planned for discussion at next board meeting. May be discussed sometime. |
| North Carolina | Yes | By reference. |
| North Dakota | No | Informal discussions have taken place. BOP exec indicated there hasn't been time to officially to discuss at BOP mtgs. |
| Ohio | No | BOP was asked to delay by national associations (APhA, NCPA, NACDS). |
| Oklahoma | No | Task force reviewing. Possibly in 2018 may propose through rulemaking. |
| Oregon | No | BOP is having issue in deciding whether USP 800 is OSHA, pharmacy, or both. There will be further discussion. May be several months before anything is finalized. Compounding rules are scheduled for rewriting in the fall. |
| Pennsylvania | No | Has not finalized regulations regarding sterile compounding. |
| Rhode Island | Yes | Will be referenced in upcoming regulation updates. |
| South Carolina | No | No immediate plans to discuss. |
| South Dakota | Yes | Inspectors are becoming educated to the standards and helping with IV room rebuilds, etc., in order to be compliant. |
| Tennessee | Yes | Any facility that compounds sterile products shall comply with applicable USP standards. |
| Texas | No | BOP formed a task force to make recommendations. Report is scheduled for August 1 BOP mtg. |
| Utah | No | Compounding task force is reviewing the standard. |
| Vermont | No | |

*Compiled by NASPA – current as of 8/9/2017. Support your state pharmacy association!*

| | | |
|---|---|---|
| Virginia | Yes | Inspectors are getting educated on the standards and will be helping to educate pharmacists on the requirements. |
| Washington | Yes | By reference. Must follow USP standards. PQAC instructed staff to begin work on the intersection and coordination of USP 800 with the state's labor & industry laws on hazardous materials. Commission is considering a complete rewrite of all rules, which will be discussed Sept. 13-15 and will include how to include USP 800. |
| West Virginia | Yes | Board inspector said they won't be enforced until 2021. |
| Wisconsin | No | |
| Wyoming | No | National pharmacy associations (APhA, NCPA, NACDS) asked BOP to delay rulemaking. |

*Compiled by NASPA – current as of 8/9/2017. Support your state pharmacy association!*

## CHAPTER 114

*An Act to require the Board of Pharmacy to develop guidelines for the provision of counseling and information regarding disposal of unused drugs.*

[H 2046]

Approved February 21, 2017

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

**1.** *§ 1. That the Board of Pharmacy shall develop guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs, including information about pharmacy drug disposal programs in which the pharmacy participates pursuant to § 54.1-3411.2, by pharmacists to patients for whom a prescription is dispensed.*

# VaAware (http://vaaware.com/)

## Addiction, prevention & recovery resources

MENU

### Disposal

**Drug Take-Back Programs** are the safest method for disposing of prescription drugs because they are organized and closely monitored by local, state, and federal government agencies. These agencies ensure and oversee the proper disposal of the drugs in accordance with federal law. Check with your pharmacist and local law enforcement agency for more information about drug-take back days and locations. Here are two drug disposal locator tools:

AwareRx (https://nabp.pharmacy/initiatives/awarxe/drug-disposal-locator/)

DEA Diversion (http://www.deadiversion.usdoj.gov/drug_disposal/takeback/)

**Certain Local Pharmacies** are authorized to collect drugs for destruction, and the Board of Pharmacy maintains a list (http://www.dhp.virginia.gov/Pharmacy/destructionsites.asp) of those authorized collectors, and the DEA has a locator (https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1) of public disposal locations.

**Home Disposal** has risks of diversion and environmental contamination, but when completed correctly is a viable option if a take back program is not available.

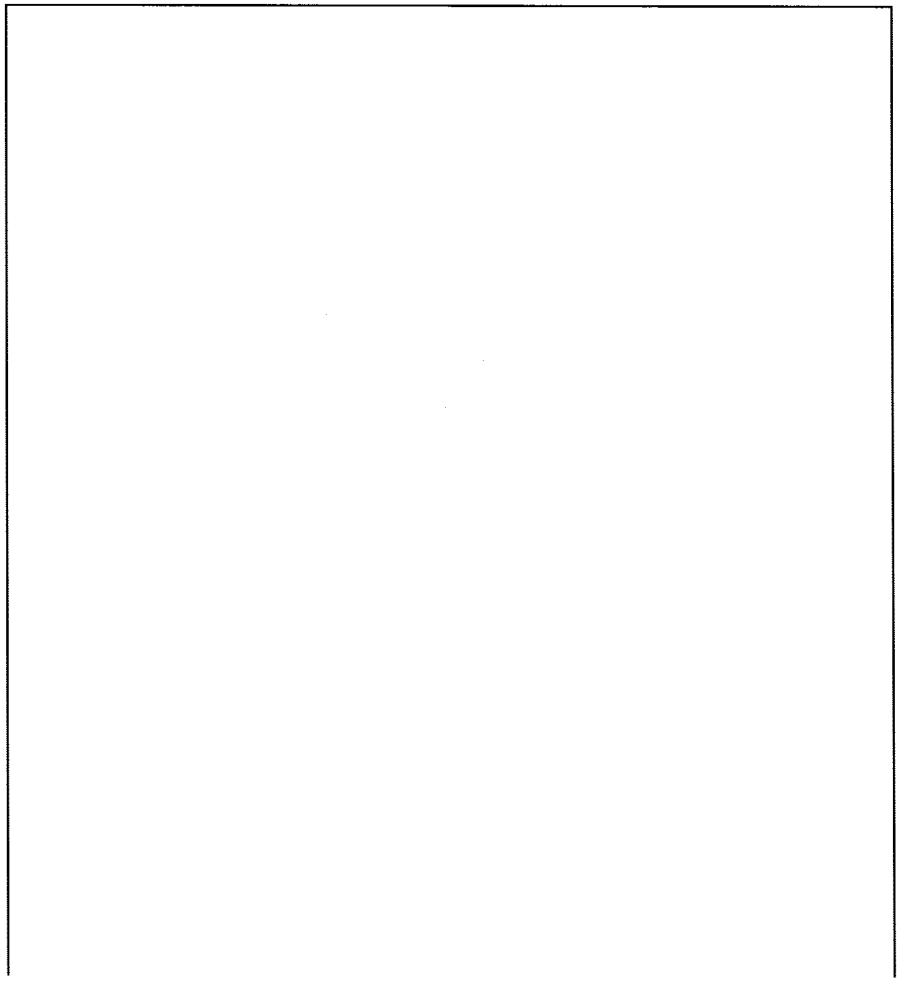
- **Step 1**– Remove medications from their original containers. If the medication is solid, crush it or add water to dissolve it and then mix the medication with an undesirable substance, such as kitty litter or coffee grounds. This makes the mixture unattractive to children and pets and unrecognizable to potential abusers who may go through your trash.
- **Step 2**– Place the mixture in a container with a lid or in a sealable baggie to prevent the medication from leaking, and throw it into the trash.
- **Step 3**- When discarding the original containers, scratch out or remove identifiers on the bottle and/or packaging. Remember: DO NOT dispose of medications in the toilet or sink, unless specifically instructed to on the label. DO NOT give medicine to friends or family. This is not only potentially illegal, but a drug that works for you could be dangerous for someone else.

For more information, check out the FDA's Disposal of Unused Medicines: What You Should Know (http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicir

A note on **Environmental Contamination-** Many people believe that flushing or simply throwing away drugs is the best way to dispose of medications; however, if not disposed of properly, the drugs can contaminate the ground and waterways. Wastewater treatment plants are not designed to remove or process many compounds found in medications. Instead, when flushed or put in a landfill, the drugs are discharged into our surface and ground water. Pharmaceutical contaminants in water have been shown to cause serious harm to fish and wildlife living in and near rivers and lakes. Humans can also be exposed to these chemicals when they drink water drawn from contaminated bodies of water or eat wild game or fish.

Learn More

- The Virginia Board of Pharmacy offers a comprehensive list of authorized collectors (http://www.dhp.virginia.gov/Pharmacy/destructionsites.asp) of drugs for safe destruction.
- The AwareRX Pharmacy (http://www.awarerx.pharmacy/) offers a wealth of resources on the proper use, storage and disposal of prescription drugs.
- Additionally, the U.S. Food and Drug Administration details best practices (http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm) for safe disposal of unused medications.
- Learn more about proper storage of prescription drugs on the homepage of Safeguard My Meds (http://www.safeguardmymeds.org/how-to-safeguard-your-prescription-meds/).
- The National Council on Patient Information and Education's "Tips on Safe Storage and Disposal of Your Prescription Medicines" give specific recommendations for the safe storage and disposal of prescription drugs. Click through the document below to learn more.




(http://vaaware.com/storage/disposal/)

### Useful Links

- Governor's Task Force On Prescription Drug And Heroin Abuse (https://www.dhp.virginia.gov/taskforce/)
- CDC Information on Opioids (http://www.cdc.gov/drugoverdose/index.html)
- US HHS's Law Enforcement Responses to Opioids (http://www.hhs.gov/opioids/law-enforcement-resources/index.html)

### Resources

- Facts (http://vaaware.com/storage/facts/)
- Storage (http://vaaware.com/storage/storage/)
- Disposal (http://vaaware.com/storage/disposal/)
- Drug Takeback Information (http://vaaware.com/storage/drug-takeback-information/)
- Where to Seek Treatment (http://drugfreeva.org/)

### News Feed

- A New Direction on Drugs (http://A%20New%20Direction%20on%20Drugs)
- Public wants more government action against opioid abuse (http://Public%20wants%20more%20government%20action%20against%20opioid%20abuse)
- Many addicts going without meds that curb opioid abuse
- Authorities in Va. debate how to treat addictions (http://www.richmond.com/news/article_8fb88c61-f117-569a-9614-32681f5277da.html)
- Addicted to a Treatment for Addiction (http://www.nytimes.com/2016/05/29/opinion/sunday/addicted-to-a-treatment-for-addiction.html?_r=0)
- Long-Acting Opioid Treatment Could Be Available In A Month (http://www.npr.org/sections/health-shots/2016/05/27/479755813/long-acting-opioid-treatment-could-be-available-in-a-month)
- House Passes Bills to Combat Opioid Abuse in U.S. (http://www.wsj.com/articles/house-passes-bills-to-combat-opioid-abuse-in-u-s-1463090994)

VaAware | Addiction, prevention & recovery resources

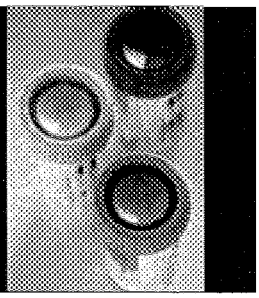
VAAWARE

(http://vaaware.com)

Email us at info@vaaware.com (mailto:matt.treacy@dhp.virginia.gov)

# Tips on Safe Storage and Disposal of Your Prescription Medicines

National Council on Patient Information and Education



**Where do you keep your medicines?** Are they in different places—with some in the medicine cabinet, some in the kitchen, and some in the bedroom or elsewhere? As a parent, grandparent, or family member, it's important that you organize and keep track of your medicines.

After all, you will want to know where a particular medicine is when you or someone else needs to find it. And you will want to keep your medicines secure so that a child, or a teenager, or even a stranger, does not get into them. That way, you can help prevent an accidental injury, as well as do your part to stop the possible abuse of prescription medicines.

The first step in getting organized is to take a look at all the medicines you have. You should try to do this type of inventory every six months, or at least once a year.

Start by checking the expiration date on the bottle—you don't want to take any chances with a medicine that no longer works the way it's supposed to. Also, look for medicines that are discolored, dried out, crumbling, or show other signs that they are past their prime. Check the expiration date for eye drops and eardrops, too. They may no longer be effective and, worse, could be a breeding ground for bacteria or fungus.

In addition, look for leftover prescription medicines from a previous illness or condition. You will want to discard these since you should never try to treat yourself (or anyone else) with a prescription medicine. Your symptoms might seem similar to what you had before, but the cause could be different or the medicine may not be the right one this time around.

## Proper Disposal of Prescription Medicines

Federal Guidelines encourage consumers to:

- Take unused, unneeded, or expired prescription drugs out of their original containers and throw them in the trash.
- Mixing prescription drugs with an undesirable substance, such as used coffee grounds or kitty litter, and putting them in impermeable, non-descript containers, such as empty cans or sealable bags, will further ensure the drugs are not diverted.
- Flush prescription medications down the toilet only if the label or accompanying patient information specifically instructs doing so.
- Take advantage of community pharmaceutical take-back programs or community solid waste programs. Where these programs exist, they are a good way to dispose of unused pharmaceuticals.

## Find a cool, dry area

Now that you've identified the medicines you want to keep, the next step is to find a safe place to keep them.

You'll want to store your medicine in an area that is convenient, but is also cool and dry – since heat and humidity can damage medicines. That's why a bathroom is not a good place to keep your medicines unless you are able to keep the room well ventilated. (However, the bathroom medicine chest is an ideal place to keep items such as bandages, tweezers, gauze, cotton balls, scissors, and other products that aren't affected by heat or humidity.)

## Lock up your medicines

If there are children around, you might want to find an area where you can lock up your medicines. A cabinet or a drawer with a lock on it would work.

It's also an excellent idea to lock up any controlled substances that have been prescribed for you. These include medicines such as hydromorphone (Dilaudid®), oxycodone (OxyContin® and Percocet®), hydrocodone (Vicodin®), and alprazolam (Xanax®).*

The theft and abuse of prescription medicines is a serious problem. You play a big role in keeping these powerful medicines out of the hands of those who shouldn't have them. Since it is dangerous, as well as illegal, for anyone but you to use a controlled substance prescribed for you, a locked storage area can help keep a stranger or someone else from gaining access to them.

## Be smart...and safe

Here are some other suggestions that can help you be smarter about storing and using your medicines.

- Keep your medicines separate from those of your spouse or other family members (for instance, on a different shelf or at least on a separate side of a shelf). This will make it less likely that you take the wrong ones by mistake.
- You may find it helpful to have a countertop or tabletop near where you keep your medicine so you can open the bottle with it resting on the flat surface. In case you drop your pill, it will land on the tabletop and not be lost down the drain or on the floor. (But be sure not to leave your medicine bottles out on the counter afterwards.)
- Good lighting near where you store your medicines will help you make sure you are taking the right medicine. Never take medicines in the dark.
- Keep the medicine in the bottle it came in. The amber color protects the medicine from light. You will also have the information right there about what the medicine is and how often to take it. The label will also have the phone number of the pharmacy so you can call when it is time for a refill.
- Never mix different medicines in the same bottle. You might end up taking the wrong one by mistake. It is also possible that some of one medicine could rub off on another and affect how well it works.
- Keep the lids on your pill bottles tightly closed. A cap can't be childproof if it's not fastened correctly.
- If there is cotton in the pill bottle when you first open it, remove the cotton and throw it away. The cotton can absorb moisture and affect the medicine that is inside.

*Dilaudid is a registered trademark of Abbott Laboratories. OxyContin is a registered trademark of Purdue Pharma, L.P. Percocet is a registered trademark of Endo Pharmaceuticals. Vicodin is a registered trademark of Abbott Laboratories. Xanax is a registered trademark of Pfizer Inc.

EDUCATE *before* YOU MEDICATE

The NCPIE Coalition–working together to promote safe medicine use

**National Council on Patient Information and Education**
200-A Monroe Street, Suite 212
Rockville, MD 20850
Telephone: (301) 340-3940
Fax: (301) 390-3944
Email: ncpie@ncpie.info

www.mustforseniors.org
www.talkaboutrx.org
www.bemedwise.org

This flyer contains general information and is not intended to take the place of any advice given by your healthcare professional(s). They know about your specific medical conditions and medicines.

**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 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 for placement of chemicals in Schedule I. Action to be filed after October 4, 2017. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

**Project 5254 - none**

## BOARD OF PHARMACY

## Scheduling of chemicals 9-17

### 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. 1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-1-pentanone (other names: N,N-Dimethylpentylone, Dipentylone);

2. 4-chloro-alpha-Pyrrolidinovalerophenone (other name: 4-chloro-alpha-PVP);

3. 4-methyl-alpha-Pyrrolidinohexiophenone (other name: MPHP);

4. 4-fluoro-alpha-Pyrrolidinoheptiophenone (other name: 4-fluoro-PV8);

5. 1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)octan-1-one (other name: 4-methoxy-PV9);

6. 4-allyloxy-3,5-dimethoxyphenethylamine (other name: Allylescaline);

7. 4-methyl-alpha-ethylaminopentiophenone; and

8. N-(4-fluorophenyl)-2-methyl-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: para-fluoroisobutyryl fentanyl).

The placement of drugs listed in this subsection shall remain in effect until August 22, 2018, 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. 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD), its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation;

2. 6-allyl-6-nor-lysergic acid diethylamide (other name: AL-LAD), its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation;

3. Synthetic opioids:

a. N-[1-[2-hydroxy-2-(2-thienyl)ethyl]-4-piperidinyl]-N-phenylpropanamide (other name: beta-hydroxythiofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation;

b. N-(2-fluorophenyl)-N-[1-(2-phenylethyl)-4-piperidinyl]-propanamide (other names: 2-fluorofentanyl, ortho-fluorofentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation; and

c. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-propenamide (other name: Acryl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation;

4. Cannabimimetic agents:

a. 1-pentyl-N-(phenylmethyl)-1H-indole-3-carboxamide (other name: SDB-006), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation; and

b. Quinolin-8-yl 1-(4-fluorobenzyl)-1H-indole-3-carboxylate (other name: FUB-PB-22), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation; and

5. Benzodiazepine: flubromazepam, its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until December 13, 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:

1.4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. Methyl N-[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]valinate (MMB-CHMICA ), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3.N-(1-phenethylpiperidin-4-yl)-N-phenyltetrahydrofuran-2-carboxamide (Tetrahydrofuran fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

The placement of drugs listed in this subsection shall remain in effect until February 18, 2019, unless enacted into law in the Drug Control Act.

D. 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. 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

2. 5-methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MIPT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. 5-methoxy-N-ethyl-N-isopropyltryptamine (5-MeO-EIPT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. 4-hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

5. (N-methyl aminopropyl)-2,3-dihydrobenzofuran (MAPDB), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

6. 3,4-tetramethylene-alpha-pyrrolidinovalerophenone (TH-PVP), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

7. 4-chloro-alpha-methylamino-valerophenone (4-chloropentedrone), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

8.2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (Methoxyacetyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

9. N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (Cyclopropyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

10.N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (5-fluoro-ADB-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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 action on Controlled Substance Registration for entities that distribute naloxone or for teleprescribing**

**Staff Note:**

Emergency regulations were required to meet the mandate of the statute; they became effective on 5/8/17. A NOIRA was published simultaneously with the emergency regulations to replace them with permanent regulations.

The comment on the NOIRA ended 6/28/17; there were no comments.

**Included in your package are copies of:**

Copy of the posting on the Virginia Regulatory Townhall

Proposed regulations which are identical to the emergency regulations currently in effect.

**Action:**

Motion to adopt the proposed regulations for controlled substances registration for certain entities

Virginia.gov Agencies | Governor


Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]**

**Action**: Controlled substances registration for nalozone and teleprescribing

Action 4789 / Stage 7890

## Emergency/NOIRA Stage

Edit Stage | Go to RIS Project | Request Emergency Extension

| Documents | | |
|---|---|---|
| Emergency Text | 3/30/2017 4:38 pm | Sync Text with RIS |
| Agency Statement | 3/29/2017 | Upload / Replace |
| Attorney General Certification | 4/7/2017 | |
| Governor's Approval Memo | 5/5/2017 | |
| Registrar Transmittal | 5/8/2017 | |

| Status | |
|---|---|
| **Public Hearing** | Will be held at the **proposed** stage |
| **Emergency Authority** | 2.2-4011 |
| **Exempt from APA** | No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process. |
| **Attorney General Review** | Submitted on 3/29/2017<br>Review Completed: 4/7/2017<br>Result: Certified |
| **DPB Review** | Submitted on 4/8/2017<br>Policy Analyst: Melanie West<br>Review Completed: 4/18/2017<br>*DPB's policy memo is "Governor's Confidential Working Papers"* |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 4/20/2017 |
| **Governor's Review** | Review Completed: 5/5/2017<br>Result: Approved |
| **Virginia Registrar** | Submitted on 5/8/2017 |

| | |
|---|---|
| | **The Virginia Register of Regulations**<br>Publication Date: 5/29/2017 **Volume: 33 Issue: 20** |
| **Comment Period** | Ended 6/28/2017<br>0 comments |
| **Effective Date** | 5/8/2017 |
| **Expiration Date** | 11/7/2018 |

| **Contact Information** | |
|---|---|
| **Name / Title:** | Caroline Juran, RPh / *Executive Director* |
| **Address:** | 9960 Mayland Drive<br>Suite 300<br>Richmond, VA 23233-1463 |
| **Email Address:** | **caroline.juran@dhp.virginia.gov** |
| **Telephone:** | (804)367-4456 FAX: (804)527-4472 TDD: ()- |

*This person is the primary contact for this chapter.*
14

**Project 5048 – Proposed Regulations**

## BOARD OF PHARMACY

### Controlled substances registration for nalozone and teleprescribing

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

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

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

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

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, ~~or~~ pharmacy technician for alternate delivery sites, a person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, or other person approved by the board who is authorized to administer the controlled substances.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

F. The board may issue a controlled substance registration to an entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedules II through VI controlled substances when such prescribing is in compliance with federal requirements for the practice of telemedicine and the patient is not in the physical presence of a practitioner registered with the U.S. Drug Enforcement Administration, provided:

1. There is a documented need for such registration, and issuance of the registration of the entity is consistent with the public interest;

2. The entity is under the general supervision of a licensed pharmacist or a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine; and

3. The application is signed by a person who will act as the responsible party for the entity for the purpose of compliance with provisions of this subsection. The responsible party shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.

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

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

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

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

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

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

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia; (ii) such other persons who have successfully completed a training program for repackaging of prescription drug orders in a CSB, BHA, or PACE site as authorized in § 54.1-3420.2 of the Code of Virginia; ~~or~~ (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation, or (iv) persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances

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

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

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

**18VAC110-20-710. Requirements for storage and security for controlled substances registrants.**

A. Drugs shall be stored under conditions which meet USP-NF specifications or manufacturers' suggested storage for each drug.

B. Any drug which has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.

C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedule II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs.

D. Drugs shall be maintained in a lockable cabinet, cart, device or other area which shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with 18VAC110-20-700 C.

E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area which has a security device for the detection of breaking which meets the following conditions:

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

2. The installation and device shall be based on accepted alarm industry standards.

3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.

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

5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.

6. An alarm system is not required for researchers, animal control officers, humane societies, alternate delivery sites as provided in 18VAC110-20-275, emergency medical services agencies stocking only intravenous fluids with no added drug, persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and to dispense naloxone for opioid overdose reversal, and teaching institutions possessing only Schedule VI drugs.

**18VAC110-20-735. Requirements for dispensing of naloxone by trained individuals.**

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal pursuant to subsection Y of § 54.1-3408 of the Code of Virginia shall maintain the following records:

1. The prescriber's standing order issued in accordance with subsection Y of § 54.1-3408 of the Code of Virginia authorizing the trained individual to dispense naloxone.

2. Invoices or other records showing receipts of naloxone shall be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible image of the document or in secured storage either on site or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer and the name of trained individual approved by the Department of Behavioral Health and Developmental Services.

4. Record of dispensing indicating the name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, and the name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

B. The naloxone shall be labeled with directions for use in accordance with the prescriber's standing order; date of dispensing; name of person receiving the drug; drug name and strength; and the name and the telephone number for the entity associated with the controlled substances registration.

C. The naloxone shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect them from adulteration.

D. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate shall ensure compliance with recall procedures as issued by the manufacturer, U.S. Food and Drug Administration, or board to ensure an affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

E. Except for a prescriber's standing order, which must be maintained on site for a period of not less than two years from the date of the last dispensing, records shall be filed chronologically and maintained for a period of not less than two years from the date of transaction.

**Agenda item: Revision of guidance document on dispensing of naloxone**

**Enclosed:**

An amended draft of Guidance Document 110-44

**Staff note:**

Amendments are necessary to reflect recent decisions by some hospitals to dispensed naloxone upon discharge from a hospital for patients with opioids prescriptions. Those patients would not have completed a. REVIVE! Training program, so must receive counseling on the use and purpose of naloxone within the hospital.

**Board action:**

Adoption of amendments to Guidance Document 110-44

# Virginia Board of Pharmacy

## Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities

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

1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
   **a)** Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling unless the pharmacist is able to verify successful completion of the REVIVE! training program. If the naloxone is dispensed upon discharge from a hospital or delivered by a pharmacy to an alternate delivery site, e.g., a local health department, and the recipient has not completed the REVIVE! training program, the aforementioned counseling shall be provided by a physician, nurse practitioner, physician assistant, nurse, or an approved trainer of the REVIVE! training program within the hospital or at the alternate delivery site.
   **b)** The pharmacist shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.

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

3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order issued to a specific individual, a pharmacist may dispense naloxone pursuant to a standing order. The standing order may be issued by an individual prescriber to a specific pharmacy or pharmacies, or the standing order may be issued by the Health Commissioner to all pharmacies located and permitted in Virginia. The standing order authorizes a pharmacist to dispense one or more of the specified naloxone formulations to any person seeking to obtain naloxone. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
   **a)** Name of pharmacy authorized to dispense naloxone pursuant to standing order if the standing order is issued by a prescriber for a particular pharmacy or pharmacies;
   **b)** Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration, to include quantity of drug and directions for administration;
   **c)** Prescriber's signature; and

**d)** Date of issuance.

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

| Intranasal | Auto-Injector | Intranasal |
|---|---|---|
| Naloxone 2mg/2ml prefilled syringe, # 2 syringes<br><br>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br><br>Mucosal Atomization Device (MAD) # 2<br>SIG: Use as directed for naloxone administration.<br><br>Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration. | Naloxone 2 mg<br>#1 twin pack<br><br>SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br><br>No kit is required. Product is commercially available. | Narcan Nasal Spray 4mg, #1 twin pack<br><br>SIG: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.<br><br>No kit is required. Product is commercially available. |

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

Pharmacies may obtain kits to have on-hand for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

**5) Labeling and Records:**

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation. A standing order issued by an individual prescriber or the Health Commissioner shall be maintained by the pharmacist for two years from the date of the last dispensing prior to expiration or discontinuation of the standing order.

## Protocol for Distributing to Law-Enforcement Officers, Firefighters, and Employees of the Department of Forensic Science, Office of the Chief Medical Examiner, and Department of General Services Division of Consolidated Laboratory Services

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to:

1. Designated employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, and employees of the Department of General Services Division of Consolidated Laboratory Services who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services; or

2. Designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department.

Training shall be conducted in accordance with policies and procedures of the law enforcement agency, fire department, Department of Forensic Science, Office of the Chief Medical Examiner, or the Department of General Services Division of Consolidated Laboratory Services.

**Resources:**

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials

**Agenda Item:** **Exempt Action – conforming definition**
**Revision to Guidance document: 110-35**

**Enclosed:**

Copy of Chapter 429 – E-prescribing for Schedule II drugs

Copy of 18VAC110-20-10 – Definitions.

Guidance document: 110-35 on Requirements for Prescriptions

**Staff note:**

The definition for electronic prescription in regulation in inconsistent with the definition in the Code as of July 1, 2017. It is also confusing because it implies that even electronic prescribing of Schedule VI drugs must comply with federal requirements, which is not the case.

**Board Actions:**

1) Amend 18VAC110-20-10 by exempt action to conform the regulation to the Code.
2) Revise Guidance document 110-35 on electronic prescribing

2017 SESSION

**CHAPTER 429**

*An Act to amend and reenact §§ **54.1-3401**, **54.1-3408.02**, and **54.1-3410** of the Code of Virginia, relating to prescriptions for controlled substances containing opiates; electronic prescription.*

[S 1230]

Approved March 13, 2017

Be it enacted by the General Assembly of Virginia:

1. That §§ **54.1-3401**, **54.1-3408.02**, and **54.1-3410** of the Code of Virginia are amended and reenacted as follows:

§ **54.1-3401**. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"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 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~~ *a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 C.F.R. Part 1300.*

"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 exemptions set forth in the federal Drug Supply Chain Security Act.

"Wholesale distributor" means any person 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.

§ **54.1-3408.02**. Transmission of prescriptions.

*A.* Consistent with federal law and in accordance with regulations promulgated by the Board, prescriptions may be transmitted to a pharmacy ~~by~~ *as an* electronic ~~transmission~~ *prescription* or by facsimile machine and shall be treated as valid original prescriptions.

*B. Any prescription for a controlled substance that contains an opiate shall be issued as an electronic prescription.*

§ **54.1-3410**. When pharmacist may sell and dispense drugs.

A. A pharmacist, acting in good faith, may sell and dispense drugs and devices to any person pursuant to a prescription of a prescriber as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;

2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the Board's regulations;

3. Whenever a pharmacist dispenses any drug listed within Schedule II on a prescription issued by a prescriber, he shall affix to the container in which such drug is dispensed, a label showing the prescription serial number or name of the drug; the date of initial filling; his name and address, or the name and address of the pharmacy; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the prescriber by whom the prescription was written, except for those drugs dispensed to a patient in a hospital pursuant to a chart order; and such directions as may be stated on the prescription.

B. A drug controlled by Schedules III through VI or a device controlled by Schedule VI shall be dispensed upon receipt of a written or oral prescription as follows:

1. If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

2. If the prescription is oral, the prescriber shall furnish the pharmacist with the same information as is required by law in the case of a written prescription for drugs and devices, except for the signature of the prescriber.

A pharmacist who dispenses a Schedule III through VI drug or device shall label the drug or device as required in subdivision A 3 of this section.

C. A drug controlled by Schedule VI may be refilled without authorization from the prescriber if, after reasonable effort has been made to contact him, the pharmacist ascertains that he is not available and the patient's health would be in imminent danger without the benefits of the drug. The refill shall be made in compliance with the provisions of § **54.1-3411**.

If the written or oral prescription is for a Schedule VI drug or device and does not contain the address or registry number of the prescriber, or the address of the patient, the pharmacist need not reduce such information to writing if such information is readily retrievable within the pharmacy.

D. Pursuant to authorization of the prescriber, an agent of the prescriber on his behalf may orally transmit a prescription for a drug classified in Schedules III through VI if, in such cases, the written record of the prescription required by this subsection specifies the full name of the agent of the prescriber transmitting the prescription.

*E. No pharmacist shall dispense a controlled substance that contains an opiate unless the prescription for such controlled substance is issued as an electronic prescription.*

2. That the provisions of the first enactment of this act shall become effective on July 1, 2020.

3. That the Secretary of Health and Human Resources shall convene a work group of interested stakeholders, including the Medical Society of Virginia, the Virginia Hospital and Healthcare Association, the Virginia Dental Association, the Virginia Association of Health Plans, and the Virginia Pharmacy Association to review actions necessary for the implementation of the provisions of this act and shall make an interim progress report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2017, and shall make a final report to such Chairmen by November 1, 2018. In addition, the work group shall evaluate hardships on prescribers, the inability of prescribers to comply with the deadline for electronic prescribing and make recommendations to the General Assembly for any extension or exemption processes relative to compliance or disruptions due to natural or manmade disasters or technology gaps, failures or interruptions of services.

Part I

General Provisions

**18VAC110-20-10. 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:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Authorized collector" means a narcotic treatment program, hospital, or clinic with an on-site pharmacy, or pharmacy that is authorized by the U.S. Drug Enforcement Administration to receive drugs from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent's property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility for the purpose of destruction.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs that is comprised of a series of containers for solid oral dosage forms and designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the U.S. Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist, regardless of whether the patient received the drug:

1. Variation from the prescriber's prescription drug order, including but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application and is transmitted to a pharmacy as an electronic data file; Schedule II through V prescriptions shall be transmitted in accordance with 21 CFR Part 1300 ~~and is transmitted to a pharmacy as an electronic data file~~.

"EMS" means emergency medical services.

"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.

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

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

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to

establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the United States Adopted Names (USAN) and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license that is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"On-hold prescription" means a valid prescription that is received and maintained at the pharmacy for initial dispensing on a future date.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed, or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container that meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), that is, in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy that is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children younger than five years of age to open to obtain a toxic

or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging that all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Ultimate user" means a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

Statutory Authority

§§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 1.1, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993;

# VIRGINIA BOARD OF PHARMACY

## GUIDANCE ON VIRGINIA PRESCRIPTION REQUIREMENTS

**Written Prescriptions:**

- Written prescriptions shall include the patient's first and last name. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.

- The prescription shall contain the prescriber's name, address, and telephone number, and DEA number if for a Schedule II-V prescriptions. Prescriber information shall be either preprinted on the blank, electronically printed, typed, stamped, or printed by hand in a legible manner. Interns and residents in a residency program may use the hospital DEA number and an assigned suffix.

- Prescriptions issued by physician assistants for drugs in Schedule II-V shall also include the name of their supervising physician. Note: The physician is not required to *co-sign* a physician assistant's prescription for a Schedule II-VI drug.

- Nurse practitioners who are authorized by a practice agreement to prescribe Schedule II-VI drugs are not required to include the prescriptive authority number issued to them by the Boards of Nursing and Medicine if their DEA registration number is included on the prescription. Nurse practitioners who are authorized by a practice agreement to only prescribe Schedule VI drugs must include the prescriptive authority number issued to them by the Boards of Nursing and Medicine.

- Written prescriptions shall be legibly written with ink or individually typed or printed.

- Written prescriptions may be prepared by an agent for the prescriber's signature, but shall be manually signed by the prescriber.

- Computer-generated prescriptions that are printed out shall be manually signed by the prescriber.

- Written prescriptions shall be dated with the date the prescription is written.

- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

- Prescriptions for Schedule VI drugs may be preprinted with the drug name, directions for use, quantity, but must still meet all other requirements of individually written prescriptions for patient name, signatures, issue date, and any other required information. Preprinted prescriptions may contain a list of drugs with a checkbox beside the drug name to be selected by the prescriber, but only one drug may be selected for each prescription.

- Schedule II prescriptions shall be written and may not be refilled.

- There is no longer a specific format required for written prescriptions. A pharmacist may substitute an Orange-Book rated "therapeutically equivalent drug product" for a brand name drug unless the prescriber prohibits substitution by indicating "brand medically necessary."

- A prescription blank may only contain one prescription. There are a few limited exceptions to this law such as multiple blanks for the Department of Corrections and chart orders for hospital, nursing home, home infusion, and hospice patients.

- A chart order may be filled by an outpatient (community/retail) pharmacy for outpatient use provided the following conditions are met:

    - The chart order was written for a patient while in a hospital or long term care facility.
    - The pharmacist has all information necessary to constitute a valid outpatient prescription.
    - The pharmacist in an outpatient setting must have direction, either written or obtained verbally, that the chart order is actually intended to be outpatient or discharge prescription orders, and not merely a listing drugs the patient was taking while an inpatient.
    - The orders include some direction related to quantity to be dispensed or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration.

**Requirements of the Virginia Department of Medical Assistance Services for written prescriptions for Medicaid and FAMIS fee-for-service patients:**

- Tamper-resistant prescriptions are required for all prescriptions used for Medicaid and FAMIS fee-for-service recipients. Tamper resistant pads are defined as having at least one feature in all three of the following categories:

    1) One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form,
    2) One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber, or
    3) One or more industry-recognized features designed to prevent the use of counterfeit prescription forms.

**Oral Prescriptions:**

- Oral prescriptions shall contain all the same information as written prescriptions except for the prescriber's signature, and shall be reduced to writing by the pharmacist receiving the prescription.

- The prescriber or his authorized agent may transmit the prescription. If transmitted by an authorized agent, the pharmacist shall record the full name of the agent. According to Virginia law, an authorized agent may only be an employee of the prescriber under his immediate and personal supervision, or if not an employee may only be someone who holds a license to administer drugs, such as a nurse, physician assistant, or another pharmacist. For Schedule II-V oral prescriptions, DEA may interpret the authority of an agent differently, as well as who can be an authorized agent.

**Faxed Prescriptions:**

- A faxed prescription that starts out as a written prescription and is placed onto a fax machine in the physician's office and sent via phone to a pharmacy's fax machine where a facsimile image is printed for the pharmacy records must meet all requirements for a written prescription, to include the manual signature of the prescriber.

- Computer-generated prescriptions that are faxed must be manually signed by the prescriber.

- Schedule III-VI prescriptions may be faxed to a pharmacy.

- Schedule II prescriptions (or chart orders) may **only** be faxed to a pharmacy for long term care facility patients, home infusion patients, and hospice patients.

- Pharmacies may not begin the dispensing process when a prescription is faxed directly from the patient, even if the patient brings in the hard copy when they come to pick up the medication. Prescriptions may only be faxed from the prescriber's practice location

**Electronically transmitted prescriptions:**

- An electronically transmitted prescription is one that is generated from the prescriber's office electronically, sent out as an electronic transmission, is normally routed through a switch to the appropriate pharmacy, and is received by the pharmacy in the form of an electronic transmission or is converted by the switch to a fax, and is printed out on the pharmacy's fax machine. "Electronic prescription" means a written prescription that is generated on an electronic application and transmitted to a pharmacy as an electronic data file. An electronically transmitted prescription does not have a manual signature, but would contain an electronic or digital signature of the prescriber that identifies him as the source of the message and indicates his approval of the information contained in the message. If the prescription is generated electronically, but then is printed out in the office and given to the patient, it is no longer an electronic prescription and must follow the guidelines of a written prescription to include bearing the prescriber's manual signature.

- Schedule II - VI prescriptions may ~~now~~ be transmitted electronically. ~~DEA has issued interim final rules, which take effect June 1, 2010, that will authorize the electronic transmission of Schedule II-V prescriptions. *Electronic prescriptions*~~ Schedule II-V prescriptions must meet all federal requirements including required security and authenticity features, as well as required recordkeeping for the prescriber and pharmacy.

- The application provider used by a prescriber or a pharmacy for electronic prescriptions of Schedules II-V drugs must be reviewed and certified by an approved certification body for compliance with DEA's standards. The application provider must provide a copy of this report to the pharmacy or prescriber using its services. A pharmacy or prescriber shall not dispense or issue an electronic prescription for Schedules II-V drugs until a report is received from the application provider indicating full compliance with DEA's standards. A pharmacy or prescriber may continue dispensing or issuing electronic prescriptions for Schedule VI drugs in compliance with Board regulations prior to receiving a report from the application provider regarding its status of compliance with federal law.

- Individual prescribers authorized to prescribe Schedules II-V drugs who choose to issue electronic prescriptions for Schedules II-V drugs shall first apply to certain federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their two-factor authentication credential or digital certificates.

- An electronic prescription for a Schedule VI drug may either directly populate the pharmacy's automated dispensing system or may be converted by the switch to a fax, and printed out on the pharmacy's fax machine. Federal law does not permit an electronic prescription for a Schedule II-V drug to be converted to the pharmacy's fax machine. It must directly populate the pharmacy's automated dispensing system in conformity with federal law.

- Please refer to the federal regulations for additional guidance.

Guidance document: 110-26 Adopted: September 29, 2015

# Virginia Board of Pharmacy

## Re-dispensing Drugs Previously Dispensed in Compliance Packaging

Subsection A, 2 of 54.1-3411.1 of the *Code of Virginia* states:

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

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

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

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

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

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

**Reference from Code of Virginia:**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

# Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

## Guidance for Industry

**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Drug Evaluation and Research (CDER)**

**January 2017**
**Compounding and Related Documents**

# Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities

## Guidance for Industry

*Additional copies are available from:*
*Office of Communications*
*Division of Drug Information, WO51, Room 2201*
*Center for Drug Evaluation and Research*
*Food and Drug Administration*
*10903 New Hampshire Ave., Silver Spring, MD 20993*
*Phone: 301-796-3400; Fax: 301-847-8714*
*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)**

**January 2017**
**Compounding and Related Documents**

*Contains Nonbinding Recommendations*

## TABLE OF CONTENTS

*Contains Nonbinding Recommendations*

# Guidance for Industry[1] Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities[2]

This guidance represents 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 the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance.

## I. INTRODUCTION AND SCOPE

This guidance sets forth the FDA's policy regarding repackaging by State-licensed pharmacies, Federal facilities, and facilities that register with FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act). This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), 582, and where specified, section 501(a)(2)(B) of the Act, when a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages human prescription drug products.

This guidance **does not address** the following:

- Biological products that are subject to licensure under section 351 of the Public Health Service (PHS) Act. The repackaging of biological products subject to licensure under section 351 is addressed in a separate guidance document.[3]
- Repackaging drug products for use in animals.
- Repackaging non-prescription drug products.
- Radiopharmaceuticals.[4]

---

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] *Outsourcing facility* refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the Federal Food, Drug, and Cosmetic Act.

[3] FDA has issued a draft guidance entitled, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. Once finalized, that guidance will represent FDA's thinking on this topic.

> All FDA guidances are available on the Agency's guidance website at http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234622.htm. FDA updates guidances regularly. To ensure that you have the most recent version, please check this web page.

[4] FDA has issued draft guidances entitled, *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Pharmacies and Federal Facilities* and *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities*. Once finalized, those guidances will represent FDA's thinking on that topic.

- Repackaging by entities that are not State-licensed pharmacies, Federal facilities, or outsourcing facilities (e.g., repackers registered with FDA under section 510 of the FD&C Act).
- Removing a drug product from the original container at the point of care (e.g., patient's bedside) for immediate administration to a single patient after receipt of a valid patient-specific prescription or order for that patient (e.g., drawing up a syringe to administer directly to the patient). FDA does not consider this to be "repackaging," for purposes of this guidance document.
- Upon receipt of a valid patient-specific prescription, a licensed pharmacy removing from one container the quantity of non-sterile drug products[5] (e.g., oral dosage forms) necessary to fill the prescription and placing it in a different container to dispense directly to the patient.
- Investigational new drugs being studied under an investigational new drug application. This guidance does not alter FDA's existing approach to regulating investigational new drugs.

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. Repackaging, Generally

FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.[6] Repackaging also includes the act of placing the contents of multiple containers (e.g., vials) of the same finished drug product into one container, as long as the container does not include other ingredients. If a drug is manipulated in any other way, including if the drug is reconstituted, diluted, mixed, or combined with another ingredient, that act is not considered repackaging.[7]

Repackaging is performed by a range of entities, including pharmacies and other facilities that specialize in repackaging drug products. FDA is aware that repackaging is done for a variety of

[5] For purposes of this guidance, a sterile drug is a drug that is intended for parenteral administration, an ophthalmic or oral inhalation drug in aqueous format, or a drug that is required to be sterile under Federal or State law.

[6] For example, if tablets are removed from a blister pack and placed into a different container, that would be repackaging. However, if the blister packs containing tablets are placed into a different container for later use (without opening the individual blister packs), that would not be repackaging.

[7] This guidance does not apply to the compounding of drug products. Compounding is addressed in other guidance documents. *See*, for example, the guidances *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* and *For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

reasons including: to meet the needs of specific groups of patients (e.g., pediatric patients or patients receiving drugs for ophthalmic use) who require smaller doses of approved sterile drug products that may not be available commercially; to reduce medication errors associated with drawing up a dose from a vial at the point of patient care; to reduce the availability of drug products that could be abused when controlled substances are left over in a vial after a dose is drawn out; to provide a particular sized container to fit into a particular device to administer the drug (such as a particular pain medication pump); for convenience for the practitioner administering an injection to a patient; to reduce waste and conserve drug supplies; and in some cases to reduce cost. Some repackagers repackage both sterile and non-sterile drug products. Examples of repackaging include tablets and capsules that are repackaged from large containers into smaller containers or blister packs, and creams and lotions are sometimes purchased in bulk and repackaged into smaller tubes or containers.

As part of the drug application review and approval process, FDA evaluates the container closure system and the packaging into which the drug will be placed, as well as the conditions under which the drug will be packaged. The container closure system and packaging can affect the quality of the drug product when it is on the market. In particular, during the approval process, FDA reviews whether the container closure system and the packaging are appropriate for maintaining the stability of the drug product through its expiration date, as long as the container-closure and package are not breached, and the drug is stored according to the conditions specified in the application. For drug products required to be sterile, FDA also considers whether the container closure system and packaging are adequate to ensure that the drug product will remain sterile until its expiration date, as long as the container closure is not breached and the drug product is stored appropriately.

When a drug product is repackaged, its characteristics may change in ways that have not been evaluated during the FDA approval process and that could affect the safety and efficacy of the drug product. Improper repackaging of drug products can cause serious adverse events. Of particular concern is repackaging of sterile drug products, which are susceptible to contamination and degradation. For example, failure to properly manipulate sterile drug products under appropriate aseptic conditions could introduce contaminants that could cause serious patient injury or death. Repackaging practices that conflict with approved product labeling could result in drug product degradation and adverse events associated with impurities in the product or lack of efficacy because the active ingredient has deteriorated.

### B. Regulatory Framework for Repackaging

Repackaged drug products are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. For example, repackaged drug products are generally subject to the premarket approval, misbranding, adulteration, and drug supply chain security provisions of the FD&C Act, including section 505 (concerning new drug applications),[8] section 502(f)(1)

[8] *But see U.S. v. Kaybel*, 430 F.2d 1346 (3d Cir. 1970) (holding that repackaging of approved Enovid (estrogen) tablets from large bottles into small bottles did not require pre-approval under section 505 of the FD&C Act).

(concerning labeling with adequate directions for use), section 501(a)(2)(B) (concerning current good manufacturing practice (CGMP)), and section 582 (concerning drug supply chain security).

Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act.[9] Therefore, drug products repackaged by State-licensed pharmacies, Federal facilities, or outsourcing facilities are not eligible for the exemptions provided under those sections. In this guidance, FDA describes the conditions under which it does not intend to take action regarding violations of certain requirements of the FD&C Act, in the context of drug repackaging.

## III. POLICY

### A. General Policy[10]

As discussed above, repackaged drug products are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act.[11] FDA does not intend to take action for violations of sections 505, 502(f)(1), and 582 if a State-licensed pharmacy, a Federal facility, or an outsourcing facility repackages drug products in accordance with the conditions described below, and any applicable requirements.[12, 13] In addition, FDA does not intend to take action for violations of section 501(a)(2)(B) of the FD&C Act if the drug product is repackaged by a State-licensed pharmacy or a Federal facility in accordance with the conditions described below, and any applicable requirements.[14]

The conditions referred to in the preceding paragraph are as follows:

---

[9] Section 503A of the FD&C Act exempts compounded drug products from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act provided certain conditions are met, including that the drug product is compounded pursuant to a valid prescription for an individually identified patient from a licensed practitioner. The Drug Quality and Security Act added a new section 503B to the FD&C Act. Under section 503B(b), a compounder can register as an outsourcing facility with FDA. Drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility qualify for exemptions from the FDA approval requirements in section 505 of the FD&C Act, the requirement to label drug products with adequate directions for use under section 502(f)(1) of the FD&C Act, and the Drug Supply Chain Security Act requirements in section 582 of the FD&C Act, if the conditions in section 503B are met. Drug products compounded in outsourcing facilities are not exempt from CGMP requirements under section 501(a)(2)(B).

[10] Portions of this guidance are shaded in gray to indicate that they constitute collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

[11] *See* footnote 8.

[12] Applicable requirements include, for example, the requirement that manufacturers not adulterate a drug product by preparing, packing, or holding the drug product under insanitary conditions. *See* section 501(a)(2)(A) of the FD&C Act.

[13] FDA is considering the applicability of the policies described in this guidance to hospitals and health systems and intends to address these issues in separate guidance.

[14] For purposes of the applicability of the conditions in this guidance document, references to a State-licensed pharmacy or Federal facility do not include a facility that is registered as an outsourcing facility under section 503B of the FD&C Act.

1. The drug product that is being repackaged is a prescription drug product that:

   a. is approved under section 505 of the FD&C Act, or

   b. is an unapproved drug product that appears on the drug shortage list in effect under section 506E of the FD&C Act, and the repackaged drug product is distributed during any period in which it is listed on that drug shortage list or during the 30 days following such period.

2. The drug product is repackaged in a State-licensed pharmacy, a Federal facility, or an outsourcing facility.

3. The drug product is repackaged by or under the direct supervision of a licensed pharmacist.

4. If the drug product is repackaged in a State-licensed pharmacy or a Federal facility, it is distributed[15] only after the receipt of a valid prescription for an identified, individual patient (including a written order or notation in a patient's chart in a health care setting) directly from the prescribing practitioner or patient.[16] This condition does not apply to drug products repackaged in an outsourcing facility.[17]

5. Except as provided below for a single-dose vial, the drug product is repackaged, stored, and shipped in a way that does not conflict with approved drug product labeling.[18]

   For a drug product that is packaged in a single-dose vial that is repackaged into multiple units, the drug product is repackaged in a way that does not conflict with the

[15] "Distributed" means that the repackaged drug product has left the facility in which it was repackaged.

[16] FDA is considering the applicability of this condition to certain non-sterile drug products repackaged by State-licensed pharmacies for distribution to long-term care facilities, and intends to revise this guidance or issue separate guidance to address this issue. During this interim period, FDA does not intend to apply this condition to non-sterile drug products repackaged by State-licensed pharmacies for use in long-term care facilities.

[17] Note, however, that drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, a prescription drug cannot be dispensed to a patient without a prescription.

[18] If the approved labeling contains instructions for handling or storage of the product, the drug product is repackaged in accordance with those instructions. Otherwise, the repackaging would be considered to be in conflict with the approved labeling. For example, the approved labeling for propofol states that "propofol undergoes oxidative degradation in the presence of oxygen and is therefore packaged under nitrogen to eliminate this degradation path", and it states, "Do not freeze." Therefore, exposing propofol to oxygen during the repackaging process or freezing it would be in conflict with the approved labeling. In contrast, the labeling of propofol is silent on the type of container into which it can be packaged. Therefore, packaging it into an appropriate container would not conflict with the approved labeling. Also note that section 502(g) of the FD&C Act states that a drug is misbranded if it is a drug that is recognized in an official compendium and among other things it is not packaged as prescribed therein.

approved labeling, except for the statements designating the product as a single-dose or single-use product and related language (e.g., discard remaining contents).[19]

6. The container into which the drug product is repackaged is suitable for storage of the drug product through its beyond-use-date (BUD).[20]

7. If the labeling for the approved drug product being repackaged includes storage and/or handling instructions (e.g., protect from light, do not freeze, keep at specified storage temperature), the labeling for the repackaged drug product specifies the same storage conditions.

8. The repackaged drug product is assigned a BUD[21,22] as described below, unless literature or other scientific information suggests that a shorter BUD would be appropriate, in which case a shorter BUD is assigned consistent with such scientific information. The BUD timeframes in this condition begin from the time in which the container of the original drug product to be repackaged is punctured or otherwise opened.

    a. **Sterile drug products repackaged by State-licensed pharmacies or Federal facilities:**

        i. **FDA-approved drug product with a specified in-use time**: If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling a time within which the opened product is to be used (an "in-use" time), the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.[23]

---

[19] This condition would not be satisfied if a drug product repackaged from a single-dose vial is repackaged in a way that conflicts with other language in the approved labeling (e.g., regarding storage conditions).

[20] For example, for State-licensed pharmacies and Federal facilities, information provided by the container's manufacturer could indicate that the container is suitable for drug products repackaged in accordance with this condition. For outsourcing facilities, CGMP requirements address container suitability and drug stability.

[21] The BUD is the date beyond which a drug product should not be used.

[22] FDA does not intend to take action against an outsourcing facility for assigning a BUD to be used as an expiration date in lieu of conducting stability studies required under 21 CFR part 211 for its repackaged drug products if the outsourcing facility assigns a BUD consistent with this condition.

[23] For example, if an approved drug product that includes a 3-day in-use time and an expiration date of January 15, 2017, on the label is repackaged on January 1, 2017, the applicable BUD for the repackaged drug product would be January 4, 2017, because the labeled in-use time of 3 days is shorter than the time until the labeled expiration date of the drug product (14 days). If the drug product is repackaged on January 14, 2017, the applicable BUD for the repackaged drug product would be January 15, 2017, because the time until the labeled expiration date of the approved drug product is 1 day, which is shorter than the labeled 3-day in-use time.

ii. **FDA-approved drug product without an in-use time or unapproved drug product**: If the drug product being repackaged is an FDA-approved drug product whose labeling does not specify an in-use time, or if it is an unapproved drug product on the FDA drug shortage list (which does not have an in-use time reviewed by FDA as part of the drug approval process), the repackaged drug product is assigned a BUD (1) that is established in accordance with the proposed revision to USP Chapter <797> published in the Pharmacopeial Forum (PF) 41(6) [Nov.–Dec. 2015] on November 2, 2015,[24] or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.

b. **Sterile drug products repackaged by outsourcing facilities:**

The outsourcing facility assigns a BUD as described in the guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.*[25]

c. **Non-sterile drug products repackaged by State-licensed pharmacies, Federal facilities, or outsourcing facilities:**[26]

i. **FDA-approved drug product with a specified in-use time**: If the drug product being repackaged is an FDA-approved drug product that specifies in the labeling an "in-use" time, the repackaged drug product is assigned a BUD (1) that is established in accordance with the in-use time on the drug product being repackaged; or (2) that is the expiration date on the drug product being repackaged, whichever is shorter.

ii. **FDA-approved drug product without an in-use time or unapproved drug product**:[27]

---

[24] Once USP has considered the public comments that it received and finalizes the revised Chapter <797>, FDA intends to evaluate whether condition 8 should refer to the updated chapter or BUDs that are different than those included in final Chapter <797>. Although USP Chapter <797> addresses *compounded* sterile preparations, many of the same principles for conditions and practices to assure sterility and stability of compounded drug products, such as the requirement to maintain a sterile environment, engage in appropriate sterile processing techniques, and assign the appropriate BUD to the product, also apply to repackaged sterile drug products to help assure their quality is not compromised during and after the repackaging operation.

[25] The longer BUDs set forth for outsourcing facilities reflect that conditions maintained to comply with CGMP requirements provide greater assurance of the quality of manufacturing operations and the products that are produced at the facility, and that outsourcing facilities are subject to FDA inspections on a risk-based schedule.

[26] In lieu of the BUDs set forth in this condition, outsourcing facilities may establish BUDs for non-sterile drug products that they repackage based on stability studies conducted in accordance with 21 CFR Part 211.

[27] The BUDs in this condition are based on the BUDs applicable to non-sterile compounded preparations in USP Chapter <795>.

- For nonaqueous formulations, the BUD does not exceed six months or the expiration date of the drug product being repackaged, whichever is shorter.

- For water-containing oral formulations, the BUD does not exceed 14 days or the expiration date of the drug product being repackaged, whichever is shorter.

- For water-containing topical/dermal and mucosal liquid and semisolid formulations, the BUD does not exceed 30 days or the expiration date of the drug product being repackaged, whichever is shorter.

9. The drug product is repackaged in accordance with the following[28]:

    a. If the drug product is repackaged in a State-licensed pharmacy or a Federal facility:

        i. If it is a non-sterile drug product, it is repackaged in accordance with USP Chapter <795>, except the BUD is as specified in condition 8; or

        ii. If it is sterile drug product, it is repackaged in accordance with USP Chapter <797>, except the BUD is as specified in condition 8.

    b. If the drug product is repackaged in an outsourcing facility, repackaging is conducted in accordance with CGMP requirements.[29]

10. The drug product that is being repackaged does not appear on a list of drug products that have been withdrawn or removed from the market because they have been found to be unsafe or ineffective. For purposes of this provision, repackagers should refer to the list of drug products in 21 CFR 216.24, developed for use with sections 503A and 503B of the FD&C Act.

11. The drug product is not sold or transferred by an entity other than the entity that repackaged such drug product. For purposes of this condition, a sale or transfer does not include administration of a repackaged drug product in a health care setting.

12. The repackaged drug product is distributed only in States in which the facility repackaging the drug product meets all applicable State requirements.

---

[28] The intention is that the BUDs are set in accordance with condition 8.

[29] *See* the guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act.*

13. If the drug product is repackaged by an outsourcing facility:

    a. The label on the immediate container (primary packaging, e.g., the syringe) of the repackaged product includes the following:
        i. The statement "This drug product was repackaged by [name of outsourcing facility]"
        ii. The address and phone number of the outsourcing facility that repackaged the drug product
        iii. The established name of the original drug product that was repackaged
        iv. The lot or batch number of the repackaged drug product
        v. The dosage form and strength of the repackaged drug product
        vi. A statement of either the quantity or volume of the repackaged drug product, whichever is appropriate
        vii. The date the drug product was repackaged
        viii. The BUD as the expiry date for the repackaged drug product
        ix. Storage and handling instructions for the repackaged drug product
        x. The National Drug Code (NDC) number of the repackaged drug product, if available[30]
        xi. The statement "Not for resale," and, if the drug product is distributed by an outsourcing facility other than pursuant to a prescription for an individual identified patient, the statement "Office Use Only", and
        xii. If included on the label of the drug product from which the drug product is being repackaged, a list of the active and inactive ingredients, unless such information is included on the label for the container from which the individual units are removed, as described below in 11.b.i.

    b. The label on the container from which the individual units are removed for administration (secondary packaging, e.g., the bag, box, or other package in which the repackaged products are distributed) includes:
        i. The active and inactive ingredients, if the immediate drug product label is too small to include this information
        ii. Directions for use, including, as appropriate, dosage and administration
        iii. The following information to facilitate adverse event reporting: www.fda.gov/medwatch and 1-800-FDA-1088.

    c. The drug product is included on a report submitted to FDA each June and December identifying the drug products repackaged by the outsourcing facility during the previous 6-month period, and providing the active ingredient(s); source of the active ingredient(s); NDC number of the source ingredient(s), if available; strength of the active ingredient(s) per unit; the dosage form and route of administration; the package description; the number

[30] The NDC number of the original approved drug product should not be placed on the repackaged drug product.

of individual units produced; and the NDC number of the repackaged drug product, if assigned.[31]

d. The outsourcing facility reports serious adverse events to FDA that are associated with its repackaged drug products.[32]

### B. Establishment Registration and Drug Listing

Under section 510(b)(1) of the FD&C Act, between October 1 and December 31 of each year, every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs is required to register with FDA, and under section 510(j) of the FD&C Act, every person who registers with FDA under section 510(b) must list its drugs with the Agency. A drug is misbranded under section 502(o) of the FD&C Act if it was manufactured, prepared, propagated, compounded, or processed in an establishment that is not registered under section 510, or if it was not included on a list required by section 510(j). Pharmacies that repackage drug products may qualify for an exemption from registration and thus also not be required to list their drugs with FDA. Specifically, under section 510(g)(1), the registration and listing requirements of section 510 do not apply to:

> pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail.

With respect to entities that do not qualify for the exemptions from registration under section 510 of the FD&C Act,[33] FDA does not intend to take action for violations of section 502(o) of the

---

[31] FDA has issued a guidance for industry, *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*. This guidance describes how outsourcing facilities submit drug product reports to FDA. Although that guidance addresses reporting of compounded drug products, outsourcing facilities should follow the same procedure to electronically report the drug products they repackaged.

[32] FDA has issued a guidance for industry, *Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, which describes how outsourcing facilities submit adverse event reports to FDA and the content and format of the reports that they are required to submit. Although that guidance addresses reporting of adverse events associated with compounded drug products, outsourcing facilities should follow the procedure described in that guidance to electronically report adverse events associated with the drug products they repackaged.

[33] *See also*, 21 CFR 207.10.

FD&C Act for failure to register and list drugs under section 510 for drugs that are repackaged in accordance with this guidance.[34]

[34] FDA has developed this policy because outsourcing facilities that repackage drug products in accordance with this guidance are registered with FDA under section 503B of the FD&C Act and report repackaged drug products to FDA in accordance with condition 13.c.

# 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.

## 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 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 assembly the Virginia Multistate Pharmacy Jurisprudence Examination (MPJE) form(s) which shall be accomplished through writing, reviewing, and selecting items for the VA MPJE item pool.

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: ~~September 7, 2016~~ September 26, 2017

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

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

MEMORANDUM

TO: Members, Board of Pharmacy

FROM: David E. Brown, D.C.

DATE: August 11, 2017

SUBJECT: Revenue and Expenditure Analysis

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

The Board of Pharmacy ended the 2014 - 2016 biennium (July 1, 2014, through June 30, 2016) with a cash balance of $2,502,335. Current projections indicate that expenditures for the 2016 - 2018 biennium (July 1, 2016, through June 30, 2018) will exceed revenue by approximately $795,874. When combined with the Board's $2,502,335 cash balance as of June 30, 2016, the Board of Pharmacy projected cash balance on June 30, 2018, is $1,706,461.

We recommend the Board raise license fees at its earliest opportunity. The department staff will present the details of this proposal at a future Board meeting. Please note that these projections are based on internal agency assumptions and are, therefore, subject to change based on actions by other state agencies, the Governor and\or the General Assembly.

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

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

cc: Caroline Juran, Executive Director
Lisa R. Hahn, Chief Deputy Director
Charles E. Giles, Budget Manager
Elaine Yeatts, Senior Policy Analyst

**STATE HOLIDAYS**

# 2018 Proposed Meeting Dates

**FULL Board Meeting**

March 5, 23 or 29
June 5, 21, 26 or 27
September 4, 6, 10, 25 or 27
December 4, 10, or 18

**Regulation Committee Meeting**

May 3
November 28

### JANUARY

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | | | |

### FEBRUARY

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | 1 | 2 | 3 |
| 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | | | |

### MARCH

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | 1 | 2 | 3 |
| 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 |

### APRIL

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| 29 | 30 | | | | | |

### MAY

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | 1 | 2 | 3 | 4 | 5 |
| 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 |
| 20 | 21 | 22 | 23 | 24 | 25 | 26 |
| 27 | 28 | 29 | 30 | 31 | | |

### JUNE

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | 1 | 2 |
| 3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 |
| 24 | 25 | 26 | 27 | 28 | 29 | 30 |

### JULY

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 |
| 8 | 9 | 10 | 11 | 12 | 13 | 14 |
| 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| 22 | 23 | 24 | 25 | 26 | 27 | 28 |
| 29 | 30 | 31 | | | | |

### AUGUST

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | 1 | 2 | 3 | 4 |
| 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| 12 | 13 | 14 | 15 | 16 | 17 | 18 |
| 19 | 20 | 21 | 22 | 23 | 24 | 25 |
| 26 | 27 | 28 | 29 | 30 | 31 | |

### SEPTEMBER

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | | 1 |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 |
| 30 | | | | | | |

### OCTOBER

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 | 13 |
| 14 | 15 | 16 | 17 | 18 | 19 | 20 |
| 21 | 22 | 23 | 24 | 25 | 26 | 27 |
| 28 | 29 | 30 | 31 | | | |

### NOVEMBER

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | 1 | 2 | 3 |
| 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 | 16 | 17 |
| 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | |

### DECEMBER

| S | M | T | W | T | F | S |
|---|---|---|---|---|---|---|
| | | | | | | 1 |
| 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| 23 | 24 | 25 | 26 | 27 | 28 | 29 |
| 30 | 31 | | | | | |

Virginia Department of Health Professions

DRAFT

# Board of Health Professions Full Board Meeting

**August 31, 2017**
**10:00 a.m. - Board Room 4**
**9960 Mayland Dr, Henrico, VA 23233**

| | |
|---|---|
| **In Attendance** | Helene D. Clayton-Jeter, OD, Board of Optometry |
| | Kevin Doyle, EdD, LPC, LSATP, Board of Counseling |
| | Yvonne Haynes, LCSW, Board of Social Work |
| | Mark Johnson, DVM, Board of Veterinary Medicine |
| | Allen R. Jones, Jr., DPT, PT, Board of Physical Therapy |
| | Ryan Logan, RPh, Board of Pharmacy |
| | Trula E. Minton, MS, RN, Board of Nursing |
| | Herb Stewart, PhD, Board of Psychology |
| | Laura P. Verdun, MA, CCC-SLP, Board of Audiology & Speech-Language Pathology |
| | James Wells, RPh, Citizen Member |
| | Junius Williams, Jr., MA, Board of Funeral Directors and Embalmers |
| **Absent** | Barbara Allison-Bryan, MD, Board of Medicine |
| | Marvin Figueroa, Citizen Member |
| | Derrick Kendall, NHA, Board of Long-Term Care Administrators |
| | Martha S. Perry, MS, Citizen Member |
| | Jacquelyn M. Tyler, RN, Citizen Member |
| | James D. Watkins, DDS, Board of Dentistry |
| **DHP Staff** | Lisa R. Hahn, MPA, Chief Deputy DHP |
| | Elizabeth A. Carter, Ph.D., Executive Director BHP |
| | Elaine Yeatts, Senior Policy Analyst DHP |
| | Jay Douglas, Executive Director Board of Nursing |
| | Matt Treacy, Communications Associate DHP |
| | Laura L. Jackson, BHSA, Operations Manager BHP |
| **Presenters** | Neal Kauder, VisualResearch, Inc. |
| **Speakers** | Maxine Lee, MD, Virginia Society of Anesthesiologists |
| | Swen Laser, MD, Augusta Anesthesia Associates |
| | Michael Jawer, CAE, Alliance for Natural Health |
| | Jerrol Wallace, VANA |
| | Michele Satterlund, McGuire Woods Consulting |

| | |
|---|---|
| | Leila Saadeh, MS, ATR-BC, VATA |
| | Gretchen Graves, MS, ATR-BC, CDATA, VATA |
| | Carol Olson, VATA |
| **Observers** | Cathy Harrison, CRNA, VANA |
| | Adrienne Hartgerink, CRNA, VANA |
| | Ashleigh Harris, SRNA, VANA |
| | Tressie Turner, SRNA, VANA |
| | Kayla Katz, SRNA, VANA |
| | W. Scott Johnson, Medical Society of Virginia |
| | Sarah Anderson, SRNA, VANA |
| | Anna Lenczyk, SRNA, VANA |
| | Joseph Biscardi, SRNA, VANA |
| | Kevin Pyne, SRNA, VANA |
| | Katie Payne, Virginia Society of Anesthesiologists |
| | Patricia Diefenbach, VAANP |
| | Sara Heisler, VHHA |
| | Christina Wingate, VANA |
| | Kyu Kim, SRNA, VANA |
| | Nadia Cefton, VANA |
| | Amber Coleman, SRNA, VANA |
| | Lee Bakhxar, SRNA, VANA |
| | Eric Fries, SRNA, VANA |
| | Julie Garces, SRNA, VANA |
| | Mark Wallu, VANA |
| | Erin Grimm, VANA |
| | Rebekah Pipp, VANA |
| | Mark Hickman, CSG |
| **Emergency Egress** | Dr. Carter |

**Call to Order**

| | | | |
|---|---|---|---|
| **Chair:** | Dr. Clayton-Jeter | **Time** | 10:01 a.m. |
| **Quorum** | Established | | |

## Public Comment

### Discussion

Maxine Lee, MD, stated that she is the immediate past president of the Virginia Society of Anesthesiologists (VSA) and is from the southwestern area of the state. She said that VSA represents more than 900 physician anesthesiologist in Virginia and supports licensure of CAAs. Dr. Lee stated that there is a shortage of anesthesiology providers and that licensing CAAs would provide an additional workforce that could be utilized. Dr. Lee asked that the Board either reject the recommendation of the Regulatory Research Committee or send the issue back to the Committee for further study.

Swen Laser, MD stated he was with Anesthesiologist Associates of Augusta and has been practicing anesthesiology for 17 years. He noted that Augusta Health currently offers CAA rotation. Dr. Laser stated that the CAAs are superbly trained and are exported out of the state for employment even though they live in Virginia. Dr. Laser recommends licensure of CAAs.

Michael Jawer, CAE reported that he is the Deputy Director at Alliance for Natural Health. Mr. Jawer submitted a request for a Board study of the value of licensing Naturopathic Doctors (NDs).

Patricia Diefenbach, ND, MS, CNC, CNS, CPT, president of the Virginia Association of Naturopathic Physicians (VAANP), had submitted a request for a board study into the need for licensure of Naturopathic Doctors. On August 17, 2017, she informed the Board office by email that the VAANP is no longer requesting the Board's review because the organization is currently pursuing legislative action.

Jerrol Wallace from the Virginia Association of Nurse Anesthetists was accompanied by Michele Satterlund of McGuire Woods Consulting. Mr. Wallace acknowledged the attending Certified Registered Nurse Anesthetists (CRNAs) in the audience and stated that licensure of another anesthesia provider group would impact CRNAs and there is no proven shortage at this time. He also stated that CRNAs have some restrictions based on scope of practice. Ms. Satterlund stated that licensing another provider would be detrimental as there is no shortage and no need for another anesthesia provider. Ms. Satterlund asked that the Board support the recommendation of the Regulatory Research Committee.

Leila Saadeh, MS, ATR-BC from the Virginia Art Therapy Association spoke regarding the letter and application for study submitted to the Board for consideration of the need for regulation of the practice of art therapy in Virginia.

## Approval of Minutes

**Presenter** Dr. Clayton-Jeter

### Discussion

The May 9, 2017 Full Board meeting minutes were approved with no revisions. All members in favor, none opposed.

## Directors Report

**Presenter** Ms. Hahn

**Discussion**

Ms. Hahn provided an update on multiple activities related to addressing the opioid crisis and described DHP's evolving role and coordination with multiple partners. She provided an overview of proposed legislation along with information regarding the Board of Counseling's requirement to register Qualified Mental Health Professionals (QMHPs -Adult and Child) and Peer Recovery Specialists. She noted that workgroups have convened to discuss transforming the delivery system for community-based Substance Use Disorder services that leverage evidence based treatment approaches demonstrated to improve recovery rates substantially. The Department is also currently working with the Department of Behavioral Health and Developmental Services and the Attorney General's Office in establishing standards for mental health dockets. She further noted that the Board of Medicine has issued a letter to prescribers regarding the recently passed legislation and regulations on opioid prescribing and Buprenorphine.

## Legislative and Regulatory Report

**Presenter** Ms. Yeatts

**Discussion**

Ms. Yeatts advised the Board of updates to the laws and regulations that affect DHP currently.

## Communications Report

**Presenter** Dr. Carter

**Discussion**

Dr. Carter reviewed the meeting materials provided by the agency's Communications Department. These items included the July 14, 2017 *Virginian-Pilot* article regarding the Healthcare Workforce Data Center's *Health Care Occupation Roadmap*; collaboration with VCU in the redesign of DHPs logo; and Bayview Physicians Groups opting into Appriss Health's NarxCare Platform offered by the agency's Prescription Monitoring Program (PMP).

## Sanction Reference Point Update

**Presenter** Mr. Kauder

**Discussion**

Mr. Kauder discussed the agency's Sanction Reference Point (SRP) agreement rates by board and provided a status report on SRP update research underway for the Boards of Long-Term Care Administrators, Funeral Directors and Embalmers, and Physical Therapy. He stated that some of the boards have requested more formal training on the SRP program as many board members feel that the "on the job" training they are currently getting is not adequate. The Board asked if Mr. Kauder would be willing to work with DHPs Communications Department to create a training video. He agreed. This information will be forwarded to the Board's Education Committee and Communications Department for further discussion.

**Break 11:11 a.m. to 11:16 a.m.**

## Executive Directors Report

**Presenter** Dr. Carter

### Board Budget

Dr. Carter stated that the Board is operating under budget.

### Agency Performance

Dr. Carter reviewed the agencies performance measures in relation to clearance rate, age of pending caseload and time to disposition. She noted that while the key performance measures for patient care cases meet the goals, the length of time to resolve overall cases is on the rise. The agency is instituting a new internal tracking to assess the relative impact on performance of down time due to continuances.

### Virginia Association of Naturopathic Physicians (VAANP)

Dr. Carter provided information regarding VAANP wish to rescind their original request for a study to evaluate the need for regulation of naturopathic physicians, received May 31, 2017.

Dr. Diefenbach noted that VAANP is currently pursuing legislative action directly.

Mr. Jawer from the Alliance for Natural Health (ANH) discussed his association's request for the Board's study, and provided an overview of the rationale for the request.

VAANP and ANH are acting independently from each other.

Dr. Carter stated that it would take approximately 18 months for a study to be conducted given the existing workload. She noted the previous evaluation study was done in 2005. At that time, the Board concluded the criteria to justify regulation were not met.

Upon further discussion, Chair Dr. Clayton-Jeter proposed a motion to be made on moving forward with the request made by Alliance for Natural Health to perform the study of Naturopathic Doctors (NDs) in Virginia.

### Motion

No motion was made. Failing a motion, the Board concluded that no study would be conducted at this time.

### Virginia Art Therapy Association

Dr. Carter provided information regarding the request from the Virginia Art Therapy Association to perform a sunrise review. Ms. Graves, Ms. Saadeh and Ms. Olson all provided information regarding the profession and the need for some form of regulation to distinguish them from other professions. After much discussion, Chair Dr. Clayton-Jeter proposed that the matter be tabled until later in the meeting to allow Board members more time to review the information provided before making a decision.

### Motion

A motion was made to table the decision concerning the review of Art Therapists until later in the meeting. The motion was properly seconded. Eight (8) members were in favor, three (3) opposed.

## Practitioner Self-Referral – AnuVa Diagnostics, LLC

**Presenter** Dr. Carter

Dr. Carter provided information regarding the Practitioner Self-Referral (PSR) request made by AnuVa Diagnostics, LLC on May 26, 2017. The request was reviewed and accepted by Mr. Wells, Agency Subordinate on August 10, 2017. Details are provided in the meeting documents and the request is being presented to the Full Board for consideration and ratification today.

### Motion

A motion was made to ratify the Practitioner Self-Referral request presented by AnuVa Diagnostics, LLC. The motion was made and properly seconded by Ms. Haynes. All members were in favor, none opposed.

## Regulatory Research Committee

**Presenter** Mr. Wells

Mr. Wells provided information regarding the Committee's recommendation to not license Certified Anesthesiology Assistants (CAAs) in Virginia. He stated that the burden of regulation was not justified due to the lack of proof of a statewide shortage of anesthesia providers, the fact that AA students would be competing for already limited training sites and slots needed by Anesthesiologist and Nurse Anesthetist students, and since they cannot practice without on-site direct Anesthesiologist supervision, it was deemed unlikely that they could meaningfully address the needs of medically underserved and other rural areas. The burden on the Board of Medicine to establish a regulatory program and administer the licensure program was also taken into consideration.

### Motion

A motion was made to accept the recommendation of the Regulatory Research Committee to not license Certified Anesthesiology Assistants (CAAs) in Virginia. The motion was made and properly seconded by Ms. Minton. All members in favor, none opposed.

## Lunch break 12:30 p.m. – 1:01 p.m.

### Virginia Art Therapy Association

Discussion regarding regulation of Art Therapists in Virginia resumed and a motion offered.

### Motion

A motion to accept the Virginia Art Therapy Associations request for a sunrise review was made and properly seconded by Mr. Stewart. All members in favor, none opposed.

### Healthcare Workforce Data Center

Dr. Carter provided an update on the Data Center. She described work being done with Virginia Commonwealth University (VCU), Virginia Longitudinal Data System (VLDS) and the Federal of State Boards of Physical Therapy (FSBPT) in regards to the use of Virginia's healthcare workforce data.

## Board Reports

**Presenter** Dr. Clayton-Jeter

### Board of Nursing

Ms. Minton stated that the Board of Nursing is currently seeking changes to regulations and that the Board has four (4) newly appointed members. The board is taking action on the opioid crisis by providing education outreach and working with the Board of Medicine on opioid prescribing. The Interstate Nurse Licensure Compact is in transition to a new version in 2018. Once completed, there could be 30 states participating.

### Board of Pharmacy

Mr. Logan reported that the Board of Pharmacy is supporting the legislative proposal to require the dispensing of Schedule V drugs and naloxone to be reported to the PMP. He advised that the Board has requested that the Healthcare Workforce Data Center amend question #22 within the pharmacist healthcare workforce survey to read "Do you provide any of the following services at this location?" as it relates to better assessing pharmacist involvement in collaborative practice agreements. Mr. Logan was appointed Board Chairman and Mr. Elliott Vice-Chairman at the June 27, 2017 meeting.

### Board of Veterinary Medicine

Dr. Johnson stated that teaching schools were previously not required to have a license to practice veterinary medicine and that a new facility/intern resident license is being proposed. Regulations affecting the prescribing of opioids are also under review.

### Board of Psychology

Dr. Stewart stated that a few more states have joined the Psychology Interjurisdictional Compact (PSYPACT) bringing the total to four (4). The Board of Psychology's Regulatory Committee will recommend items identified and reviewed for inclusion in a Notice of Intended Regulatory Action (NOIRA). The Association of State and Provincial Psychology Boards (ASPBD) is reviewing standards of practice, as well. The Board of Psychology also voted to support DHP introducing legislation that would allow requiring up to 2 hours per annual renewal cycle in a specific continuing education area. Dr. Stewart has also been reappointed Chair of the Board of Psychology.

### Board of Counseling

Dr. Doyle announced that the Board of Counseling had four (4) new board members appointed. He stated that it had passed emergency regulations for registering Qualified Mental Health Professionals (QMHPs -Adult and Child) and Peer Recover Specialists and had proposed education program accreditation be done through the Council for Accreditation of Counseling and Related Educational Programs (CACREP).

### Board of Social Work

Ms. Haynes stated that the Board of Social Work's July meeting was canceled. The Board of Social Work's Regulatory Review Committee is reviewing the definition of "social work" and also revising the requirements for reactivation and reinstatement.

**Board of Physical Therapy**

Dr. Jones provided a written report that was read by Dr. Carter. The Board of Physical Therapy's Regulatory Advisory Panel (RAP) met on June 29, 2017 to discuss "dry needling". This information was shared with the Full Board August 22, 2017 and the board agreed to reconvene the RAP to discuss the number of training hours for dry needling. Dr. Jones and Ms. Tillman-Wolf, Executive Director for the Board, attended a leadership forum in Alexandria, VA in June that was held by FSBPT that focused on compact licensure and telehealth continuing competence. The Board has three (3) newly appointed board members. Election of Officers was held and Dr. Jones was reelected President and Dr. Dailey reelected Vice President. The annual meeting and delegate assembly of FSBPT will be held in November in New Mexico. Elected delegates include Dr. Jones and alternate delegate Dr. Locke. Dr. Dailey will attend as a member of the Education Task Force.

**Board of Optometry**

Dr. Clayton-Jeter reported that at the July Board of Optometry meeting an overview of the draft emergency regulations on Prescribing Opioids were considered and approved. An amendment to the regulations was made that a prescription for Naloxone should be considered for any risk factor of prior overdose, substance abuse, or concomitant use of benzodiazepine present. Dr. Clayton-Jeter was appointed Board Vice-President. At the August meeting regulations were reviewed and more specific language was added.

**Board Committee Structures**

**Presenter** Dr. Carter

Dr. Carter provided an overview of the Board's Committees and their purpose. Dr. Clayton-Jeter asked for two Board members to volunteer for the vacancies on the Education Committee. Dr. Stewart and Mr. Logan agreed to fill those vacancies. The Enforcement Committee added Mr. Williams.

Dr. Clayton-Jeter asked the Education Committee to assist in the Agency's logo branding. She also asked that the Education Committee aid in creating a Sanction Reference Point (SRP) video to be added to new board member training. She also asked that Boards be identified that need SRP training and have webinars or vignettes created. Mr. Wells recommended that "refresher" training should also be provided to existing board members.

Dr. Carter advised that the Board of Health Professions Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions manual be revised (last revised in 1998). She requested that more time needs to be added to the time-line for the completion of a study; the recommendation was for 12 to 18 months. Dr. Clayton-Jeter asked for a motion to have the Full Board review and comment on the draft policy and procedure manual.

**Motion**

A motion was made to have the Full Board review the Board of Health Professions Policies and Procedures for the Evaluation of the Need to Regulate Health Occupations and Professions manual. The motion was made and properly seconded by Mr. Stewart. All in favor, none opposed.

## New Business

**Presenter** Dr. Clayton-Jeter

The proposed 2018 meeting dates were discussed and agreed upon.

## December 7, 2017 Full Board Meeting

**Presenter** Dr. Clayton-Jeter

Chair and Vice Chair elections will be held at this meeting. The Nominating Committee will meet to propose a slate of officers.

## Adjourned

**Adjourned** 1:57 p.m.

**Chair** Helene Clayton-Jeter, OD

Signature: _____ Date: _____/_____/_____

**Board Executive Director** Elizabeth A. Carter, Ph.D.

Signature: _____ Date: _____/_____/_____