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 Hearing and Full Board Meeting

December 11, 2017

9:00AM

- Guidance Document 110-1, List of Licensure Categories 81-84
- Guidance Document 110-4, Compliance with Continuing Education Requirements 85-89

- Report from Regulation Committee Meeting on 11/2/17 and Possible Action – Michael Elliott/Elaine Yeatts
  - Adopt NOIRA to address White Bagging and Brown Bagging 90-99
  - Amend Guidance Document 110-36, *Compliance with USP Standards for Compounding* 100-120
  - Guidance Document 110-23, Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide 121-131
- Adopt Guidance Documents on Delivery of Temperature-Sensitive Drugs and Drug Disposal – Caroline Juran 132-138

New Business:

- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections 139-189

Reports:

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

Consideration of consent orders & summary suspension, if any

Adjourn

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

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:00 a.m. on December 11, 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 December 1, 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. **2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine)**, 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. **2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP)**, 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. **alpha-ethylaminohexanophenone (other name: N-ethylhexedrone)**, 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. **N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE)**, 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. **4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP)**, 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. **N-ethyl-1,2-diphenylethylamine (other name: Ephenidine)**, 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.

7. **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole 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.
8. **3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900)**, 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. **2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-48800)**, 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 compounds are classified as central nervous system stimulants. Compounds of this type have been placed in Schedule I (§ 54.1-3446(5)) in previous legislative sessions.

10. **Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (4-fluoromethylphenidate**), including its salts, isomers and salts of isomers.
11. **Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate)**, including its salts, isomers and salts of isomers.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, September 14, 2017 Commonwealth Conference Center Second Floor Board Room 1	Department of Health Professions Perimeter Center 9960 Mayland Drive Henrico, Virginia 23233

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:45 a.m.
PRESIDING:	Michael Elliott, Committee Chair
MEMBERS PRESENT:	Jody Allen, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
AMANDA J. ASHDOWN Registration No. 0230-021067	Amanda Jane Ashdown appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the August 21, 2017 Notice. This was a re-hearing following a July 17, 2017 informal conference. Gary Wilks, Ms. Ashdown's father-in-law, testified on her behalf.
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 J. 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 by Mr. Elliott, the Committee unanimously voted to enter an Order that imposed no sanction.

DAVID W. HALL
License No. 0230-01034

David Winters Hall appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 21, 2017 Notice. This was a re-hearing following a January 17, 2017 informal conference.

John Beckner, his uncle and a Virginia pharmacist, testified on behalf of Mr. Hall.

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 David Winters Hall. 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 issue an Order to dismiss this matter.

Adjourn:

With all business concluded, the meeting adjourned at 1:40 p.m.

_____
Michael Elliott, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

_____
Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 26, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:15AM

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Michael I. Elliott (arrived at 9:12AM)
Sheila K. W. Elliott (arrived at 10:09AM)
Rafael Saenz
Ellen B. Shinaberry
Rebecca Thornbury
Cynthia Warriner (arrived at 9:14AM)

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

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

APPROVAL OF AGENDA: The agenda was amended to include approval of the draft minutes (handout) for the Ad Hoc Committee meeting held September 18, 2017.

MOTION: **The Board voted unanimously to amend the agenda to include approval of the draft minutes (handout) for the Ad Hoc Committee meeting held September 18, 2017. (motion by Allen, second by Boone)**

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

- June 26, 2017, Pilot Program Informal Conference Committee
- June 27, 2017, Full Board Meeting
- June 27, 2017, Public Hearing of Scheduling Certain Chemicals
- June 27, 2017, Formal Hearing
- June 28, 2017, Special Conference Committee
- July 17, 2017, Special Conference Committee
- July 31, 2017, Formal Hearings
- September 18, 2017, Ad Hoc Committee Meeting on Delivery of

Prescription Drug Order (HB1956), Guidelines for Counseling on Drug Disposal (HB2046), and Guidance for Complying with USP Chapter <800>

MOTION: **The Board voted unanimously to adopt the minutes from June 26, 2017 through July 31, 2017 as presented, along with the handout of the minutes from September 18, 2017. (motion by Shinaberry, second by M. Elliott)**

The following minutes (handouts) were later considered for approval prior to adjournment of the Full Board Meeting:

- August 31, 2017, Formal Hearings
- August 31, 2017, Special Conference Committee

MOTION: **The Board voted unanimously to amend the minutes for the August 31, 2017 Formal Hearings to correct the spelling of Ms. Warriner's name on page 3 and to adopt the minutes as amended, along with the minutes from the August 31, 2017 Special Conference Committee as presented. (motion by Warriner, second by Shinaberry)**

PUBLIC COMMENTS: Jackie Bright, the new Executive Director for the Virginia Pharmacists Association, introduced herself to the Board.

Jill Abernathy, INOVA Health System, stated that they deliver TPN and chemo to hospitals and physician offices. She requested that they not be required to use temperature monitoring devices for these shipments as these deliveries are short and the drugs are not left in an unattended area for a long period of time. Regarding USP <800>, she requested that if the Board enforces the 3 dates of implementation, that it be clearly communicated to the licensees.

Alexander Pytlarz, Leesburg Compounding Center, shared his concerns with USP <800> and requested a delay in implementation until 2021. He stated that West Virginia will delay implementation until 2021. He recommended one date for implementation of all requirements instead of the phase-in approach considered by the ad hoc committee. Further, he requested guidance on what exactly is needed in order to perform a risk assessment.

Michele Satterlund, McGuire Woods Consulting representing Temptime, commented on patient representative letters provided to the Board regarding their concerns with the safe delivery of temperature sensitive medications and the need for assurance that the medications had not been compromised. Her client supports a guidance document related to importance of proper delivery of temperature sensitive drugs as contemplated by the ad hoc committee. She also requested that the Board take action to require mail-order pharmacies to collect and provide temperature data to the Board since brick and mortar pharmacies must keep temperature data and non-resident pharmacies must provide a toll free number to report temperature issues.

John Beckner, representing the National Community Pharmacists Association (NCPA), provided comments in opposition to USP <800>. He stated that implementation will create a substantial economic impact and will cause some providers to cease compounding and therefore limit access for many consumers in Virginia. Mr. Beckner stated that full compliance by July 1, 2018 will be too difficult and proposed a delay in the enforcement until 2021. He stated that NCPA supports the inclusion of temperature monitoring devices for mail order deliveries.

Lauren Schmitt, VSHP, supports the delay in enforcement of USP <800> and the phase-in approach. She requested that the Board appoint a task force to develop guidance.

Hunter Jamerson, attorney representing EPIC Pharmacies, supports the use of temperature monitoring devices in biologics with mail order delivery products and would like to see the development of a guidance document. He mirrored the comments of John Beckner and Alexander Pytlarz and applauded the ad hoc committee's recommendation to delay enforcement of Chapter <800>. He stated that there is a need for consistency with other states regarding compliance with the effective date. In addition, Mr. Jamerson pointed out that even if non-compliance matters are cited without a monetary penalty, such action may have an adverse effect on accreditation, Pharmacy Benefits Manager contracts and licensing. He suggested that the inspection report contain a statement clarifying that any comments regarding non-compliance with chapter <800> prior to the board's enforcement date do not constitute disciplinary action.

John Sisto, representing Express Scripts, suggested that regulation on the delivery of temperature sensitive drugs should focus on prevention, not detection. He recommended the use of qualified engineered packaging and regulation of the cold chain process in order to reduce waste. He stated that binary devices don't solve the problem and can create false positives/false negatives resulting in a false sense of security or in the drug being wasted unnecessarily. He urged the Board to consider the use of continuous quality improvement in order to identify the problem before it occurs.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, spoke about two workgroups the Secretary of Health convened. The workgroup charged with developing some core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids determined that curricula is not easily adaptable across different types of schools or professions. Therefore, a set of core competencies was developed and will be reviewed. The workgroup on electronic prescribing of opioids met twice and an interim report will be sent to the Secretary of Health and legislators in November. Dr. Brown informed the Board that an online complaint form is now available and that DHP is expanding its office space and will utilize the 1st floor of the

building as well. Dr. Brown also shared that the agency will begin filming an educational video on probable cause review.

REGULATORY UPDATE:

Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda and gave updates on the status.

REPORT FROM AD HOC COMMITTEE MEETING:

- Delivery of Prescription Drug Orders (HB1956)

Ms. Shinaberry discussed the Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted.

Ms. Warriner expressed concern regarding possible inconsistency in the enforcement of requirements between brick and mortar pharmacies and mail order pharmacies. She stated that there is a need for assurance that the drug is safe and effective. Ms. Elliott and Ms. Thornbury expressed similar concerns.

Ms. Allen expressed concern for the possibility of false positives if the device was not used correctly.

There were general comments regarding the lack of data indicating this was a problem needing a mandated solution.

Ms. Juran shared that she did not believe the board's regulations were inconsistent on this matter. The requirements for a pharmacy to store drugs within the appropriate temperature range applies to all pharmacies permitted with Virginia as an in-state pharmacy or registered as a non-resident pharmacy. Additionally, drug delivered by any pharmacy in a manner that does not maintain appropriate temperature requirements could potentially be deemed adulterated under current State and federal law. Therefore, there is already an expectation under law that pharmacies deliver drugs in a manner that maintains appropriate temperatures or they could be found in violation of dispensing adulterated drugs. Ms. Juran further stated that drug manufacturers generally provide for allowable excursions in temperature during the transport and storage of drugs. While the recommended temperature monitoring devices may indicate if a particular temperature was reached, they do not typically indicate how long the drug was held at that particular temperature. Without knowing how long a drug was maintained at a temperature excursion, it is difficult to know if the drug has been negatively affected.

Ms. Cathcart questioned how this issue was impacted by pharmacy benefit managers.

MOTION:

The Board voted unanimously to close the discussion. (motion by Cathcart, second by Allen)

MOTION: **The Board voted seven to three to approve the Ad Hoc Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted. (motion by Warriner, second by Allen; Warriner, Thornbury and S. Elliott opposed)**

- Guidance For Complying With USP <800>

Ms. Shinaberry discussed the Committee's recommendation for inspectors to begin citing deficiencies as of July 1, 2018, but not to impose monetary sanctions. Beginning January 1, 2019, monetary sanctions should be imposed for non-compliance with the non-physical standards of chapter <800>. Beginning July 1, 2019, monetary sanctions should be imposed for the physical and engineering standards of Chapter <800>.

MOTION: **The Board voted unanimously to amend the ad hoc committee's recommendation to read: ..." inspectors begin *commenting on* deficiencies as of July 1, 2018, *and* impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (motion by Warriner, second by Allen)**

MOTION: **The Board voted eight to two to adopt the ad hoc committee's recommendation on enforcement of USP Chapter <800> as amended which reads "inspectors begin commenting on deficiencies as of July 1, 2018, and impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (motion by Warriner, second by Allen; Warriner and Saenz opposed)**

MOTION: **The Board voted unanimously to review draft amendments of Guidance Document 110-36, to include frequently asked questions on the enforcement of Chapter <800>, at the November Regulation Committee meeting with recommendations to the full board in December. (motion by Shinaberry, second by Warriner)**

- Guidelines for

Ms. Shinaberry reviewed the Committee's decision for staff to create a

Counseling on Drug Disposal (HB2016)

guidance document regarding the disposal of controlled substances.

MOTION:

The Board voted unanimously to accept the ad hoc committee's recommendation for staff to create a guidance document regarding the disposal of controlled substances which should include resources of information on the subject.

REGULATORY ACTIONS:

- Adoption of Regulation to Schedule Certain Chemicals in Schedule I

There was a public hearing conducted at 9:10AM this morning pursuant to requirements of §54.1-3443 of the Drug Control Act.

MOTION:

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

Research chemicals:

- **5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT)**
- **5-methoxy-N-methyl-N-isopropyltryptamine (other name: 5-MeO-MIPT)**
- **5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT)**
- **4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT)**
- **(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB)**
- **3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: (TH-PVP)**
- **4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone)**

Synthetic opioids:

- **2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl)**
- **N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl)**

Cannabimimetic agent:

- **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA)**

(motion by Warriner, second by Boone)

- Adoption of Proposed Regulations for Controlled Substances Registration for Entities that Dispense Naloxone

Emergency regulations were required to meet the mandate of the statute; they became effective May 8, 2017. A NOIRA was published simultaneously with the emergency regulations to replace them with permanent regulations. A comment period on the NOIRA ended 6/28/17; there were no comments.

or for Telemedicine

MOTION:

The Board voted unanimously to adopt the proposed replacement regulations for controlled substances registrations issued to certain entities that use DBHDS-approved REVIVE! Trainers to dispense naloxone or that participate in telemedicine resulting in the issuance of a prescription for a drug in Schedules II-V. (motion by Saenz, second by M. Elliott)

- Adoption of Amendments to Guidance Document 110-44, Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities

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

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-44, *Protocol for the Prescribing of Naloxone and Dispensing by Pharmacists and Distribution to Authorized Entities*, as presented. (motion by Thornbury, second by Boone)

- Exempt Regulatory Action to Amend 18VAC110-20-10 to Conform Definition of "Electronic Prescription"

The definition for electronic prescription in Regulation 18VAC110-20-10 is inconsistent with the definition in §54.1-3401of the Code, as of July 1, 2017. The amendment conforms the definition in the regulations to the definition of the Code.

MOTION:

The Board voted unanimously to amend the definition of "electronic prescription" in Regulation 18VAC110-20-10 as presented, to conform with the definition in §54.1-3401. (motion by Thornbury, second by Warriner)

- Adoption of Amendments to Guidance Document 110-35, Guidance on Virginia Prescription Requirements

It was determined that clarification was needed regarding which drugs may be electronically transmitted.

MOTION:

The Board voted unanimously to amend Guidance Document 110-35, *Guidance on Virginia Prescription Requirements*, as presented. (motion by Boone, second by Allen)

- Repeal Guidance Document 110-26, Re-dispensing Drugs Previously Dispensed in

It came to the attention of board staff that Guidance Document 110-26, *Re-dispensing Drugs Previously Dispensed in Compliance Packaging*, adopted on September 26, 2015, is in direct conflict with FDA Repackaging Guidance published January 2017. Board staff requested the

Compliance Packaging — Board repeal the guidance document so that licensees are not performing tasks that are in direct conflict with FDA guidelines.

MOTION: **The Board voted to repeal Guidance Document 110-26, Re-dispensing Drugs Previously Dispensed in Compliance Packaging. (motion by Saenz, second by Boone, Cathcart abstained)**

- Adoption of Amendment to Guidance Document 110-12, Bylaws of the Virginia Board of Pharmacy

On March 21, 2017, the Board elected to discontinue the administration of the Virginia Pharmacy Technician Examination as of September 1, 2017. Beginning September 1, 2017, students who have successfully completed a Board-approved pharmacy technician training program must choose to take either the PTCE or ExCPT examination prior to submitting an application to the Board for pharmacy technician registration. As a result, the Examination Committee is no longer necessary and should be removed from Guidance Document 110-12, *Bylaws of the Virginia Board of Pharmacy.*

MOTION: **The Board voted unanimously to amend Guidance Document 110-12, *Bylaws of the Virginia Board of Pharmacy*, as presented which deletes reference to a standing Examination Committee. (motion by Warriner, second by Saenz)**

- Revenue and Budget Analysis

Following a review of the Board of Pharmacy's Projected Revenue, Expenditure and Cash Balance for July 1, 2016 through June 30, 2020, the Board is projected to incur a deficit in FY18-20. It is recommended that the Board begin the process of increasing fees for persons and entities regulated by the Board. If a fee increase is enacted in anticipation of expenditures exceeding revenue, the increase can be smaller than if the action is taken at the time the deficit actually occurs.

MOTION: **The Board voted unanimously to submit a Notice of Intended Regulatory Action (NOIRA) for an increase in fees for persons and entities regulated by the Board of Pharmacy. (motion by Allen, second by Boone)**

NEW BUSINESS:

- Conflict of Interests

James Rutkowski provided an overview of prohibited conduct, definition of gifts and criminal and civil penalties related to Title 2.2, Chapter 31 - State and Local Government Conflict of Interests Act (2.2-3100 thru 2.2-3131). He encouraged the Board to review the chapter.

- Meeting Dates For 2018

The Board discussed meeting dates for 2018 and decided upon the following dates:

FULL BOARD MEETINGS:

- March 29, 2018
- June 21, 2018
- September 25, 2018
- December 18, 2018

REGULATION COMMITTEE MEETINGS:

- May 3, 2018
- November 28, 2018

REPORTS:

- Chairman's Report:

Mr. Logan thanked the Board for the opportunity to attend the NABP-AACP District I and II Annual Meeting held on September 14, 2017 and encouraged other Board members to attend future meetings. He briefly mentioned the resolutions passed by NABP District I.

- Report on Board of Health Professions:

Mr. Logan provided an update on the most recent Board of Health Professions (BHP) meeting. Draft minutes of the BHP meeting were included in the Board's agenda packet.

- Report on Licensure Program:

Ms. O'Halloran delivered the licensing report on behalf of Mr. Johnson who was attending an FDA meeting. She provided a handout summarizing that the Board issued 438 Pharmacists licenses and 621 Pharmacy Technician registrations from June 1, 2017 through August 31, 2017. Inspectors conducted 313 facility inspections including 232 routine inspections of pharmacies: 116 (37%) resulted in no deficiency, 117 (37%) with deficiencies, and 80 (26%) with deficiencies resulting in the issuance of a consent order.

ACTION ITEM:

The Board discussed the number of repeat deficiencies listed on the report. There was consensus that the Regulation Committee should consider the need for possible disciplinary action for repeat deficiencies and provide a recommendation to the Board in December.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of September 21, 2017. The report indicates that the Board had 294 open cases as of that date with 117 being patient care cases and 177 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 include: implementation of licensing pharmaceutical processors; HB2165 E-prescribing workgroup that met August 2nd and 29th with the preparation of an interim progress report for legislators.

CONSIDERATION OF CONSENT ORDER

Closed Meeting:

Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the Board voted 10-0 to convene a closed meeting pursuant to § 2.2-3711 (A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a Consent Order. Additionally, He moved that Caroline Juran, Cathy Reiniers-Day, James Rutkowski and Sylvia Tamayo-Suijk attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its

deliberations.

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

MOTION: **Upon a motion by Ms. Warriner, and duly seconded by Mr. Saenz, the Board voted 10-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Ryan Hypes, a pharmacy technician.**

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:25pm.

Ryan Logan, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS

September 26, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:10a.m.

PRESIDING: Ryan K. Logan, Chairman

MEMBERS PRESENT:
Jody Allen
Melvin L. Boone, Sr.
Freeda Cathcart
Rafael Saenz
Ellen B. Shinaberry
Rebecca Thornbury
Michael I. Elliott (arrived at 9:12am)

MEMBERS ABSENT:
Sheila K. W. Elliott
Cynthia Warriner

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

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

PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS: Pursuant to subsection D of §54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

CALL FOR COMMENT: Mr. Logan called for comment to consider placement of the

following chemical substances into Schedule I:

Classified as research chemicals:

- 5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT)
- 5-methoxy-N-methyl-N-isopropyltryptamine (other name: 5-MeO-MIPT)
- 5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT)
- 4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT)
- (N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB)
- 3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: (TH-PVP)
- 4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone)

Classified as powerful synthetic opioids:

- 2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl)
- N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl)

Classified as a cannabimimetic agent:

- N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA)

PUBLIC COMMENT: No public comment was provided.

ADJOURN: The public hearing adjourned at 9:13am.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARINGS FOR: DISPENSING SCHEDULE VI DRUGS IN EXCESS OF QUANTITY PRESCRIBED AND USE OF AUTOMATED DISPENSING DEVICES

September 26, 2017
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearings were called to order at 9:13a.m.

PRESIDING: Ryan Logan, Chairman

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

MEMBERS ABSENT: Cynthia Warriner

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

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

PUBLIC HEARING FOR DISPENSING SCHEDULE VI DRUGS IN EXCESS OF QUANTITY PRESCRIBED AND USE OF AUTOMATED DISPENSING DEVICES

CALL FOR PUBLIC COMMENT: Mr. Logan called for comment to consider the proposed regulations for Dispensing Schedule VI Drugs in Excess and Use of Automated Dispensing Devices. No public comment was offered.

The comment period ends on November 3, 2017.

ADJOURN: The public hearing adjourned at 9:15am.

Ryan Logan, Chairman

Caroline D. Juran, Executive Director

Date

Date

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

Tuesday, September 26, 2017
Commonwealth Conference Center
Second Floor
Board Room 4

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 2:53 pm.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Michael Elliott
Cynthia Warriner

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

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

CORINTHIANS A. HUGHEY
License No. 0202-212123

A formal hearing was held in the matter of Corinthians Hughey to discuss 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. Hughey was present.

Kathy Stowe, Gloval Investigator, Walmart, testified by telephone and Albelardo Mondragon, Loss Prevention, Walmart and Kevin Pultz, DHP Senior Investigator testified in person on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Mr. Elliott, and duly seconded by Ms. Allen, 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 Corinthians Hughey. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran 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 Ms. Allen, and duly seconded by Mr. Boone, the panel voted 5-0 to accept the Findings and Facts and Conclusion of Law proposed by Mr. Halbleib and amended by the board. Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the panel voted 5-0 to indefinitely suspend Mr. Hughey's right to renew his pharmacist license for no less than two years.
ADJOURN:	With all business concluded, the meeting adjourned at 5:25 pm.

Ryan Logan, Chair

Cathy Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, September 27, 2017
Commonwealth Conference Center
Second Floor
Training Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:10 a.m.
PRESIDING:	Jody Allen, Committee Chair
MEMBERS PRESENT:	Sheila K.W. Elliott, Committee Member
STAFF PRESENT:	Beth L. O'Halloran, Deputy Executive Director Cathy Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
JORDAN ADDLEMAN Pharmacy technician registration #0230008849	Jordan Addleman, pharmacy technician, attended to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 24, 2017 Notice.
Closed Meeting:	Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jordan Addleman. Additionally, she moved that Beth L. O'Halloran and Cathy Reiniers-Day 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 Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Jordan Addleman in violation of failing to complete required continuing pharmacy education

and unanimously voted to enter an Order that imposes a reprimand of his pharmacy technician registration.

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

SENTARA RMH MEDICAL CENTER PHARMACY
Pharmacy Permit #0201000990

Jamin C. Engel, Pharmacist-In-Charge, attended the meeting to discuss allegations that Sentara RMH Medical Center Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Sentara RMH Medical Center Pharmacy. Additionally, she moved that Beth L. O'Halloran and Cathy Reiniers-Day 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 Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that found the pharmacy violated certain laws and regulations

and imposed a $500 monetary penalty.

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

KARRI ELIZABETH LOCKWOOD
Pharmacist License #0202210142

Karri Elizabeth Lockwood, pharmacist, and Robin Abbott, counsel to Ms. Lockwood, attended to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 24, 2017 Notice

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Karri Elizabeth Lockwood. Additionally, she moved that Beth L. O'Halloran and Cathy Reiniers-Day 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 Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Karri Elizabeth Lockwood in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an

Order that imposes a reprimand on her pharmacist license.

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

SURAFEL DAWIT ABEBE
Pharmacy Technician Registration
#0230018577

Surafel Dawit Abebe, pharmacy technician, did not attend to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 24, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Surafel Dawit Abebe. Additionally, she moved that Beth L. O'Halloran and Cathy Reiniers-Day 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 Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Surafel Dawit Abebe 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 Surafel Dawit Abebe, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Surafel Dawit Abebe 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 FORD BARCLAY
Pharmacy Technician Registration
#0230009543

Jennifer Ford Barclay, pharmacy technician, attended the meeting to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 24, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jennifer Ford Barclay. Additionally, she moved that Beth L. O'Halloran and Cathy Reiniers-Day 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 Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Jennifer Ford Barclay 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 Jennifer Ford Barclay, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Jennifer Ford Barclay 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.

PEGGY ALTENOR
Pharmacy Technician Registration
#0230026333

Peggy Altenor, 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 August 24, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Peggy Altenor 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 Peggy Altenor, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Peggy Altenor 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.

MELISSA MARIE ARREDONDO
Pharmacy Technician Registration
#0230020605

Melissa Marie Arredondo, 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

August 24, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Melissa Marie Arredondo 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 Melissa Marie Arredondo, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Melissa Marie Arredondo 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.

CAROLYN JOAN COMPTON
Pharmacy Technician Registration
#02030003812

Carolyn Joan Compton, 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 August 24, 2017 Notice.

Decision:

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

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

RACHEL MARCIA DIMARTINO
Pharmacist License # 0202206173

Rachel Marcia DiMartino, pharmacist, did not attend the meeting to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Rachel Marcia DiMartino in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand on their pharmacist license.

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

NADIA MOHAMED
Pharmacy Technician Registration
#0230022509

Nadia Mohamed, pharmacy technician, did not attend the meeting to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and

found Nadia Mohamed in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand on their pharmacy technician registration.

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

SAMANTHA KAY RASSIER
Pharmacy Technician Registration
#0230017246

Samantha Kay Rassier, pharmacy technician, did not attend the meeting to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Decision:

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

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

ANNA MARIE RICHARDSON
Pharmacy Technician Registration
#0230002657

Anna Marie Richardson, pharmacy technician, did not attend the meeting to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Decision:

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

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

CRYSTAL SPRATLEY
Pharmacy Technician Registration
#0230025259

Crystal Spratley, pharmacy technician, did not attend the meeting to discuss allegations that she may have violated certain laws and regulations governing the conduct of pharmacy as stated in the August 24, 2017 Notice.

Decision:

Upon a motion by Ms. Elliott, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and found Crystal Spratley in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand on 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 Spratley, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Crystal Spratley 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 2:00p.m.

Jody Allen, Chair

Beth O'Halloran, Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, October 2, 2017

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on October 2, 2017, at 12:10 p.m., to consider the summary suspension of the license of John E. Harris to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: Michael Elliott, Chair

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Freeda Cathcart
Sheila Elliott
Ellen Shinaberry

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
Mykl Egan, DHP Adjudication Specialist
James Rutkowski, Assistant Attorney General
James Schliessmann, Senior Assistant Attorney General/Chief

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

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

JOHN E. HARRIS License No. 0202-010703	James Schliessmann presented a summary of the evidence in this case.
DECISION:	Upon a motion by Ms. Allen and duly seconded by Ms. Cathcart, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by John Harris poses a substantial danger to the public; and therefore, the license of Mr. Harris shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Mr. Harris for the revocation of his license for a period of not less than two years.
ADJOURN:	With all business concluded, the meeting adjourned at 12:39 p.m.

Michael Elliott, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, October 10, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

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

PRESIDING:	Jody Allen, Committee Chair
MEMBERS PRESENT:	Rafael Saenz, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
Angela D. Hornsby-Spencer License No. 0202-009242	Angel Hornsby-Spencer appeared with Barbara Queen, her attorney, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 25, 2017 Notice.
Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, 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 Angela Hornsby-Spencer. Additionally, he 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 Mr. Saenz, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order to reprimand Ms. Hornsby-Spencer.
Yogesh G. Sapre License No. 0202-207754	Yogesh Sapre appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 25, 2017 Notice.

Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, 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 Yogesh Sapre. Additionally, he 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 Mr. Saenz, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order that Mr. Sapre must obtain two additional hours of continuing education in the subject of medication errors.
Helen J. Sands License No. 0202-010442	Helen Sands appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 25, 2017 Notice.
Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, 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 Helen Sands. Additionally, he 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 Mr. Saenz, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order to reprimand Ms. Sands.

American National University Registration No. 0229-000035	American National University did not appear to discuss allegations that it may have violated certain laws and regulations governing the practice of pharmacy as stated in the July 20, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to American National University's legal address of record. Further, Ms. Reiniers-Day advised the committee that Cathy Plunkett, the Executive Vice President of Academic Affairs and Accreditation, called and advised that no one from the program would attend.
Closed Meeting:	Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, 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 American National University. Additionally, he 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 Mr. Saenz, and duly seconded by Ms. Allen, the Committee unanimously voted to issue an Order imposing a monetary penalty.
ADJOURN:	With all business concluded, the meeting adjourned at 2:50 p.m.

_____
Jody Allen, Chair

_____
Date

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING

November 2, 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 9:10am.
PRESIDING:	Michael Elliott, Committee Chairman
MEMBERS PRESENT:	Sheila Elliott Ryan Logan Rafael Saenz Rebecca Thornbury
STAFF PRESENT:	Caroline D. Juran, Executive Director Cathy M. Reiniers-Day, Deputy Executive Director J. Samuel Johnson, Jr., Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst Sylvia Tamayo-Suijk, Executive Assistant
APPROVAL OF AGENDA:	An Amended Agenda was presented for review to include discussion of deficiency #9 regarding Enclosure as listed in Guidance Document 110-9 and amending Regulation 18VAC110-20-540 to allow naloxone in Emergency Drug Kits.
MOTION:	**The Committee voted unanimously to approve the amended agenda as presented for the Regulation Committee meeting (motion by S. Elliott, second by Saenz).**
PUBLIC COMMENT:	There was no public comment offered.
AGENDA ITEMS:	
Amend Guidance Document 110-36, *Compliance with USP Standard for Compounding*	USP published a notification of intent to revise the effective date of Chapter <800> to December 1, 2019. The committee reviewed proposed changes to Guidance Document 110-36 which reflect the new implementation deadline date for compliance with Chapter <800>. The committee recommended that the Board begin the educational process through inspections within the next six months. Additionally, the committee recommended that the Guidance Document include USP's Frequently Asked Questions for Chapter <800> and a link to the National

Institute of Occupational Safety and Health (NIOSH).

- **MOTION:** **The Committee voted unanimously to recommend to the full board to amend Guidance Document 110-36 as presented, include USP's Frequently Asked Questions for Chapter <800>, add a link to the National Institute of Occupational Safety and Health (NIOSH) list, and begin the education process though inspections (which will not result in disciplinary action prior to the effective date of the chapter) within the next six months. (motion by Saenz, second by Thornbury)**

Discuss Piloting Changes to Physician Selling Inspection Program

The Board adopted Guidance Document 110-23, *Practitioners of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide* on March 26, 2014. At that time the board wanted to pilot the issuance of an expedited pre-hearing consent order at the conclusion of routine inspections which is akin to the process used for routine pharmacy inspections. The pilot was subsequently tabled until a legislative proposal authorizing the Board to permit the facilities from where physicians dispense could be passed. Mr. Johnson briefly reviewed Guidance Document 110-23, *Practitioners of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide.* The committee recommended removing the terms "major" and "minor" from the deficiency titles to be consistent with changes made in the recent past to Guidance Document 110-9, as well as removing Minor Deficiency #13 in light of a regulatory amendment (Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.) Additionally, the committee recommended that staff cross-walk the entire document to determine if additional edits were necessary based on regulatory amendments and to move forward with the process and implement a one year pilot program.

- **ACTION ITEM:** **The Committee requested staff to cross-walk Guidance Document 110-23 with Guidance Document 110-9 for consistency and with current regulations to determine if additional edits were necessary, and to present the full Board with a timeline for the start of the one year pilot program.**

- **MOTION:** **The committee voted unanimously to recommend to the full board that it amend Guidance Document (GD) 110-23 by striking "major" and "minor" from the deficiency titles and striking Deficiency #13, and to move forward with piloting for one year the issuance of expedited pre-hearing consent orders at the conclusion of routine inspections of practitioners of the healing arts to sell controlled substances when deficiencies listed in GD 110-23 are cited. (motion by S. Elliott, second by Logan)**

Adopt Regulation to Address White Bagging/Brown Bagging

The Committee revisited discussion regarding possible regulatory concepts to address patient-safety concerns with white bagging and brown bagging.

- **MOTION:** **The Committee voted unanimously to recommend to the full board to adopt a NOIRA to address white bagging and brown bagging that includes:**
  - **A definition of white bagging and brown bagging;**
  - **Prohibition of brown bagging of drugs requiring reconstitution or compounding prior to administration;**
  - **Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care, to provide an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped. (motion by Saenz, second by Thornbury)**

Amend Regulation 18VAC110-20-390, *Kickbacks, fee-splitting, interference with supplier*

- **MOTION:** **The committee voted unanimously to recommend to the full board to amend 18VAC110-20-390 as presented which strikes the phrase in subsection A, "unless fully disclosed in writing to the patient and any third party payor". (motion by Saenz, second by S. Elliott)**

Consider Possible Disciplinary Action for Repeat Deficiencies

The Committee reviewed the chart of Repeat Deficiencies by Quarter from February 2014 to August 2017. Deficiency #15, Perpetual Inventory, was of some concern and there was discussion as to the cause of the repeats, how many are considered acceptable and how many repeats resulted from how many inspections. Ms. Elliott suggested that increasing the penalty fee from $250 to $750 might result in a decreased number of deficiencies.

- **MOTION:** **A motion to recommend to the full board to increase the penalty fee for Perpetual Inventory deficiency to $750 was made by Ms. Elliott, but died for lack of second.**

- **MOTION:** **The committee voted unanimously to request staff to continue monitoring the prevalence of repeat deficiencies, particularly the one involving perpetual inventories. (motion by Logan, second by Thornbury)**

- **ACTION ITEM:** **The committee requested that Mr. Johnson amend the licensure/inspection report he provides at the full board meetings to reflect the number of repeat deficiencies in the current quarter and cumulatively in all quarters listed on the report.**

Discuss Deficiency #9 regarding Enclosure as listed in Guidance Document 110-9, *Pharmacy*

Inspection Deficiency Monetary Penalty Guide

- **MOTION:**

The committee voted unanimously to take no action on deficiency #9. (motion by Logan, second by S. Elliott)

Amend Regulation 18VAC110-20-540, *Emergency Drug Kit*

Ms. Juran reported that the Department of Corrections would like the ability to have intranasal naloxone in the emergency drug kits. Currently, the regulation restricts the contents of the emergency drug kit to drugs for injection and inhalation, with some exception.

- **MOTION:**

The committee voted unanimously to recommend to the full board to take emergency action to amend 18VAC110-20-540 to include intranasal formulations of naloxone in emergency kits. (motion by Saenz, second by Thornbury)

ADJOURN:

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

Michael Elliott, Chairman

Caroline D. Juran, Executive Director

DATE

DATE

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

Thursday, November 2, 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 1:40 pm.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Michael Elliott
Sheila Elliott
Rafael Saenz
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, 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.

ADRIAN M. TAYLOR
Registration No. 0230-014159

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

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

Ms. Taylor was present.

Christopher Bowers, Intake Admission Coordinator, Virginia Health Practitioners' Monitoring Program testified by telephone and Kevin Pultz, DHP Senior Investigator and Jill Stepnowski, Target Pharmacy Manager, testified in person on behalf of the Commonwealth.

Ms. Taylor testified on her own behalf.

CLOSED MEETING:	Upon a motion by Mr. Elliott, and duly seconded by Ms. Thornbury, 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 Adrian Taylor. Additionally, he moved that 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. Elliott, and duly seconded by Ms. Thornbury, the panel voted 5-0 to accept the Findings and Facts and Conclusion of Law proposed by Mr. Halbleib and amended by the board and to indefinitely suspend Ms. Taylor's pharmacy technician registration until she can provide evidence that she is safe and competent to practice.
ADJOURN:	With all business concluded, the meeting adjourned at 3:45 pm.

Ryan Logan, Chair

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, November 7, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

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

PRESIDING:	Michael Elliott, Committee Chair
MEMBERS PRESENT:	Ellen Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
Bryan T. Ratliff License No. 0202-009432	Bryan Ratliff appeared with Stephen Rosenthal, his attorney, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2017 Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, 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 Bryan Ratliff. 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. Shinaberry, and duly seconded by Mr. Elliott, the Committee unanimously voted to issue an Order to dismiss this matter.
Stephanie B. Wilkerson Registration No. 0230-021206	Stephanie Wilkerson appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 11, 2017 Notice.

Closed Meeting:	Upon a motion by Ms. Shinaberry, 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 Stephanie Wilkerson. 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. Shinaberry, and duly seconded by Mr. Elliott, the Committee unanimously voted to offer Ms. Wilkerson a Consent Order for the indefinite suspension of her right to renew her pharmacy technician registration.
Myckieala C. Cooper License No. 0202-209657	Myckieala Cooper appeared with Jill R. Schmidtke, her attorney, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the April 24, 2017 Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, 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 Myckieala Cooper. 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. Shinaberry, and duly seconded by Mr. Allen, the Committee unanimously voted to issue an Order for Ms. Cooper to comply with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 2:50 p.m.

Michael Elliott, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Date

Agenda Item:

Summary of legislative proposals from the Department of Health Professions

Summary of legislation already introduced for the 2018 Session of the General Assembly

Department of Health Professions

Legislative Proposals for 2018 General Assembly

1) Delivery of DHP subpoenas
   Authorize the Department to deliver a subpoena issued pursuant to enforcement of law by registered or certified mail or by commercial parcel delivery service. It will also specify that the Department may seek enforcement of the subpoena in cases of non-compliance.

2) Clarification for electronic renewal notice
   Amend Code sections for the Boards of Funeral Directors and Embalmers, Medicine, and Nursing that require renewal notices to be sent by "mail" to licensees. The amendments will clarify that the board may send such notices electronically.

3) Addition of schedule V and naxolone to PMP
   Add Schedule V drugs for which a prescription has been written and also the drug naloxone to the definition of covered substances to be included on a Prescription Monitoring Program (PMP) report.

4) Student exemption for polysomnographic tech
   Amend the Code relating to a requirement for licensure to practice as a polysomnographic technologist to allow for practice under supervision by a student or person in training for a period of 18 months from the start of the educational program or traineeship extending to a maximum of six months from conclusion of the program to allow time for processing an application for licensure.

5) Registration of nonresident warehousers and third-party logistics
   Authorize the Board of Pharmacy to register nonresident warehousers and nonresident third-party logistics providers and to promulgate regulations as necessary to prevent diversion and to protect the public.

6) Fentanyl class in Drug Control Act
   Amend Schedule I of the Drug Control Act to place a fentanyl classification system so a drug with a new fentanyl substance could be immediately deemed to be an illegal substance.

7) Mid-level licensure for SW
   Create three levels of licensure with a distinction between the bachelor's and master's level persons with a generalist practice and the master's level person who has the education and supervised person to provide clinical social work services.

SB 23 Health insurance; coverage for limited drug refills.

Introduced by: **Lionell Spruill, Sr. | all patrons** ... **notes | add to my profiles**

SUMMARY AS INTRODUCED:

Health insurance; coverage for limited drug refills. Requires health benefit plans to cover a limited refill for up to a five days' supply of a Schedule VI drug that is dispensed by a pharmacist for a covered person whose dispensed drugs are lost, destroyed, or otherwise rendered unusable as a consequence of a natural or man-made disaster that displaces the person from his residence.

SB 25 Drug Control Act; dispensing drugs without a prescription.

Introduced by: **Lionell Spruill, Sr. | all patrons** ... **notes | add to my profiles**

SUMMARY AS INTRODUCED:

Dispensing drugs without a prescription. Authorizes a pharmacist to dispense up to a five-day supply of a Schedule VI drug to an individual who has been displaced from his residence by a natural or man-made disaster; has had his supply of the drug lost, destroyed, or otherwise rendered unusable as a consequence of the disaster; and is unable to tell the pharmacist the identity of the prescriber or his regular pharmacist or pharmacy. The bill also requires the individual to present evidence sufficient to establish, among other things, that the individual had been in lawful possession of the drug pursuant to a prescription provided to another pharmacist and that his health would be in danger without the benefits of the drug. Before prescribing the drug, the pharmacist is required to determine with a reasonable degree of certainty that the requested drug and dosage level are consistent with the drug and its dosage level that had been prescribed to the individual at the time of his displacement from his residence. During the period for which the drug has been dispensed, the pharmacist is required to diligently attempt to ascertain the identity of the prescriber and the identity of the pharmacist or pharmacy in possession of the prescriber's prescription. Upon obtaining such information, the pharmacist is required to take such additional reasonable action as will permit the individual to obtain a new or renewal prescription and resume obtaining the drug pursuant to his prescription.

Board of Pharmacy

Chart of Regulatory Actions as of November 29, 2017

Board **Board of Pharmacy**

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Requirement for applicants and licensees to have an e-profile ID number [Action 4909] NOIRA - *Register Date: 11/13/17* [Stage 8056] Comment closes: 12/13/17
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] NOIRA - *At Governor's Office for 26 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] Proposed - *Register Date: 9/4/17* [Stage 7885] Board to adopt final: 12/11/17
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Proposed - *DPB Review in progress* [Stage 8101]
[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] Proposed - *At Agency* [Stage 8119]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 175 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Chemicals in Schedule I [Action 4936] Final - *Register Date: 11/13/17* *Effective: 12/13/17*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *Register Date: 8/7/17* [Stage 7740

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 December 13, 2017. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

Project 5350 - none

BOARD OF PHARMACY

Chemicals in Schedule I 12-17

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. 2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine), 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. 2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP), 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. alpha-ethylaminohexanophenone (other name: N-ethylhexedrone), 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. N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE), 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. 4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP), 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. N-ethyl-1,2-diphenylethylamine (other name: Ephenidine), 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. Synthetic opioids.

a. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole 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.

b. 3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900), 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.

c. 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino) cyclohexyl]-N-methylacetamide (other name: U-48800), 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.

7. Central nervous system stimulants.

a. Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (4-fluoromethylphenidate), including its salts, isomers and salts of isomers.

b. Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate), including its salts, isomers and salts of isomers.

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

Agenda Item: **Final Action – Petitions for rulemaking**

Enclosed:

Copy of summary of action from the Regulatory Townhall

Copy of proposed regulation with amendment to Section 540

Staff note:

At the November 2nd meeting of the Regulation Committee, it was reported that the Department of Corrections had requested authorization to include the intranasal formulation of naloxone in emergency kits. The Committee recommended action to amend Section 540 accordingly.

Since section 540 is included in this action, the amendment has been added in the adoption of a final action.

Board action:

Motion to adopt the proposed regulations as a final action with an amendment to Section 540 to allow inclusion of the intranasal formulation of naloxone in an emergency kit.

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Department of Health Professions

Board **Board of Pharmacy**

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

Action: Response to petitions for rulemaking

Action 4694 / Stage 7885

Proposed Stage

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	4/12/2017 3:01 pm	Sync Text with RIS
Agency Statement	3/29/2017	Upload / Replace
Attorney General Certification	4/13/2017	
DPB Economic Impact Analysis	5/27/2017 (modified 5/30/2017)	
Agency Response to EIA	8/10/2017	Upload / Replace
Governor's Approval Memo	8/4/2017	
Registrar Transmittal	8/10/2017	

Status	
Incorporation by Reference	No
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 Review Completed: 4/13/2017 Result: Certified
DPB Review	Submitted on 4/13/2017 Economist: Amy Hunter Policy Analyst: Jeannine Rose Review Completed: 5/27/2017 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 6/6/2017

Governor's Review	Review Completed: 8/4/2017 Result: Approved
Virginia Registrar	Submitted on 8/10/2017 **The Virginia Register of Regulations** Publication Date: 9/4/2017 **Volume: 34 Issue: 1**
Public Hearings	**09/26/2017 9:05 AM**
Comment Period	Ended 11/3/2017 0 comments

Contact Information

Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 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.
16

Project 4952 - Proposed

BOARD OF PHARMACY

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 [, and the intranasal spray formulation of naloxone] 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.

Agenda Item: Adoption of two changes to proposed amendments for Periodic Review of Chapter 20 and new Chapter 21

Included in your agenda package is:

Copy of sections on kickbacks

Copy of definition of electronic prescriptions

Staff note:

1) The Regulation Committee recommended an amendment to section 390 to eliminate provision "unless fully disclosed in writing to the patients and any third party payor." Since this section is already being amended in the Periodic Review, the Board can add the amendment to the kickback section without starting another regulatory action.

2) The Board voted at its September meeting to amend the definition of electronic prescriptions to conform to a change in definition resulting from 2017 legislation. Since the effective date of the legislation was delayed until 2020, the action cannot be promulgated as an exempt action. Rather than starting with another regulatory action, staff recommends adding the amendment to the periodic review action.

Board action:

To amend the sections 10 and 390 in Chapter 20 and section 45 in Chapter 21 by deletion of the phrase "unless fully disclosed in writing to the patients and any third party payor" and amending the definition of "electronic prescriptions."

18VAC110-20-390. Kickbacks, fee-splitting, interference with supplier.

A. A ~~pharmacist~~ pharmacy shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payor~~.

B. A ~~pharmacist~~ pharmacy shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

18VAC110-21-45. Kickbacks, fee-splitting, interference with supplier.

A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders ~~unless fully disclosed in writing to the patient and any third party payor~~.

B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

"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~~.

Agenda Item: **Final Action – Petition for rulemaking**

Enclosed:

Copy of Petition from Mr. Lavino from CVS Health

Copy of request for comment

Copy of 2 comments posted on Townhall

Staff note:

Comment on the petition closed on 11/22/17

Board action:

Motion to adopt:

1) Accept the petitioner's request and initiate rulemaking the publication of a Notice of Intended Regulatory Action; or
2) Reject the petitioner's request and state the reasons for deciding not to initiate rulemaking.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle initial, Suffix,) Lavino, Joseph		
Street Address 1 CVS Drive, Mail Code 2325	Area Code and Telephone Number 401-369-0745	
City Woonsocket	State RI	Zip Code 01887
Email Address (optional) Joseph.Lavino@CVSHealth.com	Fax (optional)	

Respond to the following questions:

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

CVS Health is petitioning the Virginia Board of Pharmacy, to amend18 VAC 110-20-275(B)(2)(d), which pertains to the delivery of dispensed prescriptions.

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

18 VAC 110-20-275(B)(2)(d) requires that pharmacies, which fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup, maintain and comply with all procedures in a current policy and procedure manual that includes the procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription. While the regulation contemplates a model where a pharmacy is filling a prescription on behalf of a requesting pharmacy, which subsequently receives the prescription back for delivery, we do not believe the regulation contemplates situations where prescriptions are held for pick-up or further delivery at a pharmacy location, at a patient's request and without that pharmacy location's involvement in any part in the dispensing process other than delivery to the patient or the patient's agent ("Depot pharmacy").

Based on the current interpretation of the Virginia Board of pharmacy, in those cases where prescriptions are held for pick-up or further delivery at a depot pharmacy, the label on the prescription container would require the name and address of the pharmacy holding the prescription for pick-up or further delivery. This creates potential patient safety risks, confusion for patients and a redundancy.

As the Board is aware, the ability to craft a prescription label with adequate font size, white space, and highlighting of critical prescription elements is an essential component in driving patient adherence to medication as prescribed. The addition of a depot pharmacy name and address to a label may have the potential of encroaching on the essential elements of a label needed to drive adherence. Per the NABP Model State Pharmacy Act and Model Rules, the pharmacy name, while considered important information on a label, is not considered critical information for patients and should not supersede critical label information. Additionally, the Institute for Safe Medication Practices ("ISMP"), whose position is that the risk of medication error can occur when labels are poorly designed, made several recommendations on pharmacy label design based on an analysis of actual medication errors reported and a review of pharmacy-generated labels produced by a number of systems. Based on those recommendations, ISMP concluded that a pharmacy's information, if required at all, is not a critical element to reduce medication errors and may be placed at the bottom of the label. Of note, this recommendation contemplates the inclusion of information on a single pharmacy rather than multiple pharmacies, if required at all.

Secondly, the addition of a depot pharmacy name and address to a label may cause confusion to the patient. A pharmacy that did not participate in the filling and dispensing of a prescription, and serves solely to deliver the prescription to the patient or their agent, would not be best positioned to answer patient questions on the filling and dispensing processes of that prescription from a patient. The patient may be further confused as to which pharmacy(s) actually performed prescription processing or filling functions, mistaking the depot pharmacy as providing those functions.

Lastly, the addition of a depot pharmacy name and address to a label, for the sole purpose of providing the patient information on which pharmacy held the prescription for pick-up or further delivered it is a redundancy. The patient would likely be provided additional information or documentation (i.e. a leaflet or receipt) indicating the name and address of the pharmacy, which held the prescription for pick-up or further delivered the prescription to the patient. In the case of a patient or patient's agent physically presenting to a depot pharmacy, the patient or patient's agent would be physically present and have firsthand knowledge of which pharmacy delivered the prescription. Lastly, the patient or patient's agent would have knowledge of the name and address of the depot pharmacy because they would be in control of requesting the pharmacy location at which to pick-up the prescription.

Given these factors, CVS Health proposes the following amendments to 18 VAC 110-20-275(B)(2)(d):

d. The procedure for identifying on the prescription label a unique identifier for all pharmacies involved in filling and dispensing the prescription. This unique identifier is not required to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions;

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

The general powers and duties of the Virginia Board of Pharmacy shall be to promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.

Signature:	Date: 7/21/2017

Request for Comment on Petition for Rulemaking

Promulgating Board: Board of Pharmacy

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

Agency Contact: Caroline Juran, RPh
Executive Director
(804)367-4456

caroline.juran@dhp.virginia.gov

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

Chapter Affected:

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

Date Petition Received 09/28/2017

Petitioner Joseph Lavino for CVS Health

Petitioner's Request

To amend 18VAC110-20-275(B)(2)(d) to read: d. The procedure for identifying on the prescription label a unique identifier for all pharmacies involved in filing and dispensing the prescription. This unique identifier is not required to identify a pharmacy solely involved in the holding of a prescription for pick-up or further delivery when that pharmacy has not shared in other filling or dispensing functions;

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on October 30, 2017. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until November 22, 2017. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for December 11, 2017.

Publication Date 10/30/2017 *(comment period will also begin on this date)*

Comment End Date 11/22/2017

♥CVSHealth

Lauren Berton, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

November 20, 2017

Caroline Juran, RPH
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463
Caroline.juran@dhp.virginia.gov

Re: Proposed amendment to 18VAC110-20-275. Delivery of dispensed prescriptions.

Dear Executive Director Juran:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Virginia patients.

CVS Health appreciates the Board's acceptance of Petition for Rule-making to amend 18VAC 110-20-275 which changes the policy and procedure requirements for delivery to another pharmacy allowing for a unique identifier to be used in identifying all pharmacies used in filling and dispensing the prescription. Amendments also include the allowance for the unique identifier to not be placed on the label if the pharmacy solely holds the prescription for further pick up and delivery without being involved in the filling and dispensing. The Institute for Safe Medication Practices provided industry guidelines for medication labels for community and mail order pharmacies. They suggest maximixing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors. These changes would assist in achieving maximum white space, while still providing an audit trail for the tracking of the prescription as required.

CVS Health appreciates the opportunity to submit comments for this proposed rule amendment. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

CVSHealth

Lauren Berton, PharmD | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

November 20, 2017

Caroline Juran, RPH
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Suite 300
Richmond, VA 23233-1463
Caroline.juran@dhp.virginia.gov

Re: Proposed amendment to 18VAC110-20-275. Delivery of dispensed prescriptions.

Dear Executive Director Juran:

I am writing to you in my capacity as Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points to care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the Virginia Board of Pharmacy proposed amendment to 18VAC110-20-275 Delivery of Dispensed Prescriptions. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Virginia patients.

CVS Health appreciates the Board's acceptance of Petition for Rule-making to amend 18VAC 110-20-275 which changes the policy and procedure requirements for delivery to another pharmacy allowing for a unique identifier to be used in identifying all pharmacies used in filling and dispensing the prescription. Amendments also include the allowance for the unique identifier to not be placed on the label if the pharmacy solely holds the prescription for further pick up and delivery without being involved in the filling and dispensing. The Institute for Safe Medication Practices provided industry guidelines for medication labels for community and mail order pharmacies. They suggest maximixing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors. These changes would assist in achieving maximum white space, while still providing an audit trail for the tracking of the prescription as required.

CVS Health appreciates the opportunity to submit comments for this proposed rule amendment. If you have any questions, please contact me directly at 540-604-3661.

Sincerely,

Lauren Berton PharmD

Lauren Berton, PharmD.
Director, Pharmacy Regulatory Affairs
CVS Health

Virginia.gov Agencies | Governor

Logged in as
Elaine J. Yeatts

Department of Health Professions

Board Board of Pharmacy

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

All good comments for this forum Show Only Flagged

Back to List of Comments

Commenter: Keith Richardson 11/6/17 9:04 am

Reply

I am okay with removing the unique identifer as suggested by the petition for rulemaking

However to the best of my knowledge

National Council for Prescription Drug Programs (NCPDP) maintains NPI
(National Provider Identifier)

· All licensed pharmacies are assigned a seven digit number known as the **NCPDP** Provider **ID**.

National Provider Identifier (NPI) is a ten digit number

A npi is searchable and accessible online

A npi is synonymous to an individual

If the unique identifer is to be removed

Other than payor sheets

By which means does anyone have the ability to reference a pharamacy?

Is there a way to find a pharmacy?

Commenter: Rx Partnership 11/17/17 2:57 pm

Rx Partnership favors amendment

Rx Partnership, a nonprofit organization working statewide to increase medication access, supports this amendment as proposed in the petition. The change would increase efficiency and ease related to providing prescriptions for individuals who need a convenient location for pick-up that may not necessarily be where the prescription was filled.

We believe this amendment will help encourage more pharmacies to be involved in helping patients receive medications at a preferred location. Many of the low income and uninsured patients Rx Partnership supports experience transportation challenges and being able to receive medication(s) at a preferred pharmacy would greatly improve medication adherence and health outcomes.

Agenda Item: Revision of guidance document on Categories of Facility Licensure

Enclosed:

An amended draft of Guidance Document 110-1

Staff note:

New licensure categories as of July 1, 2017 have been added to document.

Board action:

Adoption of amendments to Guidance Document 110-1.

VIRGINIA BOARD OF PHARMACY
CATEGORIES OF FACILITY LICENSURE

PHARMACY: This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. Federal law allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

NONRESIDENT PHARMACY: This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

MEDICAL EQUIPMENT SUPPLIER: This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

NONRESIDENT MEDICAL EQUIPMENT SUPPLIER: This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user.

NONRESIDENT WHOLESALE DISTRIBUTOR: This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors.

WAREHOUSER: This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements. This permit may be preferable to the wholesale distributor license for those entities which distribute

prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user.

NON-RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs.

RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use.

NONRESIDENT MANUFACTURER:
This registration authorizes any manufacturer located outside the Commonwealth to ship prescription drugs into the Commonwealth..

CONTROLLED SUBSTANCES REGISTRATION (CSR): This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouser, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone reversal and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration to dispense naloxone without charge or compensation. 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 Schedule II through VI controlled substances may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

OUTSOURCING FACILITY: This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite, the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

NONRESIDENT OUTSOURCING FACILITY: This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and

regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

Practitioner of the Healing Arts to Sell Controlled Substance Facility Permit: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

THIRD-PARTY LOGISTICS PROVIDER:
This permit authorizes the permit holder, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate 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.

*** § 54.1-3455. Schedule VI.**
The following classes of drugs and devices shall be controlled by Schedule VI:
1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.
2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.
3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

Agenda item: Revision of guidance document on compiling with Continuing Education requirements

Enclosed:

An amended draft of Guidance Document 110-04

Staff note:

In addition to edits recommended for clarity, staff has added a Q & A on counting volunteer hours at a free clinic as continuing education.

Board action:

Adoption of amendments to Guidance Document:110-04.

Virginia Board of Pharmacy

Guide to Continuing Pharmacy Education Requirements

Since 1993, pharmacists who are licensed in Virginia have been required to obtain a minimum of 15 contact hours of continuing pharmacy education (CE) per calendar year in order to maintain an active license. Pharmacy technicians are required to obtain a minimum of 5 contact hours of CE per calendar year. This brochure is intended to help pharmacists and pharmacy technicians better understand the CE requirements. The Board of Pharmacy prepared this document as a guide in order to promote compliance with the statutes and regulations concerning CE.

Q. What is the minimum number of CE hours required? When do I have to take them?
A. The law requires a minimum of 15 contact hours for pharmacists and 5 contact hours for pharmacy technicians per calendar year. You should receive all your certificates prior to sending in the license renewal in order to properly attest that you have met the requirements. The certificates should be dated between January 1 and December 31, inclusive, of the calendar year they are used.

Q. May I use hours worked as a volunteer at a free clinic or local health department toward the continuing education requirement?
A. Yes. Up to two contact hours of the 15 contact hours required for pharmacist annual renewal and one contact hour of the 5 contact hours required for pharmacy technician annual renewal may be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One contact hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic on the "Continuing Education (CE) Credit Form for Volunteer Practice" found at www.dhp.virginia.gov/pharmacy under "Forms and Applications".

Q. May I carry over my extra hours to next year? What if I'm licensed in another state?
A. No. The law does not allow carryover. Although some states permit courses to be taken over a two-year period, Virginia does not. This means a pharmacist licensed in Virginia must obtain at least 15 CE hours each and every calendar year and technicians 5. However, if a pharmacist resides in another state whose requirements allow the pharmacist to spread out the required number of hours for more than one year, for example 30 hours every two years, and the pharmacist meets the CE requirements of that other state, Virginia will accept this provided the resident state board of pharmacy attests that the pharmacist has met its requirements and provided the CE requirement of the other state equates to an average of 15 hours a year over the time period allowed.

Q. May I obtain an extension?
A. Yes. A one-time extension may be possible if the request is made in writing to the Board prior to renewal. Any further extension requests will only be granted for good cause shown.

Q. What is the NABP CPE Monitor and must I sign up for this?
A. NABP CPE Monitor is a collaborative service from NABP and ACPE that provides an electronic system for pharmacists and pharmacy technicians to track their completed CE credits. All ACPE-approved continuing education credits are now required to report to CPE Monitor within 60 days of completion of a

course. In order to receive credit for an ACPE-approved continuing education course, you must have an e-profile ID number obtained from CPE Monitor through www.nabp.pharmacy and provide this number to receive credit for these ACPE-approved CE courses.

Q. I recently graduated from an ACPE-approved school of pharmacy in Virginia and obtained my initial pharmacist license. Do I need to obtain CE to renew my license for the first time?
A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination are not required to attest to having obtained CE during their first licensure renewal.

Q. I recently graduated from an ACPE-approved school of pharmacy in another state and obtained my initial pharmacist license in Virginia via score transfer. Do I need to obtain CE to renew my license for the first time?
A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination, to include via score transfer, are not required to attest to having obtained CE during their first licensure renewal.

Q. I am a pharmacist who has held licensure in another state for more than one year and recently endorsed/reciprocated my license to Virginia. Do I need to obtain CE to renew my license for the first time?
A. Yes, the Board interprets the exemption from CE in §54.1-3314.1 C to apply only to pharmacists who are truly in their first year of licensure as a pharmacist by examination.

Q. I am a graduate of a foreign school of pharmacy and have obtained my initial license as a pharmacist in the United States from Virginia. Do I need to obtain CE to renew my license for the first time?
A. No, the Board interprets the exemption from CE in §54.1-3314.1 C to mean pharmacists initially licensed by examination, to include foreign graduates, are not required to attest to having obtained CE during their first licensure renewal.

Q. I am a graduate of a foreign school of pharmacy who has held licensure as a pharmacist in another state and recently endorsed/reciprocated my license to Virginia. Do I need to obtain CE to renew my license for the first time?
A. Yes, the Board interprets the exemption from CE in §54.1-3314.1 C to apply only to pharmacists who are truly in their first year of licensure as a pharmacist by examination.

~~**Q. I received my pharmacist license from Virginia in November. When will I need to renew my license for the first time?**~~
~~A. Regulation 18VAC110-20-80 states that a pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.~~

Q. I received my pharmacist license from Virginia in October~~November~~. When will I need to renew my license for the first time and how do I comply with the CE requirement?
A. Regulation 18VAC110-20-80 states that a pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year. Regulation 18VAC110-20-90 states a pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. Therefore, unless exempted from obtaining CE as indicated in §54.1-3314.1 C and discussed above, the pharmacist must obtain 1.5 CEUs or 15 contact hours of CE between the date of issuance of the Virginia pharmacist license and December 31 of the following year.

Q. I received my pharmacy technician registration from Virginia in ~~July~~August. When will I need to renew my registration for the first time and how do I comply with the CE requirement?
A. Regulation 18VAC110-20-105 states that a pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Regulation 18VAC110-20-106 states a pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved CE for each annual renewal of registration. Therefore, the pharmacy technician must obtain 0.5 CEUs or 5 contact hours of CE between the date of issuance of the Virginia pharmacy technician registration and December 31 of the following year.

Q: Are pharmacy technicians required to obtain continuing education during the first year that they are registered?
A: Yes, pharmacy technicians are required to obtain 5 hours of continuing education annually. The exemption in §54.1-3314.1 C from obtaining CE during the first licensure renewal applies only to pharmacists.

Q. Do I have to obtain credits from any particular providers?
A. Yes. In order to meet the CE requirements, courses must be ACPE-approved, Board-approved, or certain Category 1 CME. Any credits taken that do not meet these requirements cannot be used to satisfy CE hours.

Q. I am a pharmacist or pharmacy technician actively taking courses in an ACPE accredited college of pharmacy. Do I have to obtain CE as well, or will my college of pharmacy coursework count as CE?
A. College of pharmacy coursework may possibly be counted, but must be approved by the Board. There is a form on the Board's website under "Forms and Applications", "Miscellaneous" to submit in order to obtain approval of a college of pharmacy course/courses. Only didactic and laboratory coursework will be considered, and the course must be completed prior to the end of the calendar year in which it is to be counted. Experiential hours, i.e. clerkships, will not be approved. Courses taken as prerequisite coursework for a college of pharmacy program are not approved.

Q. I've lost my certificates. What should I do?
A. You should obtain a replacement from the course provider. Some providers make it possible to print duplicates from their web sites. If the CE program awards credit through the NABP CPE Monitor, you may alternatively obtain a copy of your CE transcript online from the NABP CPE Monitor at www.nabp.net.

Q. Do I have to keep my certificates or CE transcript at work?
A. No. However, the originals certificates or printout of the CE transcript must be made available for audit.

Q. I've taken a course near the end of the year and didn't get my certificate until the next calendar year. How are the hours applied?
A. CE credit is awarded based on the date the certificate is issued or the date the hours are awarded. Live courses are counted on the date of attending the course.

Q. What should I do if the Board audits me?
A. Whenever the Board contacts you, you should respond promptly. Failure to respond may cause the Board to pursue disciplinary action. If the Board audits your continuing pharmacy education credits, find your original certificates and make a copy for yourself or download a copy of your transcript from NABP CPE Monitor and provide the Board with this transcript. Send the original certificates or printed transcript to the Board office by the deadline in the letter. Although not required, you may want to send your response by certified mail so that you have proof of mailing. If you have lost some or all of your certificates, you should immediately contact the respective providers for a replacement certificate and inform the Board of your

actions. The Board has approved standard sanctions for CE non-compliance which can be found in guidance document 110-42.

Q. What can I do to keep my records better organized?
A. Here are some suggestions that may help you to keep your CE records organized and avoid disciplinary action:
1. Store your original certificates in a safe place where they are unlikely to be thrown out by mistake.
2. Keep a copy of your certificates, or at least a record of the course number, provider and date, in a secondary safe location (not with the originals). These are a back-up if you lose the originals.
3. BEFORE YOU RENEW YOUR LICENSE, look at your original certificates and/or the NABP CPE Monitor to verify compliance with the CE requirements:

- 15 contact hours -for pharmacists or 5 for pharmacy technicians (some courses may carry a different number of credits for other professions)
- ACPE approved for either pharmacists, pharmacy technicians, or both (look for the ACPE logo), or Category 1 CME courses focused on pharmacy, pharmacology or drug therapy
- each of your CE certificates or the CE transcript shows a "date issued" on or prior to December 31 for the year in question.

Note: Pharmacists and pharmacy technicians are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. For programs that no longer issue CE certificates, but award credit through the NABP CPE Monitor, it is recommended that pharmacists and pharmacy technicians maintain a copy of their CE transcript from NABP for two years following renewal.

Agenda Item: **Adoption of NOIRA on White Bagging and Brown Bagging**

Enclosed:

Excerpt from Report on Pharmacy Benefit Managers Workgroup

Copy of resolution adopted at NABP and draft language for Model Act

Copy of draft NOIRA as recommended by the Regulation Committee

Staff note:

Background: Pharmacy Benefit Manager (PBM) Workgroup agreed that the Board of Pharmacy should address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the process. Full board in March agreed that the Regulation Committee should discuss issues of white bagging and brown bagging. Staff is only aware of Oregon having addressed white bagging in regulation, however, it appears to address reconstitution, but not other forms of compounding, and does not address brown bagging.

Board action:

Motion to adopt a Notice of Intended Regulatory Action relating to white-bagging and brown-bagging.

"White bagging and brown bagging"
These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans
Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations
Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management,

Study to Review the Practices of "White Bagging" and "Brown Bagging" (Resolution 112-1-16)

June 6, 2016

Topics: **Resolutions (https://nabp.pharmacy/category/resolutions/)**

Resolution No: 112-1-16
Title: Study to Review the Practices of "White Bagging" and "Brown Bagging"
Membership Vote: PASS

WHEREAS, "white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration;

WHEREAS, the practices of "white bagging" and "brown bagging" are becoming more prevalent and often defined and mandated by third-party payers outside of the authority of the state boards of pharmacy; and

WHEREAS, the need exists for the boards of pharmacy to define such practices and ensure appropriate regulatory oversight in order to protect patients;

THEREFORE BE IT RESOLVED that NABP conduct a study, which may include, if appropriate, other key health care stakeholders to review and define the practices of "white bagging" and "brown bagging" and recommend regulatory language, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to assist boards of pharmacy in overseeing and addressing the accountability and safety of medications dispensed and administered via these methods.

(Resolution passed at the 112th Annual Meeting in San Diego, CA.)

RECENT NEWS

NABP President Receives 2017 Outstanding Alumnus Award From UT Austin's College of Pharmacy *(https://nabp.pharmacy/nabp-president-receives-2017-outstanding-alumnus-award-ut-austins-college-pharmacy/)*
November 22, 2017

Tri-Regulator Collaborative Release Position Statements Addressing Electronic Health Records, Practitioner Burnout *(https://nabp.pharmacy/tri-regulator-collaborative-release-position-statements-addressing-electronic-health-records-practitioner-burnout/)*
September 20, 2017

So-Called "Canadian" Pharmacies are a Danger to Consumers, NABP Reports *(https://nabp.pharmacy/called-canadian-pharmacies-danger-consumers-nabp-reports/)*
August 21, 2017

NABP Earns Better Business Bureau Accreditation *(https://nabp.pharmacy/nabp-earns-better-business-bureau-accreditation/)*
August 14, 2017

NABP's PMP InterConnect Forges New Partnership with St Louis County *(https://nabp.pharmacy/nabps-pmp-interconnect-forges-new-partnership-st-louis-county/)*
July 12, 2017

National Association of Boards of Pharmacy
Model State Pharmacy Act

Article I

...

Section 105. Definitions.

(i) "Brown Bagging" means the dispensing of Specialty Drugs by a Specialty Pharmacy to a patient through home delivery, who takes the Drugs to the physician's office for administration.

...

(o6) "Specialty Drug" means a Drug used to treat a chronic or specific disease or condition that requires frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver.

(p6) "Specialty Pharmacy" means a Pharmacy that is providing Specialty Pharmacy Practice services and where Drugs, Devices, and other materials used in the diagnosis and treatment of injury, illness, and disease are Dispensed and Compounded.

(q6) "Specialty Pharmacy Practice" means the provision of Pharmacist Care Services, which involves Drugs used to treat chronic or specific diseases and conditions that require frequent communication with other health care providers, extensive patient monitoring and case management, and comprehensive counseling with the patient and/or caregiver. Drugs Dispensed by a Specialty Pharmacy may also require instruction and training on complex administration processes and/or handling and storage considerations.

...

(k7) "White bagging" means the distribution of patient-specific Specialty Drug from a Specialty Pharmacy to the patient's physician's office, hospital, or clinic for administration.

Model Rules for the Practice of Specialty Pharmacy

Section 1. Facility.

(a) To operate as a Specialty Pharmacy, an applicant shall obtain licensure as a Pharmacy pursuant to Board rules.

(b) In addition to all other requirements, the Pharmacist-in-Charge shall maintain policies and procedures for the safe storage and Dispensing of the Specialty Drugs Dispensed by the Pharmacy.

Section 2. Dispensing Specialty Drugs.

(a) If Dispensing Specialty Drug(s) directly to a patient or to another Pharmacy for ultimate Dispensing to the patient, as in Brown Bagging, the Pharmacist, prior to every Dispensing shall:

(1) Ensure the integrity of the Specialty Drug(s) during shipment and if shipped to another Pharmacy, properly notify Pharmacy of such shipment.

(2) Perform a full Prospective Drug Utilization Review including all prescription and non-prescription Drugs taken by the patient.

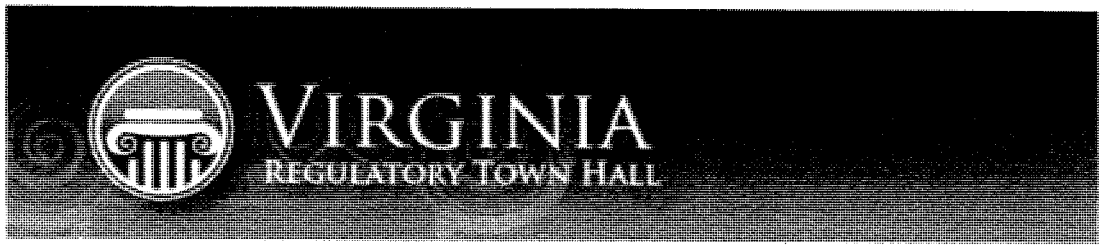
(3) Perform patient counseling.

(4) Certify that the patient has been trained on and is capable of properly storing and handling the Specialty Drug(s) prior to being Administered.

(b) If Dispensing Specialty Drug(s) directly to a physician's office, hospital, or clinic for the Administration to a specific patient, or White Bagging, the Pharmacist prior to every Dispensing shall:

(1) Perform a full Prospective Drug Utilization Review including all prescription and non-prescription Drugs taken by the patient.

(2) Inform the receiving physician's office, hospital, or clinic of the shipment of the medication and advise on the proper storage, handling, and disposal of the Specialty Drug.



townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation(s)	18VAC110-20
Regulation title(s)	Regulations Governing the Practice of Pharmacy
Action title	White bagging/brown bagging
Date this document prepared	12/11/17

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Subject matter and intent

Please describe briefly the subject matter, intent, and goals of the planned regulatory action.

The Board intends to consider adopting a regulation to prohibit brown bagging of drugs requiring reconstitution or compounding prior to administration and to set specific requirements for specialty pharmacies participating in white bagging. The intent of the regulatory action is public protection to ensure drugs are appropriately dispensed and administered.

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and(2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.

8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.
B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

Purpose

Please describe the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, please explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of the proposed regulatory action is to address patient safety concerns relating to brown bagging and white bagging. information available to the Board will enhance its ability to protect the public health and safety.

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

In the amended regulation, the Board will need to define "brown-bagging and white-bagging." At the 2016 annual meeting of the National Association of Boards of Pharmacy, a study resolution included these definitions: *"white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration.*"

In the addition to new definitions in the proposed regulations, the Board will consider regulations for:

- Prohibition of brown bagging of drugs requiring reconstitution or compounding prior to administration;
- Requiring the specialty pharmacy participating in white bagging to notify the receiving pharmacy of the shipment to ensure appropriate coordination of patient care;
- Requiring the pharmacy to provide an estimated arrival date, to provide the name of the patient to whom the drug has been dispensed, and to provide the exact address where the product has been shipped.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

On March 4, 2016, a Pharmacy Benefit Manager Workgroup issued its report to the Secretary of Health and Human Resources on a number of issues relating to the practice of PBMs. It included a discussion of some issues relating to "brown bagging and white bagging." The consensus among Workgroup members was that the Board of Pharmacy should review the practices to address issues of concern for patient safety. There are no viable alternatives to achieve the essential purpose of safety and efficacy of prescription drugs.

The Board will review regulations adopted in other states, such as provisions from Oregon which allow for "white bagging" with certain safeguards in place for reconstitution, labeling and accountability.

Public participation

Please indicate whether the agency is seeking comments on the intended regulatory action, including ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments. Please include one of the following choices: 1) a panel will be appointed and the agency's contact if you're interested in serving on the panel is _____; 2) a panel will not be used; or 3) public comment is invited as to whether to use a panel to assist in the development of this regulatory proposal.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses; and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website

(**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used for development of regulatory changes; the amendments will be drafted by the Regulation Committee.

Agenda item: Revision of guidance document on Compliance with USP Standards for Compounding

Enclosed:

An amended draft of Guidance Document 110-36

Staff note:

The Board adopted an amended guidance document at its September meeting, but shortly thereafter, USP published its intent to delay implementation to December 2019. Therefore, the Regulation Committee recommended amendments to the document in paragraph 2), inclusion of USP's Frequently Asked Questions for Chapter <800>, and a link to the National Institute of Occupational Safety and Health (NIOSH) list. It also recommended that the Board begin the education process though inspections (which will not result in disciplinary action prior to the effective date of the chapter) within the next six months.

Board action:

Adoption of amendments to Guidance Document:110-36 and approval of education on Chapter 800 through the inspection process.

Guidance Document: 110-36 **Revised: ~~December 1, 2015~~ December 11, 2017**

(DRAFT)

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 of the Code of Virginia and Regulation 18VAC110-20-321 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 first published as an official standard in February 2016 with a delayed implementation date of July 1, 2018. On September 27, 2017, USP published a notification of intent to revise the effective date of chapter <800> to December 1, 2019. ~~The Board expects that the requirements of 800 related to non-physical standards of chapter <800>, e.g., list of hazardous drugs received, stored, or dispensed, performance of assessment of risk if not complying will all containment requirements for all drugs, will be found in compliance at time of inspection beginning January 1, 2019. The Board also expects that the requirements of 800 related to physical and engineering standards will be found in compliance at time of inspection beginning July 1, 2019. Prior to these dates, inspectors will note non-compliance as a "comment" on the inspection report and no monetary sanction will be imposed. As of these dates, the Board will begin imposing monetary sanctions for non-compliance with the applicable requirements.~~

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

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

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-

compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. ~~The latest edition, USP 36–NF 31, published on November 1, 2012 becomes official May 1, 2013.~~

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

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

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

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

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

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

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

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

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

- A closed system transfer device (CSTD) should not be used to extend the BUD of a single-dose vial to exceed the 1 hour BUD when punctured outside of an ISO Class 5 environment or the 6 hour BUD when punctured within and not removed from an ISO Class 5 environment.

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

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

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

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

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

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

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

   Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be

possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

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

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

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

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

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

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

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

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

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

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

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

the twelfth month from the date the previous media-fill test was initiated. Semiannual media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.

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

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

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

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

Per USP, sterility testing is not required for autoclaved CSP prepared in batches less than 25 and if the storage times for high-risk CSPs are not exceeded. If the storage times of high-risk CSPs are exceeded, sterility testing is required. Once sterility testing is successfully completed, a longer BUD may be assigned based on the criteria described in the chapter (e.g., based on stability studies).

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 is the status of the General Chapter <800> and when will General Chapter <800> become official?

USP announced the **intent to postpone** the official date of General Chapter <800> *Hazardous Drugs – Handling in Healthcare Settings*. Per USP, the intent of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding — Sterile Preparations*, to provide a unified approach to quality compounding. The next revision to General Chapter <797> is anticipated to be published in the *Pharmacopeial Forum* 44(5) September/October 2018 for a second round of public comment. Both USP General Chapter <797> and USP General Chapter <800> are anticipated to become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

41. What does 'official date' mean?

Per USP, the USP "official date" indicates the date by which affected users are expected to meet the requirements of a particular standard. Ensuring compliance with the requirements of these standards is the responsibility of regulators such as the FDA, states, and other government authorities. USP has no role in enforcement.

42. Other than the change to the official date, are there other expected substantive changes to USP General Chapter?

Per USP, no. The only part of USP General Chapter <800> that is expected to change is the official date, which is expected to be changed to December 1, 2019.

43. Is <800> currently enforceable in the United States?

Per USP, from a compendial standpoint, a USP general chapter numbered below <1000> becomes enforceable through reference in the General Notices, a monograph, or another applicable general chapter numbered below <1000>. At this time, <800> is not specifically referenced in the General Notices, a monograph, or another applicable general chapter numbered below <1000>.

However, states may make their own determinations regarding the applicability and enforceability of <800> to entities within their jurisdiction. USP has no role in enforcement. As

a result, the specific enforceability of <800> depends on the legal framework that you are analyzing.

44. Does the December 1, 2019 official date of <800> impact my current or early adoption of the general chapter?

Per USP, no. USP encourages adoption and implementation of General Chapter <800> to help ensure a quality environment and protection of healthcare workers and patients when hazardous drugs are handled.

45. How do I adopt USP General Chapter <800> if sections are not harmonized with USP General Chapter <797>?

Per USP, two sections that are not harmonized between the two chapters are: Segregated Compounding Area and 'Low volume' hazardous drug compounding. Below please find guidance on how to adopt USP <800> until the revised USP <797> is published.

Segregated Compounding Area (SCA)

- USP <797> only allows low-risk level nonhazardous and radiopharmaceutical Compounded Sterile Preparations (CSPs) with 12 hour or less beyond-use date (BUD) to be prepared in an unclassified segregated compounding area (SCA).
- USP <800> allows low and medium risk level hazardous drug CSPs to be prepared in an unclassified containment segregated compounding area (C-SCA). The C-SCA is required to have fixed walls, be externally vented with 30 ACPH and have a negative pressure between 0.01 and 0.03 inches of water column relative to the adjacent areas.
- Note the differences in terminology and requirements in the SCA in USP <797> and C-SCA in <800>.
  - For early adoption of <800>, low- and medium- risk level HDs may be prepared in a C-SCA provided it meets the requirements in the chapter and the CSP is assigned a BUD of 12 hours or less.
  - For facilities that have not yet adopted <800>, the standards in USP <797> would apply. Only low-risk level nonhazardous and radiopharmaceutical CSPs with 12 hour or less BUD may be prepared in a SCA.

"Low volume" hazardous drug compounding

- USP <797> allows facilities that prepare a "low volume" of HDs to compound these drugs in a non-negative pressure room if "two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.
- USP <800> requires facilities that prepare HDs to have a containment secondary engineering control (C-SEC) that is externally vented, physically separated, have appropriate air exchange, and have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas.
- For early adoption of <800>, HDs must be prepared in a C-SEC meeting the requirements in the chapter.

- For facilities that have not yet adopted <800>, the standards in <797> would apply. Facilities preparing a low volume of HDs may continue to compound these CSPs outside a negative pressure room if two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room)" are used.

46. 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.

47. 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

48. 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.

49. 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)

50. 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.?

51. 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.

52. 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

53. 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.

54. What minimal questions and/or information will an inspector for the Board of Pharmacy be asking during an inspection? Note: Refer to page 1 regarding enforcement of Chapter <800>.

- 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.

55. 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 • Examples: CVE, Class I or II BSC, CACI	• Externally vented • 12 air changes per hour (ACPH) • Negative pressure between 0.01 and 0.03 inches of water column relative to adjacent areas • Fixed walls

56. 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 • Examples: Class II BSC or CACI	• Externally vented • 30 air changes per hour-ACPH • 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 • Examples: Class II BSC or CACI	• Externally vented • 12 ACPH • 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

57. 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.

58. Regarding the Segregated Compounding Area (SCA) definition, Chapter <797> states an SCA may be a designated space, room or demarcated area. Chapter <800> states SCA requires fixed walls and removes the "space or demarcated area". Please clarify the Board's expectations on this issue.

Per USP, please note the differences in terminology in <797> and <800>. General Chapter <800> specifies that this is a containment segregated compounding area (C-SCA). For hazardous drug compounding, the C-SCA must have fixed walls. For nonhazardous drug sterile compounding, the SCA may be in an unclassified area (and not necessarily have fixed walls). For the C-SCA, fixed are also necessary to maintain negative pressure.

59. Regarding low-risk level compounding with 12 hour or less beyond use dating (hood within a non-ISO Class 7 area), Chapter <797> states that this configuration does not allow hazardous compounding. Chapter <800> states that it is allowed, but only low and medium risk HDs may be prepared and beyond use dating (BUD) that cannot exceed <797> for being prepared in a SCA. Please clarify the Board's understanding on this issue.

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a containment segregated compounding area (C-SCA). USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

60. Chapter <797> also allows for placement of an isolator outside of an ISO Class 7 buffer room with meeting of specification requirements and allowance of full BUD. Chapter <800> states if the containment primary engineering control (C-PEC) is placed in a containment segregated compounding area (C-SCA), then the BUD of all compounded sterile products must be limited as described in <797>. Again, Chapter <797> states that this configuration does not allow hazardous compounding. Please clarify the Board's understanding on this issue.

Per USP, the intent of <800> is to apply a 12-hour or less BUD to low- and medium- risk level compounded sterile products prepared in a C-SCA. USP is aware of the conflict and is in the process of revising <797> to align with the requirements in <800>.

61. With the implementation of Chapter <800>, will USP continue to allow compounding aseptic isolators (CAI) placed outside of a classified area to be used to compound sterile products and assigned a full BUD as authorized in <797>?

Yes, Chapter <797> still allows for a compounding aseptic isolator (CAI) placed outside of a classified area to be used to compound sterile products and assigned the full storage period BUD provided the conditions specified in the chapter are met. Note, for compounding sterile hazardous drugs, the compounding aseptic containment isolator (CACI) must be placed in a negative pressure containment secondary engineering control (C-SEC) with adequate air changes per hour (ACPH).

62. Does Chapter <800> recommend wipe sampling and medical surveillance?

Yes, Chapter <800> states that "environmental wipe sampling for HD surface residue should be performed routinely." Medical surveillance is also a recommendation of the chapter. The chapter states that "healthcare workers who handle HDs as a regular part of their job assignment should be enrolled in a medical surveillance program." Note, both of these issues are recommendations of Chapter <800> and not a requirement.

63. USP Chapter <800> states that antineoplastic hazardous drugs (HD) that require manipulation other than counting or repackaging should be stored separately. Does this include any dosage formulation, or is that left to the risk assessment?

Per USP, this is intended to include any dosage form that does NOT require any further manipulation (i.e. counting tablets, pouring liquids).

64. USP <797> and USP <800> recommend the use of closed-system drug-transfer devices (CSTD). Is there guidance on the proper evaluation of the available technologies?

USP currently recommends the use of CSTDs for compounding HDs. Per USP, it is not a requirement as there is no published universal performance standard for evaluation of CSTD containment. NIOSH is currently working on developing such a protocol.

65. Is a line of demarcation for doffing personal protective equipment (PPE) required for all hazardous containment secondary engineering controls?

USP <800> *requires* a doffing area if the negative-pressure hazardous drug (HD) buffer room is entered through the positive-pressure non-hazardous drug buffer room. Additionally, it states a designated doffing area *should* be indicated within all containment secondary engineering controls (C-SEC). Other than the line of demarcation mentioned in section 5.3.2, General Chapter <800> does not specify where doffing should occur. However, this is entity dependent and should additionally follow garbing requirements in <797>.

66. USP <800>, within Section 5.3, indicates that an eyewash station and/or other emergency or safety precautions that meet applicable laws and regulations must be readily available. Are there applicable laws and regulations in Virginia regarding eyewash stations and/or other emergency or safety precautions?

The Board is not currently aware of laws and regulations in Virginia related to use of eyewash stations or other safety precautions related to this issue.

67. May a laminar airflow workbench (LAFW) or a compounding aseptic isolator (CAI) be used for compounding with an antineoplastic hazardous drug (HD)?

No.

68. Is it required to compound all sterile hazardous drugs within an externally vented containment primary engineering control (biological safety cabinet (BSC) or compounding aseptic containment isolator (CACI))?

No, dosage forms of non-antineoplastic and reproductive risk hazardous drugs may be handled and compounded under an assessment of risk. If, however, bulk active pharmaceutical ingredients (API) of these drugs are used as starting ingredients, all of the containment requirements in <800> would apply. Refer to Box 1 within USP Chapter <800>.

69. What are the specifications required of a pass through chamber? Is it required be interlocking and HEPA filtered purged? Between what areas may these chambers be utilized?

General Chapter <800> defines a pass-through as "an enclosure with interlocking doors that is positioned between two spaces for the purpose of reducing particulate transfer while moving materials from one space to another. A pass-through serving negative-pressure rooms needs to be equipped with sealed doors. The chapter does not require the pass-through to be HEPA filter purged and does not limit where these pass-throughs may be placed. General Chapter <800> additionally states that refrigerator pass-throughs must not be used.

70. Chapter <800> states sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area. What is the intent of this statement?

The intent of prohibiting the storage of nonsterile compounding materials in sterile compounding areas is to minimize traffic flow into the sterile classified areas.

71. May bulk active pharmaceutical ingredients (API) used for sterile compounding be stored in the negative pressure C-SEC?

Yes. Refer also to USP's frequently asked question #16 found at http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings

72. Where must manipulation of non-sterile, non-antineoplastic and reproductive risk hazardous drugs (that are not bulk active pharmaceutical ingredients (API)) occur?

The location where manipulation occurs should follow an assessment of risk for non-antineoplastic and reproductive risk hazardous drugs (that are not bulk APIs). Facilities should determine their own strategies based on its assessment of risk.

73. Does Chapter <800> address whether scrubs that are worn within the hazardous compounding/storage area may be allowed to be taken home?

No. General Chapter <800> does not specify best practices for clothing under the gown. However, section 7.2 does require gowns to be disposable and shown to resist permeability by HDs.

74. What is the best practice for receiving hazardous drugs (HD)?

USP <800>, within Section 5.1, states antineoplastic HDs and all HD active pharmaceutical ingredients (API) must be unpacked (i.e., removal from external shipping containers) in an area that is neutral/normal or negative pressure relative to the surrounding areas. HDs must not be unpacked from their external shipping containers in sterile compounding areas or in positive pressure areas. Best practice is to unpack the hazardous drugs from the delivery tote, and leave packaged in a zip-locked plastic bag. From there, the unopened plastic bags should be moved to HD storage room, where the HDs can be removed from the bags and received into inventory. HDs should never be withdrawn from the plastic transport bags in any room other than the HD storage room.

75. If the C-PEC vents externally and the room is able to maintain appropriate negative pressure and air exchanges, does the C-SEC need to be vented?

No.

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.

Agenda item: Revision of guidance document on Inspection Deficiency Monetary Penalty Guide

Enclosed:

An amended draft of Guidance Document 110-23

Staff note:

The Regulation Committee requested staff to cross-walk Guidance Document 110-23 with Guidance Document 110-9 for consistency and current regulations to determine if additional edits were necessary. It also recommended that the words "major" and "minor" be stricken and that Deficiency #13 be eliminated.

The attached Guidance Document includes changes recommended.

Board action:

Adoption of amendments to Guidance Document:110-23.

Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No designated practitioner.	18VAC110-30-70		2000
2. Designated practitioner in place, inventory taken, but application not filed with Board within the required timeframe.	18VAC110-30-70		1000
3. No change of designated practitioner inventory, inventory taken over 5 days late, or substantially incomplete, i.e. did not include all drugs in Schedules II-V,	18VAC110-30-70	Cite Deficiency 124 if only expired drugs not included in inventory.	500
4. Practitioner selling on an expired license or facility permit.	18VAC110-30-30	Per individual	100
5. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
6. Change of location, remodel, or addition of a selling location without submitting application or Board approval.	18VAC110-30-80	Must submit an application and fee	250
7. More than one person be present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	Per each person First Offense – Deficiency 104 Second Offense – Deficiency 7	100
8. Persons, other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks, are assisting in the performance of pharmacy technician duties.	18VAC110-30-40	Per individual	250

Deficiency	Law/Reg Cite	Conditions	$ Penalty
9. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	18VAC110-30-110	Determined by using inspector's calibrated thermometer	100 Drugs may be embargoed
10. Insufficient enclosures or locking devices.	18VAC110-30-130	Cite Deficiency10 if there is evidence that non-compliance contributed to a drug loss. Cite Deficiency 107 if no drug loss.	500
11. Storage of drugs for sale are not in the approved storage and selling area.	18VAC110-30-90		500
12. The alarm is not operational. The alarm is not set at all times when the licensee is not on duty. The enclosure not locked at all times when the licensee not on duty.	18VAC110-30-120 18VAC110-30-130		1000
13. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
14. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 & 18VAC110-30-180	Cite Deficiency 124 if only expired drugs not included in inventory.	500
15. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
16. Hard copy prescription or alternative record of all drugs sold not maintained or retrievable as required.	18VAC110-30-190		250
17. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250

Deficiency	Law/Reg Cite	Conditions	$ Penalty
18. Practitioner not verifying or failing to document verification of accuracy of dispensed prescriptions.	18VAC110-30-40	10% threshold for documentation	500
19. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
20. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40	10% Threshold	500
21. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000
22. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
23. No clean room.	54.1-3410.2		10000
24. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
25. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
26. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
27. High-risk compounded sterile preparations intended for use are improperly stored.	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Penalty
28. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	3000
29. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification	1000
30. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
31. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		5000

Deficiency	Law/Reg Cite	Conditions	$ Penalty
32. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill testing and gloved fingertip test was initiated.	500
33. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill testing and gloved fingertip testing was initiated	5000
34. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test and gloved fingertip test.	54.1-3410.2		500

Deficiency	Law/Reg Cite	Conditions	$ Penalty
35. Documentation that a person who failed a media-fill test or gloved fingertip test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test.	54.1-3410.2		5000
36. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
37. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
38. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

Other Deficiencies

If five (5) or more deficiencies in this category are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional deficiency cited in this category over the initial five.

Deficiency	Law/Regulation Cite	Conditions
101. Selling drugs from a location prior to approval by the Board.	18VAC110-30-20 18VAC110-30-80	
102. Special/limited-use scope being exceeded without approval.	18VAC110-30-21	
103. Failure to notify Board within 30 days of change from only one practitioner to more than one practitioner,	18VAC110-30-15.	
104. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Deficiency 104 Second Offense – Deficiency 7
105. No site-specific training program and manual.	18VAC110-30-40	
106. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
107. Insufficient enclosures or locking devices.	18VAC110-30-130	Deficiency 10 if there is evidence that non-compliance contributed to a drug loss. Deficiency 107 if no drug loss.
108. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120 18VAC110-30-130	
109. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
110. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	

111. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
112. Expired drugs in the working stock.	18VAC110-30-150	10% threshold
Deficiency	**Law/Regulation Cite**	**Conditions**
113. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	

114. Sink with hot and cold running water not available.	18VAC110-30-90	
115. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
116. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
117. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
118. No current dispensing information reference source.	18VAC110-30-110	
119. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
120. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	
121. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
122. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Deficiency	Law/Regulation Cite	Conditions
123. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
124. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
125. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
126. Offer to counsel not made as required.	18VAC110-30-40	
127. Prospective drug review not performed as required.	18VAC110-30-40	
128. Improper disposal of unwanted drugs.	18VAC110-30-160	
129. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
130. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	
131. Equipment for non-sterile compounding does not comply with USP-NF standards.	54.1-3410.2	
132. Required compounding/dispensing/distributions records not complete and properly maintained.	54.1-3410.2	

Agenda Item: Adoption of Guidance Documents on Delivering Temperature-sensitive Drugs and Guidelines for Disposal

Enclosed:

Draft guidance documents

Excerpt from September 26, 2017 Board meeting minutes

Board action:

Adopt guidance documents as presented or as amended

Board of Pharmacy

Delivery of Dispensed Drugs

Pursuant to § 314.170 of the Code of Federal Regulations, "All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act." § 54.1-3457 of the Code of Virginia prohibits the delivery of any drug that is adulterated and § 54.1-3461 describes an adulterated drug as one that "purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium". Thus, there is a legal expectation that all pharmacies, both resident and nonresident, must deliver drugs in a manner that ensures appropriate temperature ranges or else they may be in violation of possibly delivering an adulterated drug. In addition to guidance provided by the United States Pharmacopeia on temperature storage requirements and excursions, the Board provides the following guidelines.

During delivery of a dispensed drug to a patient at a location other than the pharmacy, the pharmacist should ensure that the drug is packaged in a manner that maintains appropriate storage temperature requirements, in accordance with the manufacturer's recommendations. The packaging may require the use of a temperature monitoring device, particularly for drugs that are temperature-sensitive. If cold packs are used in the packaging materials, the pharmacist should ensure that the cold packs are placed appropriately in the container to avoid freezing and to maintain the appropriate temperature range during delivery.

A pharmacist who delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location shall also comply with the requirements of § 54.1-3420.2.

§ 54.1-3420.2. Delivery of prescription drug order.

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

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

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

Guidance Document 110-_____ Adopted 12/11/2017

Board of Pharmacy

Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs

Pursuant to HB2046 passed by the 2017 General Assembly, the Board developed the following guidelines for the provision of counseling and information regarding proper disposal of unused dispensed drugs by pharmacists to patients for whom a prescription is dispensed. It is recommended that pharmacists verbally counsel or provide written information to patients or their agents, receiving drugs in Schedule II-V and any drugs of concern, on the importance of properly storing and disposing of unused dispensed drugs.

Drug Storage:

Properly securing prescription drugs can decrease the risk of diversion of drugs from the medicine cabinet, a common method for obtaining drugs for abuse. Tips on safe storage may be accessed at http://vaaware.com/storage/storage/ or http://www.safeguardmymeds.org/how-to-safeguard-your-prescription-meds/

Disposal Options:

- **Authorized pharmacy disposal site or collection site** – if the pharmacy is an authorized collection site as listed at http://www.dhp.virginia.gov/pharmacy/destructionsites.asp the pharmacist should inform the patient of how to dispose of the unused drugs via the collection box at the pharmacy.
- **Collection boxes at local law enforcement agencies** – encourage patients to use a collection box for drug destruction at a local law enforcement agency, if applicable.
- **Drug take-back programs** - pharmacists should encourage patients to take their unused drugs for destruction to take-back programs organized by local, state, or federal government agencies.
- **Home disposal** - Despite the risk of diversion and environmental contamination, home disposal is a viable option, if an authorized collection site or 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.
- Caution patients not to dispose of medications in the toilet or sink, unless specifically instructed to on the label, and not to give medicine to friends or family. This is not only potentially illegal, but a drug that works for the patient could be dangerous for someone else.
- For more information on home disposal, refer patients to FDA's *Disposal of Unused Medicines: What You Should Know* found at https://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

Additional Resources

- Flyer available for printing and sharing - https://nabp.pharmacy/wp-content/uploads/2017/02/Safe-Disposal-Why-Its-Important-11.13.15.pdf
- Tips on disposal - https://nabp.pharmacy/initiatives/awarxe/dispose-safely/ or http://vaaware.com/storage/disposal/

MOTION:

The Board voted seven to three to approve the Ad Hoc Committee's recommendation that no action be taken to mandate temperature monitoring devices, but that the Board develop guidance for pharmacies that highlights the importance for using appropriate packaging materials when delivering temperature-sensitive drugs, to include temperature monitoring devices, if warranted. (motion by Warriner, second by Allen; Warriner, Thornbury and S. Elliott opposed)

- Guidance For Complying With USP <800>

Ms. Shinaberry discussed the Committee's recommendation for inspectors to begin citing deficiencies as of July 1, 2018, but not to impose monetary sanctions. Beginning January 1, 2019, monetary sanctions should be imposed for non-compliance with the non-physical standards of chapter <800>. Beginning July 1, 2019, monetary sanctions should be imposed for the physical and engineering standards of Chapter <800>.

MOTION:

The Board voted unanimously to amend the ad hoc committee's recommendation to read: ..." inspectors begin *commenting on* deficiencies as of July 1, 2018, *and* impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (motion by Warriner, second by Allen)

MOTION:

The Board voted eight to two to adopt the ad hoc committee's recommendation on enforcement of USP Chapter <800> as amended which reads "inspectors begin commenting on deficiencies as of July 1, 2018, and impose no monetary sanctions. Beginning January 1, 2019, monetary sanctions (to be established at a later date) should be imposed for non-compliance with the non-physical standards of chapter <800>, e.g., list of hazardous drugs received or stored in the pharmacy, performance of assessment of risk, etc. Beginning July 1, 2019, monetary sanctions (to be established at a later date) should be imposed for the physical and engineering standards of Chapter <800>". (motion by Warriner, second by Allen; Warriner and Saenz opposed)

MOTION:

The Board voted unanimously to review draft amendments of Guidance Document 110-36, to include frequently asked questions on the enforcement of Chapter <800>, at the November Regulation Committee meeting with recommendations to the full board in December. (motion by Shinaberry, second by Warriner)

- Guidelines for

Ms. Shinaberry reviewed the Committee's decision for staff to create a

Counseling on Drug Disposal (HB2016)

guidance document regarding the disposal of controlled substances.

MOTION:

The Board voted unanimously to accept the ad hoc committee's recommendation for staff to create a guidance document regarding the disposal of controlled substances which should include resources of information on the subject.

REGULATORY ACTIONS:

- Adoption of Regulation to Schedule Certain Chemicals in Schedule I

There was a public hearing conducted at 9:10AM this morning pursuant to requirements of §54.1-3443 of the Drug Control Act.

MOTION:

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

- **5-methoxy-N,N-dimethyltryptamine (other name: 5-MeO-DMT)**
- **5-methoxy-N-methyl-N-isopropyltryptamine (other name: 5-MeO-MIPT)**
- **5-methoxy-N-ethyl-N-isopropyltryptamine (other name: 5-MeO-EIPT)**
- **4-hydroxy-N,N-diisopropyltryptamine (other name: 4-OH-DIPT)**
- **(N-methyl aminopropyl)-2,3-dihydrobenzofuran (other name: MAPDB)**
- **3,4-tetramethylene-alpha-pyrrolidinovalerophenone (other name: (TH-PVP)**
- **4-chloro-alpha-methylamino-valerophenone (other name: 4-chloropentedrone)**

Synthetic opioids:

- **2-methoxy-N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-acetamide (other name: Methoxyacetyl fentanyl)**
- **N-(1-phenethylpiperidin-4-yl)-N-phenylcyclopropanecarboxamide (other name: Cyclopropyl fentanyl)**

Cannabimimetic agent:

- **N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(5fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-ADB-PINACA)**

(motion by Warriner, second by Boone)

- Adoption of Proposed Regulations for Controlled Substances Registration for Entities that Dispense Naloxone

Emergency regulations were required to meet the mandate of the statute; they became effective May 8, 2017. A NOIRA was published simultaneously with the emergency regulations to replace them with permanent regulations. A comment period on the NOIRA ended 6/28/17; there were no comments.

Agenda Item: **Request for Accepting Inspection Report from Gates Healthcare Associates for Licensure Purposes of Outsourcing Facilities when FDA has Not Performed Inspection within Required Timeframe in State Law**

Enclosed:

- General information provided by Gates Healthcare Associates
- Email dated 10/11/17 with attachments
- Minutes from June 14, 2016 Board meeting (Excerpt)
- Minutes from September 7, 2016 Board meeting (Excerpt)

Board action:

- Request additional information, if necessary, for consideration at subsequent meeting, or
- Approve request, or
- Deny request

Dear Ms. Caroline Juran,

As the Virginia Board of Pharmacy,

Your role in ensuring the safe distribution of pharmaceutical products and provision of quality patient care by licensees both in-state and out of state, is essential to promote, preserve, and protect public health and safety. In this fast-changing regulatory environment, at the state and at the federal level, licensees often are uninformed, confused, and struggle with compliance.

Our firm, Gates Healthcare Associates (GHA), can serve as a common ground to understanding the regulations, and developing and implementing practices to ensure compliance with state and federal regulations.

Our team at Gates Healthcare Associates has proven exceptional skill and knowledge in the areas of Sterile and Non-Sterile Compounding practices, current Good Manufacturing Practice, Medication Error Prevention, and Controlled Substances Risk Management.

We have a great multidisciplinary team that includes nationally recognized experts in sterile and non-sterile compounding, and team members with history and background that includes: an FDA regional inspector, a patient safety expert (affiliated with ISMP), a DEA diversion investigator, the NABP Accreditation and Inspection Services Manager, members and former Executive officers of state boards of pharmacy, and an Assistant Director for Drug Control for the Massachusetts State Department of Public Health.

GHA specializes in tailoring our services to the licensee's specific needs in regard to the requirements of their state and federal licensing agencies. Our innovative and personalized consulting methods allow our clients to incorporate best practice techniques into everyday operations while being in compliance with the applicable laws and regulations.

We ask a moment of your time to review our services, and will be happy to have a brief meeting with your Board to describe how we may help you and your licensees achieve compliance, and to answer any questions you may have about our team and services.

Services Include:

- **USP Compliance (795, 797, and 800)**
- **FDA Inspection Preparation (503A and 503B)**
- **DEA Inspection Preparation**
- **Controlled Substances Monitoring**
- **Post Regulatory Inspection Remediation, Compliance with action plans**
- **Accreditation Support (Compounding, Specialty, VAWD, DMEPOS, etc.)**
- **Pharmacy Staff Training**
- **Monthly or Quarterly Compliance Monitoring for State BOP Requirements**
- **Policy & Procedure Supplementation**

Sincerely,

Ernest P. Gates Jr.

Ernest P. Gates Jr.
President & CEO

Denise Frank
R.Ph, Associate

Compounding Compliance Services

State & Federal Compliance

- State Board of Pharmacy Inspection Preparation
- Corrective Action Remediation
- USP <795> Compliance Analysis
- USP <797> Compliance Analysis
- USP <800> Compliance Analysis
- FDA Compliance Analysis
- Form 483 Remediation
- DEA Compliance

Continuous Quality Improvement

- Evaluate Quality Assurance
- Develop QA and CQI Program
- Compliance Indicator Trending

Training & Education

- USP <795>, <797>, and <800>
- Webinars Available
- Board of Pharmacy Inspector Training
- Continuing Education Credits

Pharmacy Lab Design

- Lab Design
- Equipment Recommendations
- Workflow Evaluation

Accreditation

- PCAB/ACHC Mock Survey
- Post-inspection Remediation

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation

The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare Gates

Innovation | Experience | Knowledge | Solutions

The Experts in Community Pharmacy

CommunityPharmacy

Gates Healthcare Associates is a regulatory consulting firm that specializes in the compliance of our nation's independent community pharmacies, independent pharmacy franchises, and independent chains. Our services are tailored to assist with pharmacy operations, regulatory compliance, policies and procedures, quality assurance, disciplinary action assessment or monitoring, and inspection or survey programs.

Our team of experts were heavily involved in the development and implementation of new programs for accreditations and inspections including CPPA®, VPP® and state projects, in training of state board compliance officers, and in maintaining and updating existing NABP accreditation programs to include emerging issues and changes in regulations and standards.

- Policies and Procedures
- NABP VPP Inspection Preparation
- Accreditation Programs - DMEPOS, VAWD®, VIPPS®, Vet-VIPPS® and CPPA®
- Discipline Action Remediation & Response

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Community Pharmacy Services

Accreditation

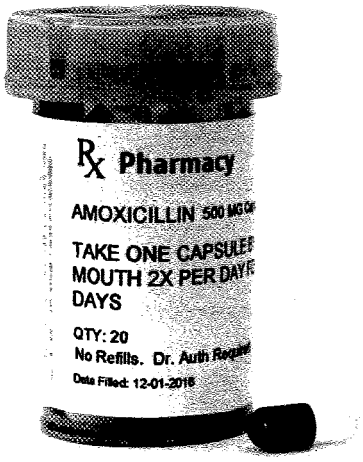
- NABP™ accreditation programs: DMEPOS, VAWD®, VIPPS® and Vet-VIPPS®
- Center for Pharmacy Practice Accreditation (CPPA®) accreditation programs
- Application and document submission
- Policy and procedure review, development, revision, and remediation
- Pre-survey assessment
- Survey findings remediation
- Staff training development

Regulatory Compliance

- Preparation for NABP VPP® inspection
- Gap analysis
- Response to deficiencies
- Remediation and response to disciplinary actions
- Policy and procedure assistance
- Internal compliance monitoring

Patient Care Compliance Programs

- Medication Therapy Management Programs
- Disease State Management Programs
- Disease State Education
- Care Transition Programs



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"During the nail-biting accreditation application processes, we were consistently met with unparalleled service and access to their vast base of industry knowledge."

- Gopesh Patel, VLS Pharmacy - New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

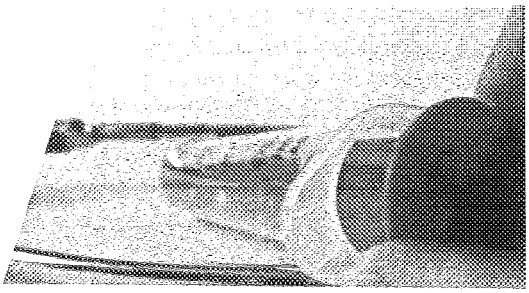
Healthcare
Gates

Innovation | Experience | Knowledge | Solutions

The Experts in Hospital Pharmacy

HospitalPharmacy

Hospital-based pharmacy practice has never been more exciting and more challenging. New federal and state laws and regulations make compliance an everyday concern. Demanding workplace and patient safety standards necessitate complex design and advanced training.



Gates Healthcare Associates has helped some of the nation's most respected academic medical centers develop and operate their pharmacies, while also assisting small community hospitals. Our team of experts helps to ensure that the hospital pharmacy is meeting and exceeding its goals in this time of intensive regulatory scrutiny and oversight.

- Regulatory Compliance
- Pharmacy Staff Training
- Facility Design & Layout
- Policies and Procedures (SOPs)
- Controlled Substance Monitoring
- Radiopharmaceutical Gap Analysis

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Hospital Pharmacy Services

State & Federal Compliance

- State Board of PharmacyCompliance
- Corrective Action Remediation
- USP <795> Compliance
- USP <797> Compliance
- USP <800> Compliance
- Compliance Monitoring

DEA Compliance

- DEA Mock Audit
- Controlled Substance Monitoring
- Accountability Audit

Training & Education

- Training for Professional Staff (tailored to each discipline; general regulatory requirements and nationally recognized best practices)
- Staff Training (On-site and Off-site Trainings)
- Webinars

Facility Design & Layout

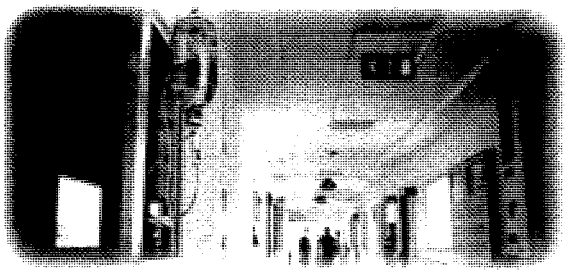
- Compounding Lab Design & Layout (not including engineering)
- Equipment Recommendations
- Workflow Evaluation

Nuclear Pharmacy

- Radiopharmaceutical Gap Analysis
- Quality and Patient Safety

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare Gates

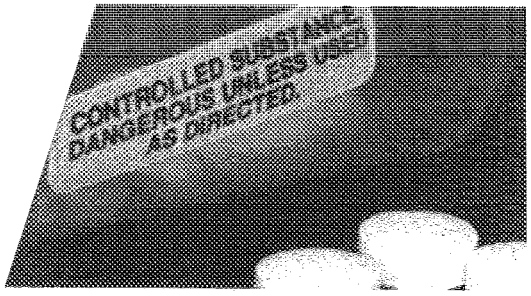
Innovation | Experience | Knowledge | Solutions

The Experts in DEA Compliance

DEA

DEACompliance

Gates Healthcare Associates supports our clients to navigate their way through DEA rules, regulations and inspections. Gates works closely with key stakeholders to ensure harmonization of approach and plays a critical role in ensuring company compliance.



Gates Healthcare Associates' DEA regulatory consultants have conducted extensive research and organizational audits that developed solutions across decision making, business processes, sales monitoring, prescription monitoring and training for companies of all sizes in the pharmaceutical industry including drug wholesalers, hospitals and specialty pharmacies.

Regulation Compliance

Training & Education

Policies and Procedures (SOPs)

Organizational Processes

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

DEA Compliance Services

Regulation Compliance

- Mock DEA Audits - Inspection Readiness Assessments
- Complete Due Diligence for Full Compliance with Applicable Laws and Regulations Governing the Handling of Controlled Substances
- Due Diligence for Controlled Substances Import and Export Act (CSIEA)
- Drug Supply Chain Security Act(DSCSA)

Policy & Procedures

- Quality Assurance/Continuous Quality Improvement Program
- Provide SOP Manual, Model Compliance Indicators, Data Collection Forms and Establish Aggregation Process

Strategic Organizational Processes

- Inventory Accountability
- Business Strategy Sessions
- Design and Implement Programs to Comply with all Applicable Laws and Regulations

Training & Education

- Manufacturing
- Distribution
- Dispensing of Controlled Substance Medications

The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare
Gates

Innovation | Excellence | Knowledge | Solutions

The Experts in Home Infusion

Home Infusion

Gates Healthcare Associates is a pharmaceutical consulting firm that develops programs designed to improve both clinical and business practices of infusion pharmacies. Gates services are comprehensive and are tailored to meet the individual needs of the organization.

Our Home Infusion Division is comprised of expert consultants with years of industry knowledge and experience. Our innovative and personalized consulting methods allow our clients to incorporate best practice techniques into everyday operations, while being in compliance with the latest laws and regulations.

- Strategic Planning
- Pharmacy Lab Design
- Accreditation Support
- Policies and Procedures (SOPs)
- On-Site Pharmacy Staff Training
- USP <797> & <800> Compliance

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Home Infusion Pharmacy Services

State & Federal Compliance

- State Board of Pharmacy Inspection Preparation
- Corrective Action Remediation
- USP <797> Compliance Analysis
- USP <800> Compliance Analysis
- FDA Compliance Analysis
- DEA Compliance

Strategic Planning

- Business Development
- Financial Analysis
- Aquisition Preparation
- Staffing

Training & Education

- USP <797> and <800>
- Webinars Available
- Board of Pharmacy Inspector Training
- Continuing Education Credits

Pharmacy Lab Design

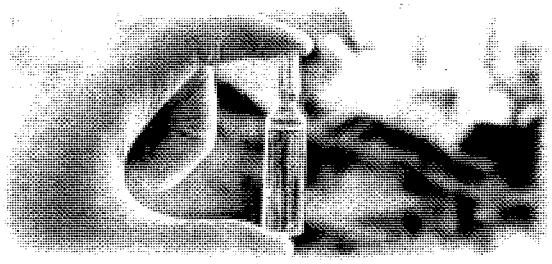
- Lab Design
- Equipment Recommendations
- Workflow Evaluation

Accreditation

- ACHC Mock Survey
- Post-inspection Remediation

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation

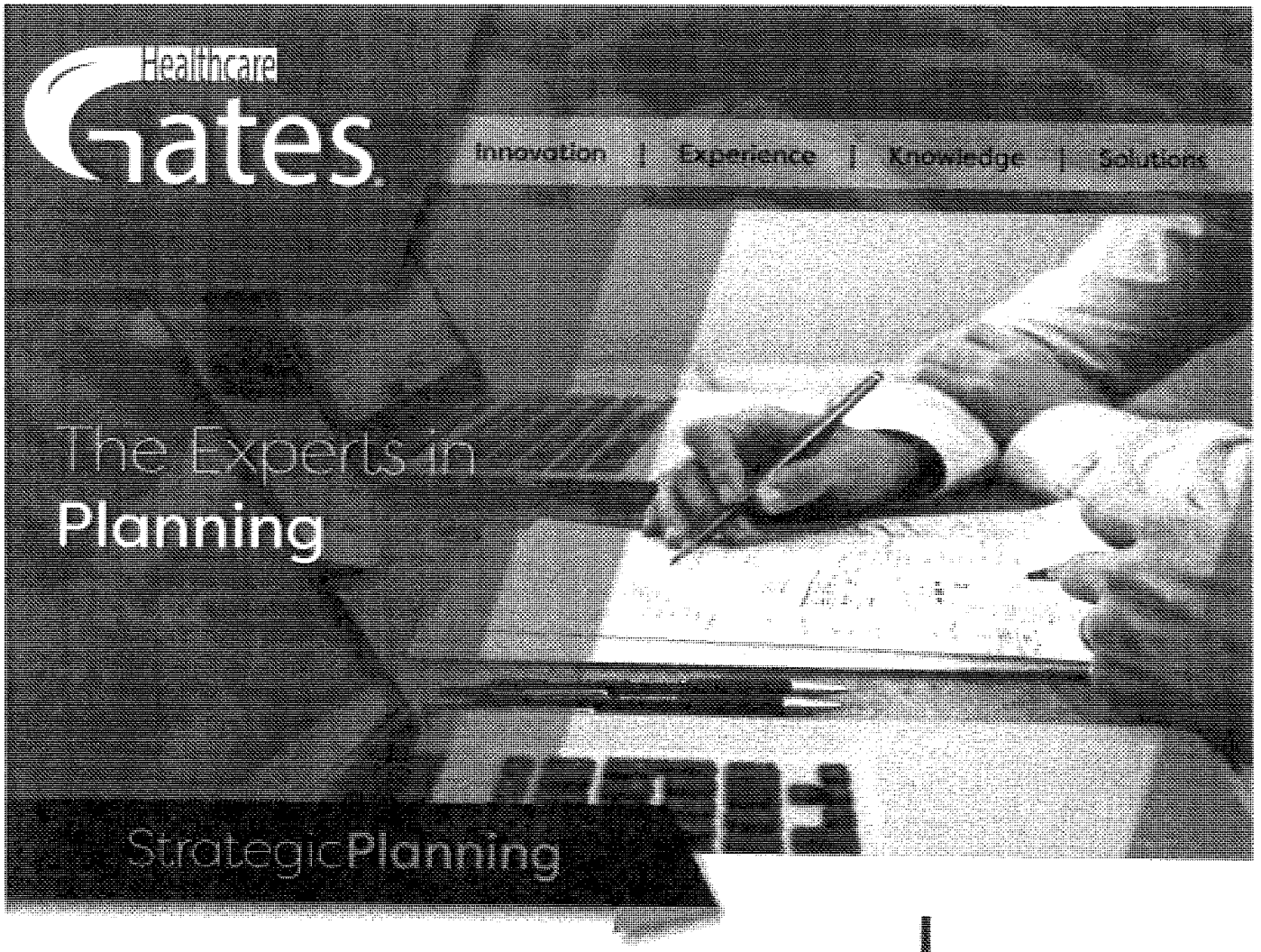


The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

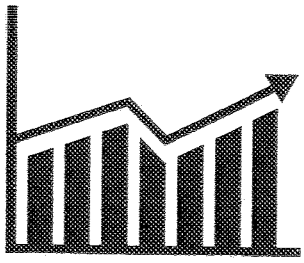
> "In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."
>
> **- Gopesh Patel, VLS Pharmacy, New York**

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949



Gates Healthcare Associates helps healthcare organizations develop strategic plans used to set priorities, focus energy and resources, strengthen operations, and assess and adjust the organization's direction in response to a changing regulatory environment.

Our expert team's disciplined effort helps produce fundamental decisions and actions that shape and guide the healthcare organization and who it serves, while ensuring that employees and other stakeholders are working toward common goals.



Staffing

Financial Analysis

Aquisition Preparation

Business Development

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Strategic Planning Services

Staffing

- Locate Potential Employees for Hire in all Sections of Operations
- Interview Potential Employees

Business Development

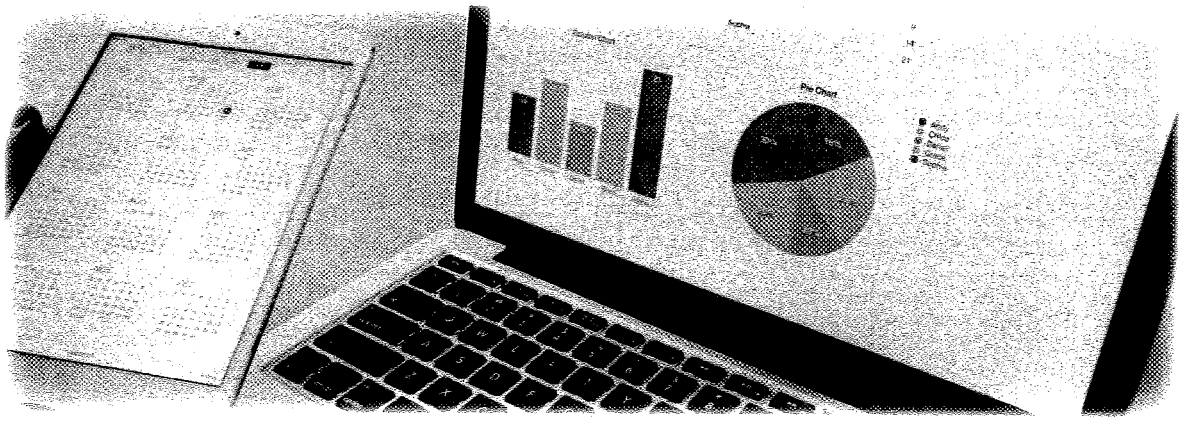
- Demographic Trend Analysis
- Financial Analysis
- Market Penetration

Acquisition Preparation

- Due Diligence
- Operations Inspection for Compliancy
- Find Potential Buyers
- Assist with Negotiations

Financial Analysis

- Profit & Loss Analysis
- Cash Flow Analysis
- Cost Analysis
- Assist in the Development of Financial Goals



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"My business has gone from being in the red to being in the black, and is now experiencing unprecedented growth, and I would give a lot of the credit for that to Ernie Gates. He brings a wealth of experience and knowledge to bear on his work."

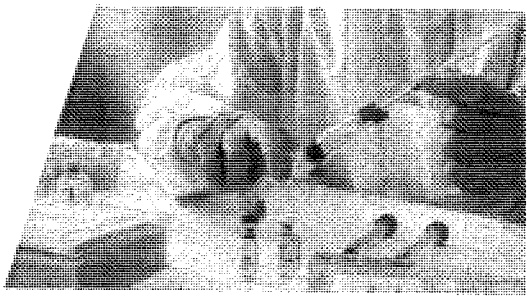
- Stephen Bernardi, Johnson Compounding & Wellness - Massachusetts

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare Gates

Innovation | Experience | Knowledge | Solutions

Gates Healthcare Associates develops programs designed to improve clinical practices of both large and small compounding pharmacies. Gates services are comprehensive and range from design and licensure to full compliance and accreditation with everything in between.



Our Pharmaceutical Compounding Division is comprised of expert consultants located in the United States and Canada. Our innovative and personalized consulting methods allow our clients to incorporate best practice techniques into everyday operations, while being in compliance with the latest sterile, non-sterile, and hazardous compounding laws and regulations.

- FDA Compliance
- Pharmacy Lab Design
- Accreditation Support
- Policies and Procedures (SOPs)
- On-Site Pharmacy Staff Training
- USP <795>, <797> & <800> Compliance

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Compounding Compliance Services

State & Federal Compliance

- State Board of Pharmacy Inspection Preparation
- Corrective Action Remediation
- USP <795> Compliance Analysis
- USP <797> Compliance Analysis
- USP <800> Compliance Analysis
- FDA Compliance Analysis
- Form 483 Remediation
- DEA Compliance

Continuous Quality Improvement

- Evaluate Quality Assurance
- Develop QA and CQI Program
- Compliance Indicator Trending

Training & Education

- USP <795>, <797>, and <800>
- Webinars Available
- Board of Pharmacy Inspector Training
- Continuing Education Credits

Pharmacy Lab Design

- Lab Design
- Equipment Recommendations
- Workflow Evaluation

Accreditation

- PCAB/ACHC Mock Survey
- Post-inspection Remediation

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation

The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Community Pharmacy Services

Accreditation

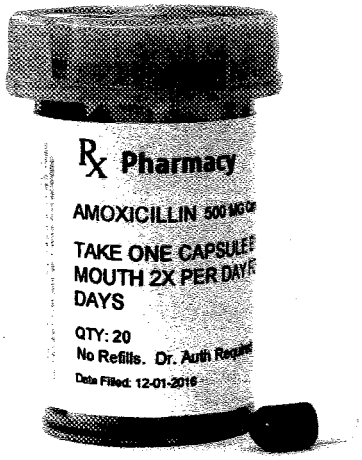
- NABP™ accreditation programs: DMEPOS, VAWD®, VIPPS® and Vet-VIPPS®
- Center for Pharmacy Practice Accreditation (CPPA®) accreditation programs
- Application and document submission
- Policy and procedure review, development, revision, and remediation
- Pre-survey assessment
- Survey findings remediation
- Staff training development

Regulatory Compliance

- Preparation for NABP VPP® inspection
- Gap analysis
- Response to deficiencies
- Remediation and response to disciplinary actions
- Policy and procedure assistance
- Internal compliance monitoring

Patient Care Compliance Programs

- Medication Therapy Management Programs
- Disease State Management Programs
- Disease State Education
- Care Transition Programs



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"During the nail-biting accreditation application processes, we were consistently met with unparalleled service and access to their vast base of industry knowledge."

- Gopesh Patel, VLS Pharmacy - New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Hospital Pharmacy Services

State & Federal Compliance

- State Board of PharmacyCompliance
- Corrective Action Remediation
- USP <795> Compliance
- USP <797> Compliance
- USP <800> Compliance
- Compliance Monitoring

DEA Compliance

- DEA Mock Audit
- Controlled Substance Monitoring
- Accountability Audit

Training & Education

- Training for Professional Staff (tailored to each discipline; general regulatory requirements and nationally recognized best practices)
- Staff Training (On-site and Off-site Trainings)
- Webinars

Facility Design & Layout

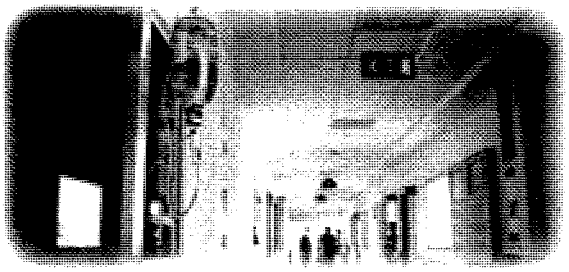
- Compounding Lab Design & Layout (not including engineering)
- Equipment Recommendations
- Workflow Evaluation

Nuclear Pharmacy

- Radiopharmaceutical Gap Analysis
- Quality and Patient Safety

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare Gates

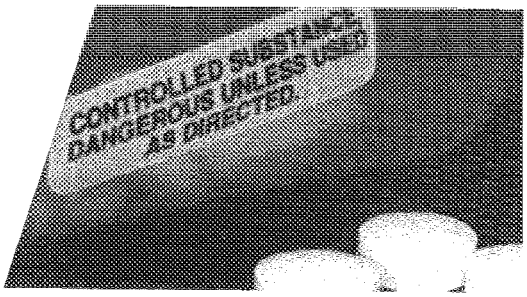
Innovation | Experience | Knowledge | Solutions

The Experts in DEA Compliance

DEA

DEACompliance

Gates Healthcare Associates supports our clients to navigate their way through DEA rules, regulations and inspections. Gates works closely with key stakeholders to ensure harmonization of approach and plays a critical role in ensuring company compliance.



Gates Healthcare Associates' DEA regulatory consultants have conducted extensive research and organizational audits that developed solutions across decision making, business processes, sales monitoring, prescription monitoring and training for companies of all sizes in the pharmaceutical industry including drug wholesalers, hospitals and specialty pharmacies.

- Regulation Compliance
- Training & Education
- Policies and Procedures (SOPs)
- Organizational Processes

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

DEA Compliance Services

Regulation Compliance

- Mock DEA Audits - Inspection Readiness Assessments
- Complete Due Diligence for Full Compliance with Applicable Laws and Regulations Governing the Handling of Controlled Substances
- Due Diligence for Controlled Substances Import and Export Act (CSIEA)
- Drug Supply Chain Security Act(DSCSA)

Policy & Procedures

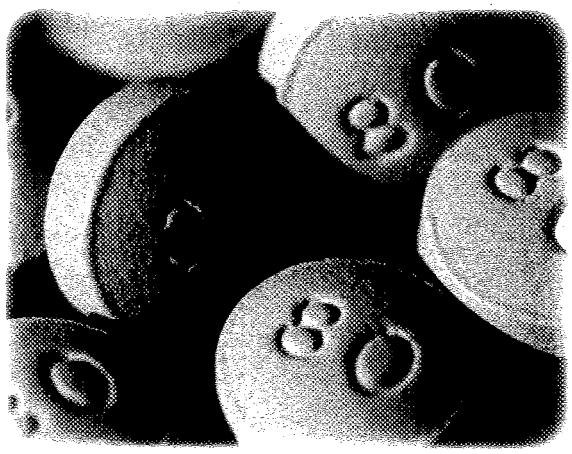
- Quality Assurance/Continuous Quality Improvement Program
- Provide SOP Manual, Model Compliance Indicators, Data Collection Forms and Establish Aggregation Process

Strategic Organizational Processes

- Inventory Accountability
- Business Strategy Sessions
- Design and Implement Programs to Comply with all Applicable Laws and Regulations

Training & Education

- Manufacturing
- Distribution
- Dispensing of Controlled Substance Medications



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Healthcare
Gates

Innovation | Experience | Knowledge | Solutions

Gates Healthcare Associates is a pharmaceutical consulting firm that develops programs designed to improve both clinical and business practices of infusion pharmacies. Gates services are comprehensive and are tailored to meet the individual needs of the organization.

Our Home Infusion Division is comprised of expert consultants with years of industry knowledge and experience. Our innovative and personalized consulting methods allow our clients to incorporate best practice techniques into everyday operations, while being in compliance with the latest laws and regulations.

- Strategic Planning
- Pharmacy Lab Design
- Accreditation Support
- Policies and Procedures (SOPs)
- On-Site Pharmacy Staff Training
- USP <797> & <800> Compliance

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Home Infusion Pharmacy Services

State & Federal Compliance

- State Board of Pharmacy Inspection Preparation
- Corrective Action Remediation
- USP <797> Compliance Analysis
- USP <800> Compliance Analysis
- FDA Compliance Analysis
- DEA Compliance

Strategic Planning

- Business Development
- Financial Analysis
- Aquisition Preparation
- Staffing

Training & Education

- USP <797> and <800>
- Webinars Available
- Board of Pharmacy Inspector Training
- Continuing Education Credits

Pharmacy Lab Design

- Lab Design
- Equipment Recommendations
- Workflow Evaluation

Accreditation

- ACHC Mock Survey
- Post-inspection Remediation

Policy & Procedures

- Evaluate Policy & Procedures on Completeness and Utilization
- SOP Manual Supplementation

The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

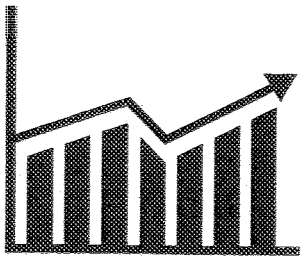
"In a space where regulations and laws are constantly changing, Gates proved to be ahead of the curve and always dedicated to making sure things were done right the first time."

- Gopesh Patel, VLS Pharmacy, New York

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Gates Healthcare Associates helps healthcare organizations develop strategic plans used to set priorities, focus energy and resources, strengthen operations, and assess and adjust the organization's direction in response to a changing regulatory environment.

Our expert team's disciplined effort helps produce fundamental decisions and actions that shape and guide the healthcare organization and who it serves, while ensuring that employees and other stakeholders are working toward common goals.



Staffing

Financial Analysis

Aquisition Preparation

Business Development

www.gatesconsult.com

Phone: 978-646-0091 - Email: info@gatesconsult.com

Strategic Planning Services

Staffing

- Locate Potential Employees for Hire in all Sections of Operations
- Interview Potential Employees

Business Development

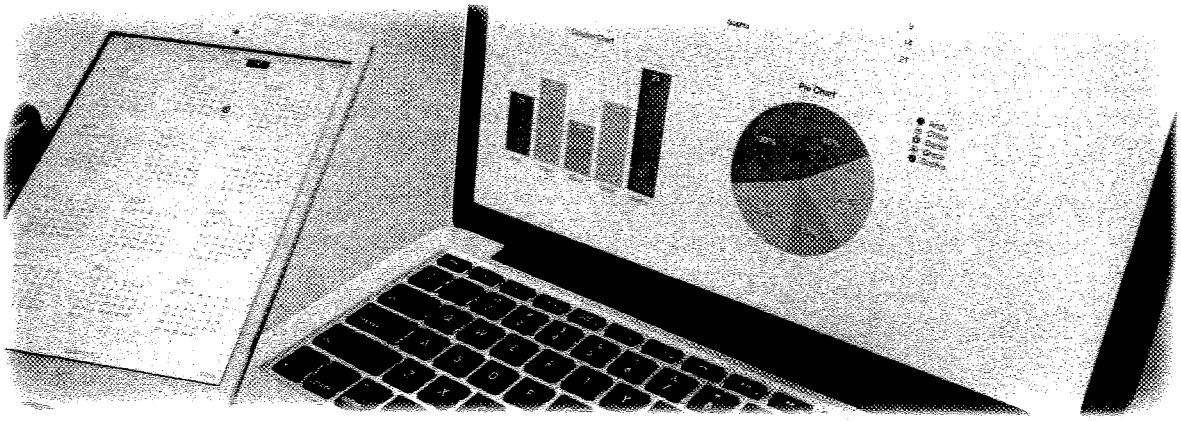
- Demographic Trend Analysis
- Financial Analysis
- Market Penetration

Acquisition Preparation

- Due Diligence
- Operations Inspection for Compliancy
- Find Potential Buyers
- Assist with Negotiations

Financial Analysis

- Profit & Loss Analysis
- Cash Flow Analysis
- Cost Analysis
- Assist in the Development of Financial Goals



The Gates Advantage

Far too often we find healthcare practices hiring several different consulting firms to handle individual challenges when they arise. We find this an unnecessary and costly approach. With Gates Healthcare Associates' "All-In-One" approach, we work as a team so you can get the help you need all under one roof, saving you time and money.

"My business has gone from being in the red to being in the black, and is now experiencing unprecedented growth, and I would give a lot of the credit for that to Ernie Gates. He brings a wealth of experience and knowledge to bear on his work."

- Stephen Bernardi, Johnson Compounding & Wellness - Massachusetts

Gates Healthcare Associates, Inc.
1 Central St., Suite 201
Middleton, MA 01949

Juran, Caroline (DHP)

From: Mike Consolazio <mike.consolazio@gatesconsult.com>
Sent: Wednesday, October 11, 2017 3:17 PM
To: Juran, Caroline (DHP)
Subject: Additional Information Gates Healthcare Associates
Attachments: Engagements.docx; GHA,Speidel BIO.doc; GHA, Watson.docx; GHA, JCabaleiro.docx; GHA.Frank.docx; GHA,Horn Donna.doc

Caroline,

Our Associate, Denise Frank, asked that we forward further information regarding our compliance work for your review. I have attached CV/Resumes of our Associates who have been involved in 503B evaluations and engagements for cGMP, 503A and 503B work. We cannot at this time disclose any checklists, or audit processes as they contain Intellectual Property of Gates Healthcare and our Associates

Our team at Gates Healthcare Associates has proven exceptional skill and knowledge in the areas of Sterile and Non-Sterile Compounding practices, current Good Manufacturing Practice, Medication Error Prevention, and Controlled Substances Risk Management. We have a great multidisciplinary team that includes nationally recognized experts in sterile and non-sterile compounding, and team members with history and background that includes: an FDA regional inspector, a patient safety expert (affiliated with ISMP), the NABP Accreditation and Inspection Services Manager.

Gates Healthcare Associated was founded in 1994 by President and CEO Ernest P. Gates Jr. Since its inception, Gates Healthcare has provided strategic advice, counsel, and compliance support to a broad cross-section of hospitals and health care organizations, including acute, chronic and rehabilitation hospitals; physician practices; pharmacies; and professional associations.

Brief Overview: Compliance Services Expansion Timeline

1994 - Founded Gates Healthcare Associates (operated locally in New England)
2012 - Compounding Compliance Services expanded across entire United States (Accreditation Support, USP 795 & 797 Support, Training, P&P, etc.)
2014 - Compounding Compliance Services expanded into Canada
2014 - Compounding Inspection Training to State Boards of Pharmacies added to List of Services
2014 - DEA Compliance added to List of Services
2016 - USP 800 Compliance added to List of Services
2016 - FDA Section 503B and cGMP Compliance added to List of Services
2016 - PBM Compliance Services added to List of Services
2017 - Community Pharmacy Support Services added to list of Services
2017 - Long Term Care Facility Compliance added to List of Services

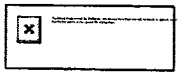
Please feel free to reach out to us with any questions once you have had a chance to review our information.

Best regards,

Mike Consolazio
Chief Operating Officer

Gates Healthcare Associates, Inc
1 Central Street., Suite 201

Middleton, MA 01949
Office: 978-274-7264
Fax: 978-646-0092
Email: mike.consolazio@gatesconsult.com
Web: www.gatesconsult.com
Twitter: @GatesConsult



Newsletter - Sign Up!!!!

FAQ's

- Began 503B/cGMP Consulting in January 2016
- Jeff Watson - Lead Consultant

Fresenius Kabi Compounding LLC - Canton, Massachsuetts

Project- On-Site FDA Section 503B & cGMP Mock Audit of US based Outsourcing Facility

Eagle Pharmacy - Birmingham, Alabama

Project - On-Site FDA Section 503B & cGMP Mock Audit

Haldey Pharmaceutical Compounding - Bronx, New York

Project - 503A Transition to 503B Consultation and Requirement Guidance

AmEx Pharmacy - Melbourne, Florida

Project - Off-Site Consulting - Obtaining Compliance with 503A and 503B Operations

Elements Compounding Pharmacy - Mesa, Arizona - In Progress

Project - 503A Transition to 503B Quality System Development

Project: FDA Mock Inspection/cGMP review of 503A Pharmacy

Clients:

SMP Pharmacy

Village Pharmacy

Apothecary by Design

Johnson Compounding & Wellness

VLS Pharmacy

Schraft's 2.0

Project: FDA 483 Remediation Support/Consultation

Absolute Pharmacy

Pencol Pharmacy

Dr. Ken Speidel R.Ph., BS Pharm., PharmD., FIACP., FACA.
Vice President Compounding Compliance
Gates HealthCare Associates

Dr. Ken Speidel is known for his experience in pharmacy practice and education including his national recognition as a pharmacotherapeutic specialist in endocrinology and pain management, as well expertise in sterile and non-sterile compounding processes and USP Standards of Practice. He has been instrumental in the development of national standards for pharmacy compounding practices and authored several chapters of a review text including; Sterile and Nonsterile Compounding for the North American Pharmacist Licensure Exam (NAPLEX).

Concurrent with his worldwide consulting and educational work, Dr. Speidel formerly was a Professor of Pharmacy Practice. In addition to being course coordinator and lead professor, he was also a clinical site faculty for Advanced Pharmacy Practice Experience student rotation programs for several doctoral programs. He has also assisted in the development and facilitation of many nationally recognized ACPE educational programs. He is a frequent presenter at hospital grand rounds lecture programs as well as national forums and has published articles in the professional literature on compounding, home infusion pharmacy and specialty therapeutics. Ken is a consultant to many organizations including Boards of Pharmacy as well as hospitals and health systems across the United States.

Establishing more stringent standards for accreditation and increased surveyor expertise in the pharmaceutical compounding industry has been a major area of interest for Ken. He was an advisor to the development of the Pharmacy Compounding Accreditation Board (PCAB) and was appointed to an eight-member national standards committee responsible to draft the initial national pharmacy compounding standards. He remains an active surveyor and accreditation expert for PCAB/ACHC (Accreditation Commission for Health Care).

Ken's knowledge and experience in formulation practices led to an entrepreneurial pursuit with the development of a specialty non-sterile and sterile compounding facility. As President and Clinical Director, he was responsible for clinical assessments and consultations, compounding formulation and evaluation, quality assurance, performance improvement as well as business development.

Throughout his career, Ken has been active in a number of professional societies. He was a member and past multi- term President of the National Home Infusion Association (NHIA) and a Multi term President of a large Hospice Program in the United States. Dr. Speidel has been awarded Fellowship status with the International Academy of Compounding Pharmacists as well as the American College of Apothecaries.

Ken received a Doctor of Pharmacy and a Bachelor of Science in Pharmacy from Ohio Northern University. He has additional post graduate training in endocrinology, aseptic compounding, extemporaneous compounding, functional medicine, and pain management.

Jeffrey M. Watson

PROFESSIONAL EXPERIENCE

Watson Pharmaceutical Consulting/**Gates Healthcare Associates**
National, 2016 - Current

Founder and President, Watson Pharmaceutical Consulting
Senior Associate, Gates Healthcare Associates, Inc.
Assisting all human and animal pharmaceutical manufacturers in the nation to implement and adhere to regulatory compliance in order to produce, hold, package, test, monitor, and distribute pharmaceuticals; including 503A, 503B, and global pharmaceutical manufacturers.

Maintain up-to-date regulatory information in this industry through industry contacts; US FDA website www.fda.gov, newsletters, communications, e-mails, guidance documents, regulatory information and updates; consultant co-workers, and working with industry.

Leiter's Compounding, San Jose, CA
2013- 2015
Vice President of Quality:
As the Vice President of Quality with this 503B Outsourcing Facility firm as registered with the US FDA on 01/2014, I created, interviewed, hired, implemented, put into effect, and oversaw the entire operation of non-sterile and sterile drugs as operated under US FDA cGMP regulations and methods including raw materials, production, holding, packaging, shipping, expiration dating, and regulatory inspections by the US FDA and multiple state BOP's. This oversight included all systems involved in human drugs including materials, facilities and equipment, production, packaging and labeling, laboratory control, and the overall quality system including all elements necessary for each system are established, maintained, operated, and administered including SOP's, cleaning, contamination, change control, facility and layout design, staff, training, documentation, qualifications, validations, recalls, investigations, analytical testing, product failures, customer complaints, adverse events, regulatory communications and drug reporting, and reviews of operations to ensure consistent, safe, pure, and effective production/distribution of all human drug products. This department creation included a dedicated and independent quality assurance/control department that consisted of 15 staff members to cover day-to-day operations and continuous quality improvements. **The success of my operations were validated by all regulatory inspections including one of the best US FDA inspections in the nation for this industry as evidenced by the US FDA Inspectional Observations Form 483 that was issued to this firm on 10/2014 that can be accessed at www.fda.gov. No further regulatory actions were ever levied against this firm during my tenure.**

United States Food and Drug Administration (US FDA), San Francisco District Office (SAN-DO), CA. 1989 - 2012
CONSUMER SAFETY OFFICER (CSO/FIELD INVESTIGATOR): 2000 - 2012

- Senior CSO responsible for SAN-DO jurisdiction of current Good Manufacturing Practices (cGMP) for sterile and non-sterile dosage forms of therapeutic biologics and all pharmaceutical drug dosage forms: tablets including immediate release, extended release, single active, bi and tri-layer; viscous and topical liquids/gels; ophthalmic solutions; aerosols; transdermal patches; products for injection including lyophilized; implantable; capsules; large and small volume parenterals. Covering all processes, systems, and procedures for the dosage forms above for the manufacture, storage, laboratory control, quality systems including CAPAs, investigations, complaints, adverse events, facilities, equipment, materials, personnel, training, cleaning, labeling and packaging, and documentation.
- Completed over 200 inspections/investigations independently, as leader of teams consisting of up to five members, or as trainer; for cause, recalls, seizures, New Drug Applications (NDA), Pre-Approval Inspections (PAI), Biological License Agreements (BLA), post-marketing,

adverse drug events, and cGMPs; of biologic/drug/device firms including contract operations regulated by the US FDA for compliance with the Food, Drug, and Cosmetic Act (FD&C Act), Code of Federal Regulations (CFR), and the Public Health Service Act (PHS Act).

- Primary focal point of oral communications with all levels of personnel from technicians to Presidents in industry; and from US FDA SAN-DO Management/Compliance to Center personnel in CDER/CBER.
- Wrote all Establishment Inspection Reports (EIR), Collection Reports, Affidavits, and official memos.
- Testified for the State of California Food and Drug Branch regarding my GMP investigation of a drug compounder responsible for producing contaminated sterile drugs for injection, epidurals.
- First San Francisco District Level III Pharmaceutical Inspectorate/PI certified by the US FDA. 02/11
- Received multiple Commissioners' Letter of Recognition awards, Individual Act awards, District Director Letters of Recognition, bonuses and time off awards.

MICROBIOLOGIST/CONSUMER SAFETY OFFICER: 1997 - 2000

- While maintaining Microbiologist duties, assisted CSOs with inspections of drug and device manufacturers with an emphasis in aseptic processing including filtration, irradiation, steam, gas, and validation of these sterilization techniques; design and equipment validations; laboratory operations including validation of analytical methods, environmental monitoring, facilities, personnel, equipment, water systems, and HVAC systems including controlled environments.
- Received the SAN-DO Team Leader of the Year award for demonstrating highly desirable leadership skills for coordinating/supervising a team of 12 microbiologists and support staff.
- First SAN-DO employee to be Computer Systems Validation certified by the US FDA. Assisted CSOs with inspections of drug and device manufacturers covering a firm's computerized systems of adverse drug events, laboratory and manufacturing equipment/operations, and facility utilities/controlled environments.

MICROBIOLOGIST: 1989 - 2000

- Specialized in sterility (direct inoculation, filtration, and isolators) and endotoxin (LAL-gel clot) analyses on drugs and devices independently utilizing aseptic technique; prep of facility, equipment, sample, and line clearance; performing analytical methodology from the USP, AOAC, FDA Bacteriological Analytical Manual (BAM) and the FDA Sterility Analytical Manual including all controls and validations; and preparing all appropriate procedures, reports, and documents.1993 - 2000
- Performed the spectra of microbiological analyses and documentation on food and cosmetic products as regulated by the US FDA.
- Authored the US FDA San Francisco District Laboratory Class 100 Clean Room SOP.
- Contributed as author to the Department of Health and Human Services (DHHS), Public Health Service, FDA Sterility Analytical Manual.

EDUCATION

- BS in Biology, University of San Francisco, with an emphasis in Microbiology. 1989
- Computer Systems Validation certified by the US FDA. 1996
- Level II Pharmaceutical Investigator certified by the US FDA. 01/07
- Level III Pharmaceutical Inspectorate (PI) certified by the US FDA. 02/11
- Completion of graduate courses through San Diego State University for Regulatory Affairs in Biotechnology, Pharmaceuticals, and Medical Devices Industry Master's Program focusing on FDA law with a 4.0 GPA. 2009 – 2010
- Completion of graduate courses through North Carolina State University for BioManufacturing Principles focusing on all operations of the biotechnology industry. 2011-2012

COMPUTER SKILLS

- Proficient in Excel, Word and PowerPoint applications.
- Working knowledge of Laboratory Information Management System (LIMS) databases.
- Validations of all computerized systems relating to manufacturing, laboratory, equipment, facilities, monitoring, operating parameters, data collection, audit trails, security, and adverse drug events.

PRESENTATIONS

- Presented "Validation Issues and Inspection Techniques for the Microbiology Laboratory", Burlingame, CA, as part of a seminar entitled "Microbiology...Current Issues and Applications in the Pharmaceutical Industry", sponsored by Pharmaceutical Seminars, a division of Applied Analytical Industries, Inc. (AAI). Attendees numbered over 50 representing regulatory, compliance, QA, manufacturing, and laboratory operations from Allergan Pharmaceuticals, Shaklee Corporation, SmithKline Beecham, Procter & Gamble, ALZA Corporation, Eli Lilly & Co., Genentech, and others.
- Presented "Official Action Indicated", White Oak, MD, Center for Drug Evaluation and Research (CDER)-US FDA, to CDER personnel and management regarding US FDA law, regulations, and approaches of enforcing the FD&C Act in the field.

PUBLICATIONS

- Authored San Francisco District Office Microbiology Laboratory's Clean Room SOP for cleaning, preventative maintenance, environmental monitoring, HEPA laminar air flow, particle monitors, air (fall out plates and automated instrumentation) and surface (RODACs) sampling, clean room hood certifications, appropriate gowning techniques, bioburden monitoring of personnel, sample disinfection, clean room air pressures/differentials and all appropriate documentation records.
- Department of Health and Human Services, Public Health Service, FDA Sterility Analytical Manual, 3rd Edition, listed author. Manual served as a supplement to the USP for FDA's sterility analyses for all drugs and devices within the Agency. Included topics are Antimicrobial Preservation Effectiveness, Microbial Limit Tests, Sterility Tests, Closed System Sterility Tests, Bacterial Endotoxins Tests, Particulate Matter in Injections and Device Bioburden Test.

Joe Cabaleiro R.Ph., FACA

EXPERIENCE

Gates Healthcare Associates (10/2014-Present)

Senior Associate Provide programmatic, clinical and regulatory consulting to a variety of organizations including home infusion pharmacies, compounding pharmacies, and pharmaceutical manufacturers.

Accreditation Commission for Healthcare, Cary NC (1/2014-10/2014)

ASSOCIATE DIRECTOR OF PHARMACY Operational responsibility for pharmacy accreditation programs in Home Infusion, Specialty Pharmacy and Compounding Pharmacy

- Revised sterile and non-sterile compounding standards to comply with United States Pharmacopeia (USP) requirements and clearly communicate compliance requirements.
- Participated in activities and negotiations which resulted in the Pharmacy Compounding Accreditation Board (PCAB) becoming a service of ACHC.
- Developed new business opportunities, including ACHC being selected as a contracted vendor to inspect pharmacies on behalf of the Texas State Board of Pharmacy

Pharmacy Compounding Accreditation Board, Washington, DC (2005-2014)

EXECUTIVE DIRECTOR Full operational and P&L responsibility for a national accreditation program. Assumed role Jan 2011.

- Revamped organizational processes leading to consistent, USP compliant standards interpretation for the benefit of patient safety.
- Restructured billing and accounting to significantly improve cash flow. Increased income in first year from $9,000 in 2010 to $290,000 in 2011.
- Implemented numerous improvements in survey process and communication leading to increased customer satisfaction.
- Achieved acceptance of PCAB by California Board of Pharmacy resulting in PCAB accreditation serving in lieu of sterile licensure.

DIRECTOR-

STD. INTERPRETATION Assisted in managing and operating a national voluntary standard setting organization. Integral to the initial development of the organization by assisting in the creation of the draft standards.

- Determined how PCAB Standards requirements would be interpreted by pharmacies and surveyors.
- Managed survey process and communications to keep the accreditation process flowing.
- Developed and implemented changes to improve timeliness and consistency while reducing costs.

Medisca Inc., Montreal, Canada (9/2009-1/2011, 2014-present)

CONSULTANT Worked on various projects related to pharmaceutical compounding education and services.

- Developed and wrote SOPs and educational documents to support a new business initiative related to compounding pharmacies.
- Facilitator for the company's sterile and non-sterile training courses.

Triangle Compounding Pharmacy, Cary NC (9/1999-9/2009)

OWNER Opened North Carolina's first pharmacy specializing in compounded pharmaceuticals.

- Grew revenue to $2.5 million annually.
- Responsible for all facets of operation including P&L, 12 employees & sales management.
- Provided medications and dosage forms that are not commercially available.
- Provided hospitals throughout NC with high risk sterile pharmaceuticals.

Excel Consultants Inc., Cary, NC (2/1993-9/1999)

CONSULTANT Successfully started own consulting company to provide services to the home I.V. therapy industry.

- Started up home infusion divisions for several hospitals.
- Advised customers on all aspects of operations including marketing, regulatory, financial, operational and clinical issues.
- Traveled on site to evaluate all aspects of patient care and to provide consultation. Joint

Commission On Accreditation of Healthcare Organizations, Oakbrook, Illinois (7/1992-4/1999)

PHARMACY SURVEYOR Conducted homecare program pharmacy surveys throughout the U.S. for the JCAHO.

- Evaluated home infusion organizations against JCAHO's national standards.
- Educated organizations regarding standards, quality assurance, clinical monitoring etc.
- Authored JCAHO publication "The Complete Guide to the Homecare Survey Process-Home Pharmaceutical Services".

HealthInfusion Inc., Miami Florida (11/1989-2/1993)

GENERAL MANAGER Recruited to develop the company's first facilities outside the state of Florida.

- Managed local pharmacy operation which received "Accreditation with Commendation" from the Joint Commission on Accreditation of Healthcare Organizations.
- Directed the offices' participation in homecare clinical trials.
- Purchased a local competitor and incorporated operations into HealthInfusion system.
- Expanded North Carolina operations with a second office in Fayetteville, NC.

New England Critical Care, Westborough, Massachusetts (11/1987-10/1989)

GENERAL MANAGER SOUTHEAST REGION Managed the company's North Carolina, Georgia, and Florida operations.

- Responsible for clinical and supply management of high tech homecare patients located in a five-state area.
- Coordinated the activities of staff in three separate offices to support high tech patients at home.
- Developed shipping and delivery systems to assure quality service goals were met in a large geographic area.
- Managed all facets of development and opening of Raleigh & Tampa offices.

Caremark/Home Health Care of America, Newport Beach, California (8/1983-10/1987)

GENERAL MANAGER Directed all facets of a high-tech home infusion therapy program for South Florida.

- Led Miami operation to a winning finish in the company's QA/QC contest.
- Developed computerized Barcode/Scale system for the company's TPN compounding process. This software won the company's first creative idea award contest and created an estimated $250,000 annual savings.
- Awarded the company's "Cornerstone Employee" award for outstanding service.
- Also held positions of pharmacy manager (8/1983-1/1984) and operations manager (2/1984-7/1985).

Coral Gables Hospital, Coral Gables, Florida (6/1980-7/1983)

PHARMACY SUPERVISOR Supervised all areas of pharmacy operations and personnel.

EDUCATION: University of Florida
B.S. in Pharmacy, June 1980

PUBLICATIONS:

Cabaleiro, J. New England Compounding Center Indictment. International Journal of Pharmaceutical Compounding 2015, Mar/Apr 19(2):94-102

Cabaleiro, J. PCAB Accreditation: What is it all About? Custom Rx Connection 2012, December: 8- 9.

Cabaleiro, J. 17P: Choosing a Quality Compounding Pharmacy. Contemporary OBGYN. 2012, March 01. Web.

Cabaleiro, J. Best practice recommendations for compounding 17-hydroxyprogesterone. International Journal of Pharmaceutical Compounding 2012, Jan-Feb; 16(1): 86-87.

Cabaleiro J. Obtaining Accreditation by the Pharmacy Compounding Accreditation Board, Part 4: Tips for "Last Minute" Preparations. International Journal of Pharmaceutical Compounding 2008, Sept/Oct: 432-433.

Mixon B, Cabaleiro J, Lattta K, Vail J. Microbial Air-Sampling Equipment, Part 2: Experiences of Compounding Pharmacists. International Journal of Pharmaceutical Compounding 2008, Jul/Aug: 321-327.

Cabaleiro J. Obtaining Accreditation by the Pharmacy Compounding Accreditation Board, Part 3: Developing a Program of Quality Assurance and Continuous Quality Improvement. International Journal of Pharmaceutical Compounding 2008, May/Jun: 234-236.

Cabaleiro J. Obtaining Accreditation by the Pharmacy Compounding Accreditation Board, Part 2: Developing Essential Standard Operating Procedures. International Journal of Pharmaceutical Compounding 2007, Sept/Oct: 397-398.

Cabaleiro J. Obtaining Accreditation by the Pharmacy Compounding Accreditation Board, Part 1: An Overview. International Journal of Pharmaceutical Compounding 2007, Jul/Aug: 297-298.

Cabaleiro J. Automatic Dishwashers and Detergents in the Pharmacy: The Basics. International Journal of Pharmaceutical Compounding 2004, May/Jun: 200.

Vidrine E, Cabaleiro J, Downing D, Johnson T, Travis P, Tosh E, Wepfer S. Hazard Alert: Compounding with Hazardous and/or Potent Pharmaceuticals. International Academy of Compounding Pharmacists. White Paper. 2003.

Cabaleiro J. Flavoring Meds for Children and Adults So It Goes Down Easy! Home Healthcare Nurse 2003, May; 21(5): 295-298.

Cabaleiro J. Barcode System and Computerized Balance Speed Compounding and Enhance Accuracy. International Journal of Pharmaceutical Compounding 2003, Mar/Apr; 7(2): 118-119.

Cabaleiro J. Assessing and Treating Neuropathic Pain. Home Healthcare Nurse 2002, November; 20(11): 718-723.

Cabaleiro J. The Compounding Pharmacist: A Home Care and Hospice Partner. Home Healthcare Nurse 2002, June; 20(6): 359-362.

Cabaleiro J. Power Tools for JCAHO Accreditation. Infusion 1997; 3(10): 67-70.

Cabaleiro J. Contracts under JCAHO: Unraveling the Mystery. Infusion 1997; 4(1):

47-52. Cabaleiro J: More than a square peg in a round hole. Infusion 1996; 2(6): 25-

28.

Cabaleiro J. Hiring a Computer System. Infusion 1996; 2(5): 56-48.

AWARDS:

"Healthcare Heroes: Innovator-Cabaleiro Compounds Safety" Runner-up. Triangle Business Journal. June 2003.

Denise M. Frank

Licensed Pharmacist, Minnesota License Number 114123
Pharmaceutical Care Certificate (MTM), Immunization Certificate, Sterile Compounding Boot Camp Certificate
CPR/AED certified

EMPLOYMENT

Gates Healthcare Associates/Frank Consulting, LLC

President, 1/16 to present
Provide consulting services in the areas of pharmacy practice, community pharmacy, compounding, accreditation, and regulatory compliance including monitoring. Clients include a technician training program applying for accreditation (review, revise curriculum, P&P), CPPA (updating program materials and checklists with current DQSA and other information), a methadone treatment center (relief work and assistance with regulatory compliance issues), CE webinars and written CE developed for Drug Store News (claims resolution for technicians, fraud, waste and abuse for pharmacists and technicians, DHHS antidiscrimination) and assessing sterile compounding compliance of nuclear pharmacies.

National Association of Boards of Pharmacy (NABP) Accreditation and Inspection Services Manager

8/13-1/16. Responsible for field services, managing the pool of contract surveyors and inspectors that perform site surveys and inspections for NABP Accreditation Programs (CPPA, DMEPOS, VAWD, VIPPS, Vet-VIPPS), State Inspection Programs (including training of compliance officers), and the Verified Pharmacy Program (VPP) that includes a general pharmacy inspection, nonsterile compounding and sterile compounding inspections, and nuclear pharmacy inspections. Developed new programs and maintained existing programs including updating and revising inspection tools to address emerging issues and changes in regulations (DQSA, CMS). Interviewed contract surveyor candidates, trained surveyors and inspectors and PQI (Performance Quality Improvement) of the contract surveyors and inspectors.

2013 Presentation at IEOF (Interactive Executive Officers Forum): "Training Compliance Officers – Through Obstacles to Achievements"
2013 Presentation at ICOLCF (Interactive Compliance Officers and Legal Counsel Forum): "Tool Set: Compounding Blueprint: Developing a Checklist"
Numerous Presentations to boards of pharmacy compliance officers regarding inspection of sterile compounding pharmacies, and to our surveyor/inspectors on accreditation program content, inspection program content, performance of inspections and surveys, and critical points.

In 2015 was responsible for the training, supervision and quality improvement of 41 nation-wide contract surveyors/inspectors in the performance of 1311 surveys and inspections of pharmacy practice, independent and chain pharmacies, corporate chain surveys, internet pharmacies and veterinary internet pharmacies, wholesalers (corporate surveys and distribution centers), general and mail order pharmacy inspections, sterile and nonsterile compounding pharmacy inspections (community and institutional), sterile compounding pharmacies where samples were obtained to send to a lab for testing at the request of a state, and state-specific inspections. Many of the inspections included state compliance officers observing or training in the performance of sterile compounding pharmacy inspections.

NABP Accreditation Surveyor Consultant 10/06 to 8/13

Performed accreditation document reviews, facility site surveys and inspections, surveyor/inspector training, and project development activities for the following NABP programs and projects:
VAWD: Verified Accredited Wholesale Distributor Accreditation
VIPPS: Verified Internet Pharmacy Practice Site Accreditation
Vet-VIPPS: Veterinary Internet Pharmacy Practice Site Accreditation
DMEPOS: Durable Medical Equipment, Prosthetics, Orthotics and Supplies Accreditation
Maryland Board of Pharmacy: Medical Device Distributors Inspections
Idaho Board of Pharmacy: Non-Resident Telepharmacy Site Inspections

Iowa Board of Pharmacy: Inspections of Controlled Substance Registrants and secret shopper program
CPPA: Community Pharmacy Practice Accreditation (joint project with APhA and ASHP)
Iowa Board of Pharmacy: Non-Resident Pharmacy Inspections including Compounding Pharmacies
New Jersey Board of Pharmacy: Inspections of Compounding Pharmacies and training of compliance officers

PharmServ Staffing – Pharmacist and Consultant 9/12 to present.
Relief work as a pharmacist and project work.

Float Pharmacist – Grocery Store Pharmacy 9/10-3/12.
Part-time for Cub Pharmacies in Minnesota. Included dispensing, non-sterile compounding, immunization services and targeted MTM.

Staff Pharmacist – Grocery Store Pharmacy 1/09-9/10.
Cub Pharmacy in Cambridge, MN. Traditional retail dispensing, non-sterile compounding, immunization services and targeted MTM.

Pharmacy Manager – Grocery Store Pharmacy 3/07-12/08.
Cub Pharmacy in Cambridge, MN. Traditional retail dispensing, non-sterile compounding, immunization services and targeted MTM. Special projects as needed – Goldmine, Diabetes Care, Buddy Trainer for new computer program rollout, State Fair Diabetes Screening, Diabetes Expo, etc. This was a new pharmacy and included the buyout of an independent pharmacy and incorporating their stock and staff into this new location. Received the Pharmacy Manager of the Year award.

Float Pharmacist – Grocery Store Pharmacies 9/06-3/07.
Traditional retail dispensing, non-sterile compounding, immunization services and targeted MTM. Special projects (State Fair, Diabetes Expo, new store construction) and participant in Goldmine program, Diabetes Care program, and temporary management of locations needing assistance.

District Manager – Grocery Store Pharmacies 7/02-9/06.
SUPERVALU Pharmacies – Responsible for operations and regulatory compliance for 19-23 Cub pharmacies in Minnesota. District included out-state rural locations (Grand Rapids, Brainerd, Baxter, Willmar, Buffalo, Monticello, Elk River), and the north and west suburbs of Minneapolis. Received Legislative Awareness award. Position eliminated upon restructuring after the Albertson's acquisition.

Pharmacy Manager – Grocery Store Pharmacy 3/01-7/02.
Cub Pharmacy in Maple Grove, MN. Traditional retail dispensing, non-sterile compounding, immunization services and targeted MTM. As the PIC and pharmacy manager at this location, the pharmacy grew from #3 to #1 in sales volume. Received Pharmacy of the Year award, as well as awards for sales and volume.

Pharmacy Manager – Independent Rural Pharmacy 2/99-3/01.
Frank Pharmacy in Princeton, MN. Traditional retail dispensing, non-sterile compounding, and served a long-term care facility.

Pharmacy Manager – Clinic Pharmacy 2/96-2/99.
Fairview Northland Pharmacy Milaca, MN and the opening of a new site for Fairview in the Princeton, MN Clinic. Traditional retail dispensing, non-sterile compounding, and hospice care. Received 'Fairview Cares Award' in 1998. This certifies "recognition and deep appreciation for community service activity exhibiting initiative, commitment and creativity in bringing Fairview's community service mission into people's lives".

Pharmacy Owner and Manager – Independent Rural Pharmacy 9/87-2/96.
Frank Pharmacy in Milaca, MN. Traditional retail dispensing, non-sterile compounding, serving a nursing home, a juvenile care facility, and consulting services for a group home. Received an Honorable Mention in *Drug Topics Magazine* Annual Drug Superstars Issue. Opened a Frank Pharmacy location in the Zimmerman Clinic Building in 1992.

Staff Pharmacist – Independent Rural Pharmacy 7/86-9/87.
Frank Pharmacy in Princeton, MN. Traditional retail dispensing, non-sterile compounding, and served a nursing home.

Staff Pharmacist – Hospital Pharmacy 7/86-12/94.
Part-time relief and emergency coverage for Fairview Princeton and Milaca Hospitals in Princeton and Milaca, MN including limited sterile compounding.

Staff Pharmacist – Clinic Pharmacy 8/85-7/86.
Group Health (now HealthPartners) in St. Paul and White Bear Lake. Traditional retail pharmacy.

Technician – Wholesale, Hospital Pharmacy and Independent Pharmacies 2/77-8/85.
Twin City Wholesale Drug in Minneapolis, Abbott Northwestern Hospital in Minneapolis, (including sterile compounding, IV and TPN), Fairview Hospital in Minneapolis (including sterile compounding, IV and TPN), Carlson North Drug in Minneapolis (traditional retail including non-sterile compounding), Desnick Bros. Drug in St Paul (traditional retail including non-sterile compounding).

PROFESSIONAL

Minnesota Board of Pharmacy Member 1991-1998. Appointed by Governor Arne Carlson in 1991 and 1995. Served as vice president and president (twice) and served on the following: Complaint Committee, Jurisprudence Exam Committee, Internship Committee, Lab Practical Exam Committee, Rules and Legislation Committee, Health Board Presidents Group, Minnesota Coalition of Pharmacy Practitioners

National Association of Boards of Pharmacy Member 1991-2003 NABP and NABP/AACP District V.
Served on the following: District V Audit Committee (chair), NABP Nominations Committee (member), Alternate to NABP BVC Committee, and member of the NABP Task Force on the Development of the Multistate Pharmacy Jurisprudence Examination (MPJE).

MPJE Review Committee (MRC) member 1997-2013, including participation on the original NABP Task Force on the development of the MPJE. Reappointed every 3 years until accepting full-time employment with NABP in 2013. Participated in the annual MRC meeting, item review, item coding, standard setting, and facilitated at item-writing workshops by working with various states to develop and review items for their exams. From 2013 to 2016, provided interdepartmental assistance to facilitate item writing and for the annual MRC meeting.

Hired by NABP as an independent contractor to perform VAWD documentation reviews and facility inspections in October 2006 (see employment above) and expanded to include other programs. Hired full time in August 2013 as Accreditation and Inspection Services Manager.

Minnesota Pharmacists Association (MPhA) Member 1985-present.
As a student member, served as Legislative Committee Chair and Fundraising Committee Chair. As a pharmacist member, served on the Community Pharmacy committee, worked on legislative issues, participated on the AwareRx task force to combat the abuse of OTC and prescriptions drugs, and a delegate to the MPhA annual meeting. 2016 Co-Chair of the Education and Events Advisory Committee.

American Pharmacists Association (APhA) Member 1985-present.
Primary Academy: Academy of Pharmacy Practice and Management (APhA – APPM). Special Interest Group (SIG) Membership: Compounding, Immunizing Pharmacist, Medication Management, Nuclear Pharmacy Practice.

American Society of Health-System Pharmacists (ASHP) Member 2013-present.
Primary Section Membership: Ambulatory Care Practitioners. Secondary Section Membership: Section of Pharmacy Practice Managers and Section of Pharmacy Informatics and Technology. Participated in the 2014 Ambulatory Care Conference and Summit.

Minnesota Society of Health-System Pharmacists (MSHP) Member 2016-present

American Society for Pharmacy Law (ASPL) Member 2013-present.

Pharmacy Technician Educators Council (PTEC) Member 2016-present

Valu-Rite (McKesson) National Advisory Board Member 1991-1994.

NCPA (formerly NARD) Student member 1983-1985, member 1985-2005.

University of Minnesota College of Pharmacy Century Mortar Club Member, Pharmacy College Board Senior Representative 1985, Kappa Psi Professional Pharmacy Fraternity 1982 (*Pharmacopa* Business Manager 1984-85).
Currently preceptor and mentor for pharmacy students.

University of Minnesota Pharmacy Alumni Society Board Member June 2015-present, Events Committee Chair 2016-present

EDUCATION

June 1985 Bachelor of Science in Pharmacy from the University of Minnesota College of Pharmacy
Received the Hallie Bruce Memorial Award for outstanding achievement in clinical pharmacy as a student.

November 1998 Pharmaceutical Care Certificate from the Peters Institute of Pharmaceutical Care at the University of Minnesota (30 hours didactic, 30 hours self-directed home study, 60 hours of direct patient care)

April 2007 Completed APhA Pharmacy-Based Immunization Delivery Certificate program

March 2013 Completed CriticalPoint Sterile Compounding Boot Camp (10 hours eLearning CE, 19 credit hours in 2 ½ days of live training, lecture, discussion, and hands on labs at Baxter's STAR Center)

June 2015 Completed USP <795> Pharmaceutical Compounding – Nonsterile Preparations Training

COMMUNITY

Princeton Area Health Fair 1988-1993 Committee Member (Chair in 1989)

American Cancer Society, Mille Lacs South Chapter 1989-2007.
Served as: Professional Education Chair, Vice President, President, Public Education Committee, Fundraising, Committee, Professional Education Chair, participant in Relay for Life events.

Milaca Area Chamber of Commerce 1988-1996.
Served as Board Member, Secretary, Treasurer, Vice-President, President, and Retail Committee President.

Milaca Economic Development Commission Member 1992-1997

Princeton Lions Club 1999-present.
Served as Chair of Public Relations Committee, Historian, Chair of Diabetes Committee, Drug Awareness Committee, Habitat for Humanity Project, and the Membership Committee. I received the Diabetes Awareness Program Dream Catcher Award in 2004 for outstanding service in Community Diabetes Awareness and Detection. Currently Historian. Facilitated the Diabetes Screening Event (including blood borne pathogen and glucose meter training of our Lions members that assisted in the screening event) at the Princeton Business Expo until 2014.

Milaca Lions Club 1991-1999.
First female member in our district (5M8). Served as Director, Tail-Twister, Vice-president, President, and was appointed Lions District 5M8 Region 1 Chair. Region 1 was composed of 2 Zones encompassing 15 clubs. Transferred membership to Princeton Lions Club in 1999.

Rum River Health Services Inc. Board Member 1993-2013.
Served as chair, treasurer, and hospice merger chair. Received a Distinguished Service Award in 2003. Received Leadership Award in recognition and honor of 20 years of service to Rum River Health Services in 2013.

East Central Electric Association served on ECE Member Resource Council 1994-1996

CHAC (Community Health Advisory Board) Princeton 1998-2001.

Zion Lutheran Church, Princeton, MN. 1995-present.
Chair of Church Directory Project 1998, Choir member, Church Financial Secretary 1998-2005, and Trustee 2005-present. Responsible for the church audio/visual services, PA and sound system both inside the church and for outdoor services, and for video recording services for shut-ins and nursing home residents.

Mission Work 1996-present.
HELPS International team member on medical missions to Guatemala yearly since 1996. More information about HELPS: www.helpsintl.org. In 2007, received 'Diploma de Honor al Merito' for Christian humanitarian service to the people of Guatemala. In 2016, received award for 20 years of participation in HELPS International Medical Missions in Guatemala.

OTHER BUSINESS ACTIVITIES

Consulting Projects 2010-2013.
Provided assistance and support to a drug wholesaler and a county jail regarding new pharmacies. Also helped develop community pharmacy policies and procedures for a group.

Rum River Promotions 2006-present.
Started a business screen printing and pad printing promotional items. Also provides apparel, embroidery and print for businesses and at retail. I am working towards CAS/MAS certification as an advertising specialist. 519 First Street, Princeton MN. www.rumriverpromos.com

Electric Norseman Music Store 2002-2005.
Started a business selling instruments (guitars, band instruments, etc), accessories and gear (amps, mics, sound systems, DJ setups, etc.).

Donna M. Horn, MS, RPh, DPh (Hon.)

Summary:

- Over 10 years of medication error analysis and prevention recommendations experience.
- Combined community pharmacy and pharmacy regulatory board expertise as evidenced in ISMP projects including developing the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy*, revising the *Self-Assessment for Community/Ambulatory Practice,* developing and presenting *Using Failure Mode and Effects Analysis (FMEA) to Identify Potential Errors*" continuing education, and developing the *Improving Medication Safety in Community Pharmacy: Assessing Risk and Opportunities for Change* which is designed to help community pharmacy personnel identify potential medication safety risks and prevent error.
- Worked collaboratively with pharmacy leaders and clinical staff participating in proactive risk assessments, targeted risk assessments, root cause analysis, and failure mode and effects analysis, in order to define and improve medication safety initiatives.
- Highly sought speaker for pharmacists, healthcare institutions, retail pharmacy operations, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention.
- Performed risk assessment and quality review consultations for healthcare organizations in the acute care, ambulatory/community, long term care, and other settings throughout the US.
- Role model to pharmacy students, as an educator and preceptor, exemplifying the highest levels of pharmacy practice while teaching medication safety prevention in the dispensing process.
- Over 15 years of combined regulatory and community pharmacy experience.
- A national leader with a 50- state and an international perspective of regulations and laws that pertain to the practice of pharmacy.
- Served as a member, hearings officer, secretary and president during an 11 year period on the Massachusetts Board of Registration in Pharmacy.
- Elected to various positions in the National Association of Boards of Pharmacy, serving as the association's President and as its Chairman of the Board.
- Served on the American Society of Pharmacy Law Board of Directors for 4 years and the elected as the association's first ever non-attorney President.
- Proven ability to develop systems that streamline procedures, increase productivity while complying with federal and state regulations and laws.
- Skilled at designing and implementing educational programs for pharmacists and technicians.
- Expert witness for medication errors and pharmacy standards of practice for both state and federal regulatory cases

Education:

University of Florida College of Pharmacy, Department of Pharmaceutical Outcomes & Policy, Master of Science in Pharmacy, May 2017

University of Florida College of Pharmacy, Graduate Certificate in Patient Safety in Medication Use, May 2017

Massachusetts College of Pharmacy and Allied Health Sciences, BS Pharmacy, cum laude
RHO CHI National Honor Society

University of Utah School of Alcohol and other Drug Dependencies - Dupont Merck Grant

Licensure:

Commonwealth of Massachusetts: Registered Pharmacist
Oklahoma State Board of Pharmacy: Doctor of Pharmacy (Hon.)

Professional Experience:

Institute for Safe Medication Practices (ISMP), Horsham, PA, May 2006 to present

- Director Patient Safety- Community Pharmacy

  Directs ISMP's patient safety activities in community/ambulatory practice
  Responsibilities include community/ambulatory consulting, on-site safety consults for national health care organizations and health care systems, as well as, writing recommendations for safety improvements for these organizations, contributing editor for ISMP newsletters and national publications, participant in analysis of ISMP's error reporting program, medication error prevention research through government and private grant foundations and various special projects

  Member Technical Expert Panel for safety culture surveys, commissioned by Westat for the Agency for Healthcare Research and Quality
  Responsible for developing the Pharmacy Survey on Patient Safety Culture

MCPHS University, Boston and Worcester, MA 2012 to present

- Adjunct Instructor, School of Pharmacy/Pharmacy Practice department

  Provide direct student instruction focused on the practice-based aspects of community pharmacy.

- Experiential Education Program Preceptor, 2010 to present

Gates Healthcare Associates, Middleton, MA 2014 to present

- Senior Associate

  Instrumental in advising clients on community pharmacy practice, regulatory compliance, medication safety initiatives and continuous quality improvement.

Brooks Pharmacy, Warwick, RI, 2002 to May 2006

- HIPAA Privacy Officer, Brooks Pharmacy and Eckerd Pharmacy

  Merged, relocated and transitioned the Privacy Office and Legal Compliance Offices of Brooks and Eckerd Pharmacy Corporations with little previous knowledge of the scope of responsibilities entailed and without involving other departments, well within the imposed deadline.

  Identified differences in operating procedures between the two companies and wrote all new policies and procedures for pharmacy teams in regards to HIPAA rules.

  Continuous monitoring of state laws as they apply to HIPAA rules in the states in which Brooks/ Eckerd operates.

  Respond to HIPAA complaints, requests for confidential communications and access of records as needed from outside the company and from the stores.

- Manager of Regulatory Affairs, Assistant Privacy Officer,

  Recognized by field staff for improving communications between regulators and store staff in order for all stores to comply with necessary regulations.

  Established protocol for a company-wide Quality Assurance Program and procedure for monitoring prescription incidents.

Spearheaded implementation of an on-line Store Operations Manual containing policies and procedures, as well as, quick regulatory look-up guide for all department and store staff use resulting in increased compliance and less regulatory complaints.

Instituted an on-line HIPAA Privacy Training program for all pharmacists, technicians and store managers, resulting in a greater than 96% training compliance rate.

Developed and wrote more than 25 policies and procedures for pharmacists in regards to operating procedures, state and federal guidelines and regulatory compliance issues.

- Pharmacy Specialist 2/02 to 9/02
  Pharmacy Operational support for 28 stores in Metropolitan Boston and Southeastern Massachusetts
  Successfully converted 28 Osco Drug stores to Brooks Pharmacies to include all personnel, data and technical training well before deadline.
  Professional Relations: Liaison to Massachusetts College of Pharmacy and Allied Health Sciences, Worcester Campus, and Northeastern University.
  Government Affairs: Liaison for Massachusetts Board of Registration in Pharmacy, Massachusetts State Legislature, Drug Enforcement Agency, Massachusetts Department of Public Health

Osco Drug, Boston, MA, 1983 –2002

- Regional Pharmacy Manager,
  Pharmacy Operational support for 28 stores in Metropolitan Boston and Southeastern Massachusetts, including direct accountability for over 80 registered pharmacists and annual pharmacy sales in excess of 25 million dollars, government affairs liaison, professional liaison and human resources responsibilities

  Previous Responsibilities included:
  Pharmacist Contributor Editor for Savon (Osco) Healthy Living Magazine
  Pharmacy and Government Affairs Specialist
  Manager of Provider Relations of New England
  Pharmacy Manager and staff pharmacist

Teaching Experience:

Teaching Assistant, PHA 6799: Patient Safety Program Evaluation, Pharmaceutical Outcomes and Policy, MS Online Program, University of Florida Graduate school, Summer B 2017

Guest Lecturer, "Proactively Minimizing Risk in a Community Pharmacy Setting", presented to PharmD Candidates MCPHS University, Boston, MA February 2015

Guest Lecturer "Preventing Medication Errors in Community Pharmacy: Case Study in 4 Acts" presented to PharmD Candidates Jefferson School of Pharmacy, Philadelphia PA, October 2014

Guest Lecturer "Jail time for a medication error: Lessons learned from a pharmacy compounding error", presented to PharmD Candidates and faculty at University of Rhode Island, Kingston, RI, April 2014

Guest Lecturer, "How to Find Risk in A Community Pharmacy Setting", presented to PharmD Candidates MCPHS University, Boston, MA February 2014 and February 2013

Guest Lecturer, "Medication Errors in Community Pharmacy", presented to PharmD Candidates and faculty at Jefferson School of Pharmacy, Philadelphia PA, October 2013

Guest Lecturer, "Error Reporting", presented to PharmD Candidates Jefferson School of Pharmacy, Philadelphia PA, October 2013

Guest Lecturer "Jail time for a medication error: Lessons learned from a pharmacy compounding error", presented to PharmD Candidates and faculty at Daniel K. Inouye College of Pharmacy University of Hawai'i Hilo HI, April 2013

Guest Lecturer, Preventing Medication Errors in Community Pharmacy", presented to PharmD Candidates Jefferson School of Pharmacy, Philadelphia PA, October 2012

Guest Lecturer, "Lithium Citrate, Community Pharmacy Case Study", presented to PharmD Candidates MCPHS University, Boston, MA February 2012

Guest Lecturer, "Recognizing and Defining Quality Problems", presented to PharmD candidates, University of Arizona, via webinar, August 2011

Guest Lecturer, "Jail time for a medication error Lessons learned from a pharmacy compounding error", presented to PharmD Candidates MCPHS University, Worcester, MA, March 2011

Guest Lecturer, "Medication Safety in Community Pharmacy Practice" presented to PharmD Candidates MCPHS University, Boston, MA, February 2011

Guest Lecturer, "CQI and Boards of Pharmacy" presented to PharmD Candidates, Temple University, Philadelphia, PA May 2007

Preceptor Experience:

Preceptor of MCPHS Doctor of Pharmacy students on clinical clerkship in Medication Safety, the Institute for Safe Medication Practices, 2010 to present

Regulatory Experience:

Massachusetts Board of Registration in Pharmacy, member 1993 to 2004

- President 2002-2003

Secretary 2001-2002

Continuing Education programs on Pharmacy Law
Chairperson, Strategic Planning Committee
Chairperson, Technician Regulations Committee
Liaison to Massachusetts Health Council
Liaison to Massachusetts Chain Pharmacy Council
Chairperson of Pharmacy Board Regulations Committee

National Association of Boards of Pharmacy, 1993 to 2006

- President 4/04- 5/05, Chairman of the Board through 2006

President-Elect 5/03-5/04 Treasurer 5/02-5/03
Executive Committee Member for District 1 5/96 to 5/99, re-elected 5/99 to 5/02
EPIC Committee (NABP Ex-Presidents in Collaboration)
Task Force 'Privacy'
Budget and Finance Committee
Committee on Constitution and Bylaws
Government Affairs Committee
Task Force 'Model Guidelines for Formulary Development'
Task Force 'Standardization of Technicians' Role and Competencies'

Task Force 'Patient Compliance and Intervention Program'
Executive Committee Liaison to Advisory Committee on Examinations
Automation Task Force

Massachusetts Department of Public Health, 1993 to 2005

Member Medical Review Group for Electronic Data Transfer Program
Editorial Board for 'Pharmacy Update'
Member 'Medication Dispensing Advisory Group' and 'Automation Task Force'

Publications:

Horn D, *Importance of a CQI program in ambulatory practice*, Pharm Today. 2016;22(11):63–75, published on line Nov 2016, available at http://elearning.pharmacist.com/products/4668/the-importance-of-a-continuous-quality-improvement-cqi-program-in-ambulatory-practice

Goldman JD, **Horn D**. *Overcoming challenges and barriers to insulin therapy in type 2 diabetes.* Pharmacy Times; 2015; 81(5):89-100. Published online May 2015, available at http://www.pharmacytimes.com/publications/issue/2015/may2015/overcoming-challenges-and-barriers-to-insulin-therapy-in-type-2-diabetes.

Cohen MR, Smetzer JL, Westphal JE, Comden SC, **Horn DM**. *Risk models to improve safety of dispensing high-alert medications in community pharmacies* J Am Pharm Assoc. 2012;52:584-602 available at https://psnet.ahrq.gov/resources/resource/25232

Horn D, *Rooting Out Errors in Your Pharmacy* Drug Store News May/June 2012 available at https://drugstorenewsce.com/content/rooting-out-errors-your-pharmacy

Gaunt M, **Horn D**. *A Pharmacist's Guide to Preventing Vaccine Errors* Pharmacy Times May 2012, available at https://www.pharmacytimes.org/landing/280

Horn D. *Assessing Risk and Developing Strategies to Keep Patients Safe in Community Pharmacy: a case study* Drug Store News February 2011

Horn D. *Long Working Hours and Pharmacy Errors: Could There be a Correlation?* Rx Ipsa Loquitur 2011 (Jan/Feb); 37(1)

Horn D. *A Community Pharmacy Team's Role in Medication Reduction Strategies* California Pharmacist Spring 2009 Vol. LVI, No. 2 www.cpha.com

Horn D. *Medication Reconciliation: A Survey of Community Pharmacies and Emergency Departments*
Patient Safety and Quality Healthcare May/June 2010 Volume 7 issue 3 www.psqh.com

Text Book Chapter:

Horn D. *Providing a Framework for Ensuring Medication Use Safety* Remington's Pharmaceutical Science 2013 Ch 68

Research:

Preventing Errors Introduced by the Use of Electronic Prescribing, Poon, E, et al 2006

Using Risk Models Identify and Prioritize Outpatient 'High-Alert' Medications, Cohen, M, et al 2007

Risk-Informed Interventions in Community Pharmacy: Implementation and Evaluation, Cohen, M, et al 2008

Donna M. Horn, MS, RPh, DPh (Hon.)

Awards:

Distinguished Service Citation, 2016 Lambda Kappa Sigma, International Professional Pharmacy Fraternity

Bowl of Hygeia award winner, 2010, Massachusetts Pharmacists Association

"Award of Merit", 2005, Lambda Kappa Sigma, International Professional Pharmacy Fraternity

"Commissioner's Special Citation" presented by the Food and Drug Administration (FDA), Dept of Health and Human Services, May 2004 for my contribution to the NABP Model Rules for the Licensure of Wholesale Distributors to combat counterfeit drugs entering the US drug supply

"2003 Alumni Achievement Award", Massachusetts College of Pharmacy and Health Sciences, June 2003

"Nathan Goldberg Award", Massachusetts Pharmacists Association

"Ruth Davies Flaherty Service Award" Lambda Kappa Sigma

Professional Associations:

American Society for Pharmacy Law
- ➢ President 2012-2013
  Board of Directors 2006 to 2014

URAC Healthcare Accrediting Organization
  Pharmacy Accreditation Advisory Group 2008 to present
  Pharmacy Measurement Development Group 2008 to 2010

Massachusetts State Pharmacist Association
  Awards Committee 2015 to present
  Nomination Committee 2012-2014
  Convention and Conference Committee member, 2010-2012
  Continuing Education Programs on 'Board of Pharmacy Update'
  Pharmaceutical Care Committee
  Membership Committee

Massachusetts College of Pharmacy/AHS alumnae member
  Dean's Advisory Council – School of Pharmacy- Boston, 2010 to present
  Preceptor for interns and externs, 2008 to present
  Strategic Planning Retreat - External Environment Subcommittee member

Lambda Kappa Sigma - professional fraternity for women in pharmacy
  Educational Grants Committee
  Educational Trust Committee
  Continuing Education Committee
  Archives Committee
  President, Alpha Alumnae Chapter
  Regional Supervisor for New England and New York Chapters
  President, Alpha Collegiate Chapter

American Pharmacists Association
  APhA Foundation: Peoples Pharmacy School committee member 2010
  Strategic and Tactical Analysis Team on Payment
  2006-2007 Policy Committee

Massachusetts Pharmacists Recovery System

Boston Druggist Association

Massachusetts Chain Pharmacy Council

New England Sinai Hospital and Rehabilitation Center, Sinai Board of Advisors

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

a controlled substances registration prior to using an automated dispensing system, regardless of its intended use for obtaining routine or non-routine drugs. Additionally, while 18VAC110-20-555 3c does allow access to drugs in the device that would be stocked in an emergency drug kit pursuant to 18VAC110-20-540, it does not specifically authorize access to drugs that would be stocked in a stat-drug box in 18VAC110-20-550. However, the board has historically applied the regulation in a manner to permit such. Lastly, Mr. Johnson indicated the quantity limitations of Schedule II-V drugs in 18VAC110-20-550 5b may not be appropriate when using an automated dispensing device.

MOTION:

The Board voted unanimously to accept the petition for rulemaking and adopt a notice of intended regulatory action (NOIRA) for amending Regulation 18VAC110-20-555 to specifically authorize the use of an automated dispensing device in a nursing home for obtaining drugs that would be stocked in a stat-drug box and to clarify the quantity of drugs in Schedules II-V that may be stocked in the device for this purpose, and to consider the appropriateness of requiring a provider pharmacy to the nursing home to obtain a controlled substances registration at the location of the facility for the purpose of placing an automated dispensing device in the facility. (motion by Saenz, second by M. Elliott)

OLD BUSINESS:

* Consideration for accepting inspection from Bestech GMP Contracting, Inc. in lieu of FDA inspection for outsourcing facility

Matthew Bestercy, Owner and Principal Consultant for Bestech GMP Contracting, Inc., provided a handout with additional information for board consideration in follow-up to the discussion during the June 2016 full board meeting. He is requesting the board to accept an inspection report of outsourcing facilities resulting from inspections performed by his company for satisfying the requirement for an outsourcing facility to submit a current inspection report when the FDA has not performed an inspection in the required timeframe as authorized in 54.1-3434.05 and 54.1-3434.5. Bestech would provide the board with the complete inspection report, collect a written corrective action plan from the outsourcing facility within 15 days of the inspection, and provide the board with a written opinion regarding the appropriateness of the written corrective action plan. Mr. Bestercy indicated his inspectors would be able to provide testimony during a disciplinary case, if necessary. It was stated that all inspection reports of outsourcing facilities resulting from an FDA inspection must be considered by the board and that an inspection from Bestech would not preclude this requirement. However, the board could consider accepting an inspection from Bestech for licensure purposes when the FDA had not performed an inspection in the required timeframe.

MOTION:

The board voted 7 to 3 in support of accepting an inspection report

from Bestech GMP Contracting, Inc. for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a "current" inspection report pursuant to 54.1-3434.05 and 54.1-3434.5. (motion by Saenz, second by Shinaberry; M. Elliott, Boone, and S. Elliott opposed)

NEW BUSINESS:

- Amend Bylaws

Ms. Juran stated the description of the Examination Administrator Selection Committee and Item Review Committee in the bylaws needed to be amended to reflect the change from no longer administering the Virginia Federal and State Drug Law Exam and the board's participation in the Multistate Pharmacy Jurisprudence Examination.

MOTION:

The Board voted unanimously to amend the bylaws as presented. (motion by S. Elliott, second by Cathcart)

- FDA Guidance Document, Insanitary Conditions at Compounding Facilities

The open comment period for an FDA proposed a Guidance Document regarding Insanitary Conditions at Compounding Facilities closes October 3, 2016. The board considered a draft comment supporting the publishing of the guidance document as written.

MOTION:

The Board voted unanimously to submit the draft comment as presented to support the FDA publishing the proposed guidance document for insanitary conditions at compounding facilities as written. (motion by Allen, second by Logan)

- Requests for Waivers of the 91-day Waiting Period between Retakes of the NAPLEX after Receiving a Failing Score

Ms. Juran stated that the National Association of Boards of Pharmacy (NABP) currently requires a candidate who fails the NAPLEX examination to wait 91 days before being eligible to sit for the exam again. However, NABP will decrease this waiting period to 45 days effective November 1, 2016. In the interim, NABP will allow a candidate to test after waiting 45 days if a board approves such a waiver. Board staff has received approximately 5 waiver requests. Most are residents who failed their first attempt at NAPLEX. They are requesting a shorter waiting period for retaking NAPLEX so as to remain eligible for their residency program or to progress through the residency program in a timeframe that is contemporary with their peers who passed NAPLEX.

MOTION:

The board voted 8 to 2 to reduce the waiting period between retakes of the NAPLEX examination to 45 days and to apply this approval retroactively to any candidates who recently received a failing score on the NAPLEX. (motion by M. Elliott, second by Cathcart; Warriner and S. Elliott opposed)

REPORTS:

- Chairman's Report

Ms. Thornbury provided a report to the Board mentioning that three