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
March 29, 2018
9:00AM

TOPIC	PAGE

Call to Order of Public Hearing for Scheduling Certain Substances: Ryan Logan, Chairman
- Welcome & Introductions
- Reading of Emergency Evacuation Script

Public Hearing on Scheduling:
- Possible Scheduling of the Certain Chemicals in Schedule I of the Drug Control Act 1

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Ryan Logan, Chairman
- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - December 4, 2017, Inspection Special Conference Committee 2-8
  - December 7, 2017, Special Conference Committee 9-10
  - December 11, 2018, Public Hearing for Scheduling Certain Chemicals 11-12
  - December 11, 2018, Full Board Meeting 13-23
  - January 11, 2018, Telephone Conference Call 24-25
  - January 17, 2018, Special Conference Committee 26-27
  - February 14, 2018, Special Conference Committee 28-29
  - February 27, 2018, Formal Hearings 30-34

Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

Legislative/Regulatory/Guidance: Elaine Yeatts
- Legislative Update on 2018 General Assembly 35-46
- Regulatory Update 47
- Adoption of exempt regulation to add certain chemicals to Schedule I 48-58
- Petition for Rulemaking from Judy Dietrick regarding record retention for immunizations 59-61
- Adoption of proposed regulations for:
  - Requirement for E-profile number on applications 62-67
  - Fee increase for all professions and facilities Handout
- Amend Guidance Document 110-45 "Protocol for the Prescribing of Naloxone and Dispensing by Trainers" 68-75
- Amend Guidance Document 110-5 "Theft or Loss of Drugs" 76-78

- Amend Guidance Document 110-47 "Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs" 79-80

New Business:

- Request from Gates Healthcare Associates, Inc. regarding cGMP inspections – Ernie Gates and Denise Frank 81-95
- Update on pharmaceutical processor Request for Application process
  - Request to delegate authority to chairman, in consultation with executive director, for appointing persons to evaluation committee

Reports:

- Chairman's Report – Ryan Logan
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr. 96-108
- Report on Disciplinary Program – Ellen B. Shinaberry 109-119
- Executive Director's Report – Caroline D. Juran 120

Consideration of consent orders & summary suspension, if any

Adjourn

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

*****A panel of the Board will convene at 1:30pm or immediately following adjournment of the board meeting, whichever is later.*****

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at **9:05 a.m. on March 29, 2018** 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 Virginia Department of Forensic Science (DFS) has identified seven (7) compounds for recommended inclusion into the Code of Virginia.

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-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine)**, 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. **3,4-methylenedioxy-N-tert-butylcathinone**, 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. **4-fluoro-N-ethylamphetamine**, 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. **beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)**, 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.

5. **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl 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.
6. **2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)**, 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. **N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)**, 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.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Monday, December 4, 2017
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Sheila K.W. Elliott, Committee Chair
MEMBERS PRESENT:	Jody Allen, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Jr., Deputy Executive Director Beth L. O'Halloran, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
BRITTANY THALIA LEWIS Pharmacy technician registration #0230026815	Brittany Thalia Lewis, pharmacy technician, did not attended to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 2, 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 Brittany Thalia Lewis in violation of failing to complete required continuing pharmacy education and unanimously voted to enter an Order that imposes a reprimand of her pharmacy technician registration. As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Brittany Thalia Lewis, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Brittany Thalia Lewis 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.

ELIZABETH MULUGETA
Pharmacy Technician Registration
#0230015307

Elizabeth Mulugeta, 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 November 2, 2017 Notice.

Decision:

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

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

CLARKSVILLE COMMUNITY PHARMACY, INC.
Pharmacy Permit #0201003454

Kevin S. Allgood, Pharmacist-In-Charge, attended the meeting to discuss allegations that Clarksville Community Pharmacy, Inc. may have violated certain laws and regulations governing the conduct of pharmacy as stated in the November 2, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Clarksville Community Pharmacy, Inc. Additionally, she moved that Beth L. O'Halloran and Sammy Johnson 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. Allen, and duly seconded by Ms. Elliott, the Committee made certain Findings of Facts and Conclusions of Law and found Clarksville Community Pharmacy, Inc. in violation of certain laws and regulations of the Board of Pharmacy and unanimously voted to enter an Order that imposes a $500 monetary penalty.

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

LAFAYETTE PHARMACY
Pharmacy Permit #0201002357

James H. Fitzgerald, Pharmacist-In_Charge, attended the meeting to discuss allegations that Lafayette Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the November 2, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Lafayette Pharmacy. Additionally, she moved that Beth L. O'Halloran and Sammy Johnson 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. Allen, and duly seconded by Ms. Elliott, the Committee made certain Findings of Facts and Conclusions of Law and found Lafayette Pharmacy in violation of certain laws and regulations of the Board of Pharmacy and unanimously voted to enter an Order that imposes a $500 monetary penalty.

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

GROVE AVENUE PHARMACY
Pharmacy Permit #0201002049

William Toler, owner, attended the meeting to discuss allegations that Grove Avenue Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the November 2, 2017 Notice.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Grove Avenue Pharmacy. Additionally, she moved that Beth L. O'Halloran and Sammy Johnson 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. Allen, and duly seconded by Ms. Elliott, the Committee made certain Findings of Facts and Conclusions of Law and found Grove Avenue Pharmacy in violation of certain laws and regulations of the Board of Pharmacy and unanimously voted to enter an Order that imposes a $250 monetary penalty.

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

MEDICAP PHARMACY
Pharmacy Permit #0201004165

Banyo Ndanga, Pharmacist-In-Charge, attended the meeting to discuss allegations that Medicap Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the November 2, 2017 Notice

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Elliott, 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 Medicap Pharmacy. Additionally, she moved that Beth L. O'Halloran and Sammy Johnson 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. Allen, and duly seconded by Ms. Elliott, the Committee made certain Findings of Facts and Conclusions of Law and found Medicap Pharmacy in violation of certain laws and regulations of the Board of Pharmacy and unanimously voted to enter an Order that imposes a $750 monetary penalty.

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

Sheila K.W. Elliott, Chair

J. Samuel Johnson Jr., Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, December 7, 2017
Commonwealth Conference Center
Second Floor
Board Room 1

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

PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Cathy Reiniers-Day, Deputy Executive Director J. Samuel Johnson, Deputy Executive Director (departed at 11:00 a.m.) Mykl D. Egan, DHP Adjudication Specialist
Prince William Rx d/b/a Prosperity Pharmacy Permit Number 0201-004275	Vinod Patel, the pharmacist in charge, appeared on behalf of Prosperity Pharmacy to discuss allegations that it may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 12, 2017 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Prosperity Pharmacy. 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. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order that Prosperity Pharmacy must comply with certain terms and conditions.

Daniel S. Bak License Number 0202-211153	Daniel Bak appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 15, 2017 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Daniel Bak. 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. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to issue an Order to dismiss this matter.
ADJOURN:	With all business concluded, the meeting adjourned at 11:50 p.m.

Rafael Saenz, Chair	Cathy M. Reiniers-Day Deputy Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN CHEMICALS

December 11, 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 9:12a.m.

PRESIDING: Ryan K. Logan, Chairman

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

MEMBERS ABSENT: Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Sammy Johnson, Deputy 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 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:

- 2-(methylamino)-2-phenyl-cyclohexanone (other name: Deschloroketamine
- 2-methyl-1-(4-(methylthio)phenyl)-2-morpholinopropiophenone (other name: MMMP

- alpha-ethylaminohexanophenone (other name: N-ethylhexedrone
- N-ethyl-1-(3-methoxyphenyl)cyclohexylamine (other name: 3-methoxy-PCE),
- 4-fluoro-alpha-pyrrolidinohexiophenone (other name: 4-fluoro-alpha-PHP),
- N-ethyl-1,2-diphenylethylamine (other name: Ephenidine)

Classified as powerful synthetic opioids:

- N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl),
- 3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900),
- 2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-48800)

Classified as central nervous system stimulants:

- Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (4-fluoromethylphenidate),
- Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate)

PUBLIC COMMENT: Public comment was provided by Scott May, Director of Chemistry Department, Virginia Department of Forensic Science. Mr. May requested that the Board schedule the six chemicals classified as research chemicals, three chemicals classified as powerful synthetic opioids, and two chemicals classified as central nervous system stimulants.

ADJOURN: The public hearing adjourned at 9:14am.

Ryan K. Logan, Chairman

Caroline D. Juran, Executive Director

Date

Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 11, 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
Sheila K. W. Elliott
Rafael Saenz
Ellen B. Shinaberry
Cynthia Warriner

MEMBERS ABSENT: Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Sammy Johnson, Deputy 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.

APPROVAL OF AGENDA: **The Board voted unanimously to approve the agenda as presented. (motion by Warriner, second by Shinaberry)**

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

- September 14, 2017, Special Conference Committee
- September 26, 2017, Full Board Meeting
- September 26, 2017, Public Hearing for Scheduling Certain Chemicals
- September 26, 2017, Public Hearing for Dispensing Schedule VI drugs in excess of quantity prescribed and use of automated devices
- September 26, 2017, Formal Hearings
- September 27, 2017, Inspection Special Conference Committee
- October 2, 2017, Telephone Conference Call
- October 10, 2017, Special Conference Committee

- November 2, 2017, Regulation Committee
- November 2, 2017, Formal Hearings
- November 7, 2017, Special Conference Committee

MOTION: **The Board voted unanimously to adopt the minutes from September 14, 2017 through November 7, 2017 as presented, excluding the September 26, 2017, Full Board Meeting. (motion by M. Elliott, second by Saenz)**

Prior to adjournment of the Full Board Meeting, the September 26, 2017, Full Board Meeting minutes were reviewed.

MOTION: **The Board voted unanimously to adopt the minutes of the September 26, 2017 Full Board Meeting as amended:**

- **Page 1 - Strike the arrival times for Michael Elliott and Cynthia Warriner**
- **Page 5, for the following motions, change "motion by Warriner" to "a motion was offered":**
  - **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.**
  - **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 Boone, second by Allen)

PUBLIC COMMENTS: Mark Johnston, former Executive Director of the Idaho Board of Pharmacy and currently representing CVS Health and District 7 on the NABP Executive Committee, offered support to the petition for rulemaking submitted by CVS for an amendment of Regulation 18VAC110-20-275(B)(2)(d) which pertains to the delivery of dispensed prescriptions to another pharmacy. He commented that he was not aware of any other state requiring the identity of a second pharmacy on the label. CVS proposes using a unique identifier to identify both pharmacies

except when the receiving pharmacy is simply holding the dispensed prescription for pick-up or further delivery and has not been involved in the dispensing functions. He stated that a second pharmacy name on the label creates confusion for the patient as to which pharmacy is best positioned to answer patient questions. In addition, including a second pharmacy name and address on the label encroaches on critical label information and is not an important element in reducing medication errors.

Mr. Johnston offered comment in support of a possible requirement for notification during white bagging/brown bagging processes. CVS only allows brown bagging, never white bagging. Mr. Johnston recommended the Board wait on its deliberations until February 2018 in order to receive model language that NABP may be considering on the subject.

John Lubkowski, Director of Pharmacy, Augusta Health Care, Inc., encouraged the Board to pursue a NOIRA regarding white bagging/brown bagging. He stated concerns with patient access and safety and is looking for guidance from the Board on how to handle the issue.

Michael Thomas, McGuire Woods Consulting, LLC, representing Temp Time, provided oral and written comment regarding draft Guidance Document 110- related to proper delivery of temperature-sensitive drugs. Mr. Thomas requested adding the definition for "chemical degradation" in the guidance document since it is not defined in the Code of Virginia which uses the term in §54.1-3420.2, related to the delivery of drugs by mail, common carrier, or delivery services. In addition, Mr. Thomas requested that the guidance document include language which provides a method for the patient to have knowledge if a temperature variation occurred. This would encourage the patient to have a meaningful conversation with their health care provider regarding the safety and effectiveness of the drug.

DIRECTOR'S REPORT:

Dr. David Brown, Director of the Department of Health Professions, shared that Bill Hazel, Secretary of Health and Human Resources, will not be seeking reappointment. Dr. Brown thanked the opioid workgroup charged with developing core competencies for professional schools to educate students regarding the prescribing and dispensing of opioids. A set of core competencies was developed and in Spring 2018, a steering group will discuss how they will be incorporated in schools of higher education. Dr. Brown informed the Board that Lisa Hahn is now the Chief Operations Officer of DHP. With every change of administration, the top two at-will leadership positions may be occupied by individuals who are largely unfamiliar with agency operations, issues, procedures, and policies. This new position, which is not appointed, was designed to provide the Director and Chief Deputy with an understanding of the entire agency, and to advise and support them.

REGULATORY ACTIONS:

- Legislative Update On

Ms. Yeatts reviewed the list of legislative proposals included in the

2018 General Assembly:

agenda packet and highlighted the three items related to pharmacy:

- Requirement to report the dispensing of Schedule V drugs, for which a prescription has been written, and naloxone to the Prescription Monitoring Program.
- Registration of nonresident warehousers and nonresident third-party logistics providers.
- Creating a fentanyl classification in Schedule I of the Drug Control Act.

Ms. Yeatts reviewed the two bills introduced by Lionell Spruill for an individual 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 23 Health insurance; coverage for limited drug refills.
- SB 25 Drug Control Act; dispensing drugs without a prescription.

- Regulatory Update:

Ms. Yeatts reviewed the chart of regulatory actions provided in the agenda packet and gave updates on the status. The comment period for the NOIRA for requirement for applicants and licensees to have an e-profile ID closes 12/13/17. Certain chemicals will be added to Schedule I effective 12/13/17.

- Adoption of exempt regulation to add certain chemicals to Schedule I

There was a Public Hearing conducted a 9:12 a.m. this morning pursuant to the 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 into Schedule I:
Classified as research chemicals:

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

Classified as powerful synthetic opioids:

- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-1,3-benzodioxole-5-carboxamide (other name: Benzodioxole fentanyl),**
- **3,4-dichloro-N-[2-(diethylamino)cyclohexyl]-N-methylbenzamide (other name: U-49900),**
- **2-(2,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-**

methylacetamide (other name: U-48800)

Classified as central nervous system stimulants:

- **Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (4-fluoromethylphenidate),**
- **Isopropyl-2-phenyl-2-(2-piperidinyl)acetate (other name: Isopropylphenidate)**

(motion by Warriner, second by Cathcart)

- Adoption of final regulation on refills of CVI and emergency kits/stat boxes; addition of naloxone

Ms. Yeatts provided a brief background of the proposed regulations. Ms. Juran suggested that the proposed language in 18VAC110-20-320(B) be amended to expand the allowance to include the dispensing of new prescriptions as well and not be limited to refills. Ms. Allen provided comment that the title of the regulation should be amended to make it easier to find the regulation. Ms. Warriner agreed.

MOTION:

The Board voted unanimously to amend:

- **the title of 18VAC110-20-320 to read "Dispensing or refilling of Schedules III through VI prescriptions";**
- **the proposed language in 18VAC110-20-320(B) to read "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 judgement and upon request by the patient, may dispense or refill a drug listed in Schedule VI with any quantity, up to the total amount authorized, taking all refills into consideration"; and,**
- **the proposed language of 18VAC110-20-540(A)(2) by deleting the word "and" prior to "diazepam rectal gel" and inserting ", and the intranasal spray formulation of naloxone" prior to the words "may be included." (motion by Allen, second by Warriner)**

MOTION:

The Board voted unanimously to adopt as a final action the proposed amendments to Regulations 18VAC110-20-320 and 18VAC110-20-540, both as amended, and 18VAC110-20-550 and 18VAC110-20-555, as presented. (motion by Warriner, second by Boone)

- Adoption of two changes to proposed regulations (Periodic Review) relating to kickbacks & definition of electronic prescription

Ms. Yeatts reported that the changes to amendments to 18VAC110-20-390 and 18VAC110-21-45 relating to kickbacks, are necessary due to the proposed splitting of current Chapter 20 into Chapter 20 (facilities) and Chapter 21(individuals). In Chapter 20 the word "pharmacist" will be amended to "pharmacy" and in both chapters the phrase "unless fully disclosed in writing to the patients and any third party payor" will be eliminated.

Ms. Yeatts also reported that counsel recently informed her that amending the definition of electronic prescriptions to conform to 2017 legislation may not be an exempt action since the effective date of the legislation

was delayed until 2020. Rather than starting with another regulatory action, staff recommends adding the amendment to the periodic regulatory review action.

MOTION:

The Board voted unanimously to adopt:

- **An amendment of 18VAC110-20-390 to read, "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.;**
- **A new section 18VAC110-21-45 to read, "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.**

and to include these adoptions in the current periodic regulatory review action. (motion by Saenz, second by Boone)

MOTION:

The Board voted unanimously to adopt an amendment of the definition of "electronic prescription" in 18VAC110-20-10 as presented and which reads, "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.~~" and to include this adoption in the current periodic regulatory review action. (motion by Warriner, second by Cathcart)

PETITION FOR RULE MAKING:

- Amend 18VAC110-20-275, *Delivery of Dispensed Prescriptions*

The Board reviewed a petition for rulemaking submitted by CVS Health to amend Regulation 18VAC110-20-275(B)(2)(d) to allow the prescription label to contain a "unique identifier" to identify all pharmacies involved in filling and dispensing a prescription, in lieu of listing all pharmacies on the label, as is currently required through interpretation. The petition proposes that the unique identifier would not be 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. In addition to a comment from CVS, two other comments were received during the public comment period. The Board briefly discussed the implications of the possible amendment when both pharmacies are involved in the dispensing process as opposed to the receiving pharmacy serving solely as a depot for the patient to pick up the dispensed drug. They also discussed which pharmacy may be the more appropriate pharmacy to answer the patient's questions and therefore, which pharmacy's information should be included on the prescription label. Mr. Johnston stated that if it involved a specialty drug, he believed the specialty pharmacy delivering the dispensed drug to the patient's local CVS pharmacy location would be the better pharmacy to answer the questions. Consensus on this subject was not reached.

MOTION:

The Board voted unanimously to refer the petition for rulemaking to the Regulation Committee for a recommendation on whether or not to adopt a NOIRA. (motion by Saenz, second by S. Elliott)

- Amend Guidance Document 110-1, *Categories of Facility Licensure*

As of July 1, 2017, two new categories of licensure have been added to the document: Nonresident Manufacturer and Third-Party Logistics Provider.

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-1, *Categories of Facility Licensure*, as presented. (motion by M. Elliott, second by Shinaberry)

- Amend Guidance Document 110-04, *Guide to Continuing Pharmacy Education Requirements*

In addition to edits recommended for clarity, a Question and Answer on counting hours worked as a volunteer at a free clinic or local health department as continuing education has been added.

MOTION:

The Board voted unanimously to adopt the amendments to Guidance Document 110-04, *Guide to Continuing Pharmacy Education Requirements*, as presented. (motion by Allen, second by Warriner)

REPORT FROM REGULATION COMMITTEE:

- Adopt NOIRA to address White Bagging and Brown Bagging

Mr. Elliott provided background from the Regulation Committee meeting regarding adopting regulation to define white bagging, brown bagging, prohibit brown bagging of drugs requiring reconstitution or compounding prior to administration, and setting specific requirements for specialty pharmacies participating in white bagging, which includes notifying the receiving pharmacy of the shipment to ensure appropriate coordination of patient care. The 2016 Pharmacy Benefit Manager Workgroup, a broad stakeholder group, recommended the Board of Pharmacy review the practice of white bagging and brown bagging to address any issues of

concern. The Board identified Regulation 18VAC110-20-275, *Delivery of Dispensed Prescriptions* as a regulation potentially needing amending to address white bagging and brown bagging.

MOTION:

The Board voted unanimously to adopt a NOIRA relating to white bagging and brown bagging to include the following actions:

- **Define white bagging and brown bagging;**
- **Consider regulation of brown bagging of drugs requiring special storage requirements, 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 to the receiving pharmacy an estimated arrival date, the name of the patient to whom the drug has been dispensed, and the exact address where the product has been shipped. (motion by Saenz, second by S. Elliott)**

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

USP has delayed implementation of Chapter <800> to December 1, 2019. Therefore, the Regulation Committee recommended amendments to paragraph 2 of the guidance document, inclusion of USP's Frequently Asked Questions for Chapter <800>, and inclusion of a link to the National Institute of Occupational Safety and Health (NIOSH) list. The Committee also recommended that the Board begin the education process through inspections (which will not result in disciplinary action prior to the effective date of the chapter) within the next six months.

MOTION:

The Board voted unanimously to amend Guidance Document 110-36, *Compliance with USP Standards for Compounding*, as presented and instruct the inspectors to begin educating licensees within the next six months on areas of non-compliance identified during pharmacy inspections. (motion by S. Elliott, second by Allen)

- Amend Guidance Document 110-23, *Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency Monetary Penalty Guide*

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. Mr. Logan suggested that the Board may want to re-evaluate the current pharmacy inspection program, wherein an expedited pre-hearing consent order with monetary sanctions is offered at the conclusion of a routine pharmacy inspection, prior to amending Guidance Document 110-23 and implementing a similar process for the physician selling inspections. Ms. Shinaberry commented that Guidance Document 110-9 has become quite lengthy and should be reviewed. She also questioned whether the inspection process has made pharmacies safer and whether the inspection model has made pharmacists change their practice. Ms. Warriner commented that having repeat offenders indicates that behavior hasn't always been changed by the inspection model. Mr. Johnson provided comment that the inspection program has

grown and a review may be appropriate to ensure the inspections are reviewing for substantial compliance.

MOTION: **The Board voted unanimously to table the amendment of Guidance Document 110-23, *Practitioner of the Healing Arts Selling Controlled Substances Inspection Deficiency* and to create an Ad Hoc Committee to evaluate the current routine pharmacy inspection program. (motion by M. Elliott, second by Cathcart)**

ADOPTION OF GUIDANCE DOCUMENTS:

- Adoption of Guidance Document on Delivering Temperature-Sensitive Drugs

On September 26, 2017, 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: **A motion was made to adopt the Guidance Document on Delivery of Dispensed Drugs as presented. (motion by Shinaberry, second by S. Elliott)**

An amendment to Guidance Document on Delivery of Dispensed Drugs was proposed by Mr. Saenz. The amendment substitutes the word "require" with the word "include" on line 4 of paragraph 2.

MOTION: **The Board voted five to four to amend the Guidance Document on Delivery of Dispensed Drugs by substituting the word "require" with the word "include" in the sentence "The packaging may ~~require~~ include the use of a temperature monitoring device, particularly for drugs that are temperature-sensitive." found in the second paragraph. (motion by Saenz, second by M. Elliott, opposed: Shinaberry, Cathcart, S. Elliott, Warriner)**

Ms. Shinaberry withdrew her motion to approve the Guidance Document on Delivery of Dispensed Drugs as amended.

MOTION: **The Board voted seven to one to adopt the Guidance Document on Delivery of Dispensed Drugs, as amended. (motion by Allen, second by Boone; S. Elliott opposed, Cathcart abstained)**

- Adoption of Guidance Document on Drug Disposal

On September 26, 2017, 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.

MOTION: **The Board voted unanimously to adopt the Guidance Document pertaining to Guidelines for Provision of Counseling and Information by Pharmacists regarding Proper Disposal of Unused Dispensed Drugs, as presented. (motion by M. Elliott, second by Allen)**

NEW BUSINESS:

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

Ms. Juran provided history of approving outside entities to perform current good manufacturing practices (cGMP) inspections. Ms. Allen asked if other states accept cGMP inspection reports from entities that are not state or federal regulatory agencies. Ms. Juran indicated she is not aware of any other states that accept cGMP inspection reports from entities that are not state or federal regulatory agencies. Mr. Saenz suggested the Board pursue the same process as was done with Bestech, Inc. which involved an in-person presentation to the Board.

ACTION ITEM:

Invite Gates Healthcare to make a presentation to the March 29, 2018 Full Board Meeting, offering materials in advance of the meeting, and be available to answer any related questions.

REPORTS:

- Chairman's Report:

Mr. Logan stated that he had nothing to report at this time.

- Report on Board of Health Professions:

Mr. Logan provided an update on the most recent Board of Health Professions (BHP) meeting. Mr. Logan restated Dr. Brown's announcement that Lisa Hahn accepted the new position of Chief Operating Officer. Michelle Schmidt had reported to the BHP that DHP Enforcement received 5,400 complaints last year, of which 75% were completed within 90 days. Complaints may now be submitted online which resulted in an increase in the number of complaints received. Mr. Logan shared that DHP partnered with Virginia Commonwealth University to design its new logo and provided the Board with an example. Information from a presentation to the BHP indicates that job satisfaction and education debt are most associated with delayed retirement.

- Report on Licensure Program:

Mr. Johnson reported the Board currently licenses 38,218 individuals and facilities. The Board issued 1,034 licenses and registrations for the period of September 1, 2017 through November 30, 2017. Inspectors conducted 521 facility inspections including 206 routine inspections of pharmacies: 43 (21%) resulted in no deficiency, 66 (32%) with deficiencies and 97 (47%) with deficiencies and a consent order. Mr. Johnson reviewed the chart providing a graphic display of inspection deficiencies by quarter since September 2012 and reviewed the most frequently cited deficiencies for the reporting period. Mr. Johnson corrected the statistics reported at the December 26, 2017 meeting: 52 (23%) resulted in no deficiency, 100 (43%) with deficiencies and 80 (34%) with deficiencies and a consent order.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report as of November 30, 2017. She reviewed the stages of the patient care cases as well as the non-patient care cases. The report indicates that the Board had 282 open cases as of that date with 111 being patient care cases and 171 being non-patient care cases. Further, Ms. Reiniers-Day discussed the Report for the Board's

Second Quarter for the patient care cases as well as the non-patient care cases and each relevant priority. Lastly, the HPMP Monthly Census Report for November 30, 2017 was reviewed.

- Executive Director's Report:

Ms. Juran provided an update on the pharmaceutical processor program. The Board of Pharmacy expects to begin issuing conditional permits in June/July 2018 so that construction of the facilities can begin. The facilities have one year to build and after inspection by DHP, the final permits will be issued. Ms. Juran shared that there has been a 60% increase in licensing over the past 10 years. Ms. Juran also announced that Ellen Shinaberry has accepted the new Deputy Executive Director position for the Board of Pharmacy as of February 10, 2017. This will necessitate her resigning from the Board as a board member at that time.

CONSIDERATION OF SUMMARY SUSPENSION

JASON LAMONT ROSS
Registration No: 0230-011467

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

MOTION:

Upon a motion by Mr. Saenz, and duly seconded by Ms. Allen, the Board voted 7-0 in favor of the motion that, according to the evidence presented, the continued practice by Jason Lamont Ross as a pharmacy technician poses a substantial danger to the public; and therefore, the registration for Mr. Ross shall be summarily suspended. Further, in lieu of a formal hearing, a Consent Order shall be offered to Mr. Ross for the indefinite suspension of his pharmacy technician registration for not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at approximately 1:49pm.

Ryan Logan, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, January 11, 2018

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 January 11, 2018, at 9:30 a.m., to consider the summary suspensions of the registrations of Heather D. Puckett and Kaleena McClure to practice as pharmacy technicians in the Commonwealth of Virginia.

PRESIDING: Cynthia Warriner, Chair

MEMBERS PRESENT:
Melvin Boone
Freeda Cathcart
Sheila Elliott
Rafael Saenz
Ellen Shinaberry
Rebecca Thornbury

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

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 two possible summary suspension cases. The Board members stated that they would not have been able to attend.

With seven (7) members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

HEATHER D. PUCKETT Registration No. 0230-014561	James Schliessmann presented a summary of the evidence in this case.
DECISION:	Upon a motion by Mr. Saenz and duly seconded by Ms. Thornbury, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Heather Puckett poses a substantial danger to the public; and therefore, the registration of Ms. Puckett shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Puckett for the indefinite suspension of her registration for a period of not less than two years.
KALEENA MCCLURE Registration No. 0230-023723	James Schliessmann presented a summary of the evidence in this case.
DECISION:	Upon a motion by Ms. Thornbury and duly seconded by Ms. Elliott, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Kaleena McClure poses a substantial danger to the public; and therefore, the right to renew the registration of Ms. McClure shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. for the indefinite suspension of the right to renew her registration for a period of not less than two years.
ADJOURN:	With all business concluded, the meeting adjourned at 10:00 a.m.

Cynthia Warriner, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, January 17, 2018
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	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
LARITA ALVAREZ License No. 0202-208936	The Committee continued this matter due to problematic service of the Notice.
GWYNN D. PARKINSON Registration No. 0230-004540	Gwynn Parkinson appeared to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the December 1, 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 Gwynn Parkinson. 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 Mr. Elliott, the Committee unanimously voted to issue an Order that states Ms. Parkinson shall enroll in the Health Practioners' Monitoring Program.
Adjourn:	With all business concluded, the meeting adjourned at 1:15 p.m.

Michael Elliott, Chair	Cathy M. Reiniers-Day Deputy Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, February 14, 2018
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 10:30 a.m.
PRESIDING:	Rafael Saenz, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	J. Samuel Johnson , Deputy Executive Director Ellen B. Shinaberry, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
CHARLOTTE M. LAWRENCE Registration No. 0230-002216	Charlotte Lawrence did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the December 18, 2017 Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Lawrence's legal address of record.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of Charlotte Lawrence. Additionally, he moved that J. Samuel Johnson and Ellen B. Shinaberry 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 Virginia Code § 2.2-3712, the Committee reconvened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Boone and duly seconded Mr. Saenz, the Committee unanimously voted to offer Ms. Lawrence a Consent Order for the indefinite suspension of her pharmacy technician registration and to refer this matter to a formal hearing.
Adjourn:	With all business concluded, the meeting adjourned at 11:00 a.m.

Rafael Saenz, Chair

J. Samuel Johnson
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

February 27, 2018
Commonwealth Conference Center
Second Floor
Board Room 3

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 10:12 a.m.

PRESIDING: Ryan Logan, Chair

MEMBERS PRESENT:
Jody Allen (via telephone at 1:15 p.m.)
Melvin Boone
Freeda Cathcart
Michael Elliott
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
Kennia Butler, Disciplinary Program Specialist
James Rutkowski, Assistant Attorney General
James Schliessman, Senior Assistant Attorney General (departs at 1:25 p.m.)
Wayne Halbleib, Senior Assistant Attorney General (arrives at 1:25 p.m.)
Mykl Egan, DHP Adjudication Specialist

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

KALEENA MCCLURE
Registration No. 0230-023723

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

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

Ms. McClure was not present.

Jason Lotts, Loss Prevention Manager, CVS Pharmacy testified by telephone and Jessica Wilkerson, DHP Senior Investigator and Lisa Christian, Inventory Specialist, CVS Pharmacy, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Cathcart, 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 Kaleena McClure. Additionally, he moved that Caroline Juran, Ellen Shinaberry, 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 quorum re-convened an open meeting and announced the decision.

DECISION:

Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the panel voted 5-0 to accept the Findings and Fact and Conclusions of Law proposed by Mr. Schliessmann and amended by the board.

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the panel voted 5-0 to indefinitely suspend Ms. McClure's right to renew her pharmacy technician registration for no less than two years.

HEATHER D. PUCKETT
Registration No. 0230-014561

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

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

Ms. Puckett was not present.

Jessica Wilkerson, DHP Senior Investigator, Dana Miller, Pharmacy Technician, Marion Family Pharmacy and Laura Lester, Pharmacist and Co-Owner, Marion Family Pharmacy, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Mr. Elliott, and duly seconded by Ms. Cathcart, 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 Heather Puckett. Additionally, he moved that Caroline Juran, Ellen Shinaberry, 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 quorum re-convened an open meeting and announced the decision.

DECISION:

Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the panel voted 5-0 to accept the Findings and Fact and Conclusions of Law proposed by Mr. Schliessmann and amended by the board.

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the panel voted 5-0 to revoke Ms. Puckett's registration to practice as a pharmacy technician.

PEGGY ALTENOR
Registration No. 0230-0026333

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

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

Ms. Altenor was present.

CLOSED MEETING:

Upon a motion by Mr. Elliott, and duly seconded by Mr. Boone, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to

reach a decision regarding the matter of Peggy Altenor. Additionally, he moved that Caroline Juran, Ellen Shinaberry, 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 quorum re-convened an open meeting and announced the decision.

DECISION: Upon a motion by Mr. Boone, and duly seconded by Ms. Warriner, the panel voted 5-0 to accept the Findings and Fact and Conclusions of Law proposed by Mr. Schliessmann and amended by the board.

Upon a motion by Ms. Warriner, and duly seconded by Mr. Boone, the panel voted 4-1 to issue an Order to reprimand Ms. Altenor.

Jody Allen arrives via telephone.

QUORUM: With six (6) members of the Board present, a quorum was established.

POSSIBLE SUMMARY SUSPENSION

TAMMY L. HALL
Registration No. 0230-004129

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

DECISION: Upon a motion by Ms. Warriner and duly seconded by Ms. Allen, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Tammy Hall poses a substantial danger to the public; and therefore, the registration of Ms. Hall shall be summarily suspended.

Further, upon a motion by Ms. Warriner and duly seconded by Ms. Allen, the Board unanimously voted that a Consent Order shall be offered to Ms. Hall for the indefinite suspension of her registration to practice as a pharmacy technician for not less than two years, in lieu of a formal administrative hearing.

Wayne Halbleib arrives.

Jim Schliessmann departs.

DUSTIN A. ROSS
Registration No. 0230-014440

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

DECISION:

Upon a motion by Ms. Warriner and duly seconded by Mr. Boone, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Dustin Ross poses a substantial danger to the public; and therefore, the registration of Mr. Ross shall be summarily suspended.

Further, upon a motion by Ms. Warriner and duly seconded by Ms. Allen, the Board unanimously voted that a Consent Order shall be offered to Mr. Ross for the indefinite suspension of his registration to practice as a pharmacy technician for not less than two years, in lieu of a formal administrative hearing.

ADJOURNED:

With all business concluded, the meeting adjourned at 2:00 p.m.

Ryan Logan, Chair

Caroline D. Juran
Executive Director

Date

Report of the 2018 General Assembly

Board of Pharmacy

HB 226 Patients; medically or ethically inappropriate care not required.

Summary as passed House:

Medically or ethically inappropriate care not required. Establishes a process whereby a physician may cease to provide health care that has been determined to be medically or ethically inappropriate for a patient.

HB 313 Prescription Monitoring Program; prescriber and dispenser patterns, annual review, report.

Summary as passed:

Prescription Monitoring Program; prescriber and dispenser patterns. Requires the Director of the Department of Health Professions to annually review controlled substance prescribing and dispensing patterns. The bill requires the Director to conduct such review in consultation with an advisory panel consisting of representatives from the relevant health regulatory boards, the Department of Health, the Department of Medical Assistance Services, and the Department of Behavioral Health and Developmental Services. The bill requires the Director to make any necessary changes to the criteria for unusual patterns of prescribing and dispensing and report any findings and recommendations for best practices to the Joint Commission on Health Care by November 1 of each year. This bill is identical to SB 728.

HB 322 Naloxone or other opioid antagonist; possession & administration.

Summary as introduced:

Possession and administration of naloxone. Adds employees of the Department of Corrections who are designated as probation and parole officers or correctional officers to the list of individuals who may possess and administer naloxone or other opioid antagonist, provided that they have completed a training program.

HB 424 Animal shelters; administration of Schedule VI biological products.

Summary as passed House:

Animal shelters; vaccinations; administration of biological products. Authorizes the operator or custodian of a public animal shelter to vaccinate animals that are confined in such shelter to prevent the risk of communicable diseases. The bill also provides that a public or private animal shelter may purchase, possess, and administer certain Schedule VI biological products 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 and may administer such biological products only pursuant to written protocols.

HB 501 Home hospice programs; disposal of drugs.

Summary as passed House:

Home hospice programs; disposal of drugs. Requires every hospice to develop policies and procedures for the disposal of drugs dispensed as part of the hospice plan of care for a patient, which shall include requirements that such disposal be (i) performed in a manner that complies with all state and federal requirements for the safe disposal of drugs by a licensed nurse, physician assistant, or physician who is employed by or has entered into a contract with the hospice program; (ii) witnessed by a member of the patient's family or a second employee of the hospice program who is licensed by a health regulatory board within the Department of Health Professions; and (iii) documented in the patient's medical record.

HB 520 Nonresident warehousers and nonresident third-party logistics providers; Board of Pharmacy.

Summary as introduced:

Board of Pharmacy; nonresident warehousers and nonresident third-party logistics providers. Requires warehouser or third-party logistics providers that are located outside the Commonwealth and that ship prescription drugs or devices into the Commonwealth to register with the Board of Pharmacy. The bill requires such nonresident warehousers and nonresident third-party logistics providers to maintain a license, permit, or registration in the resident state and to retain records in a certain manner. The bill authorizes the Board of Pharmacy to promulgate regulations related to the storage, handling, and distribution of prescription drugs or devices by nonresident warehousers and nonresident third-party logistics providers.

HB 793 Nurse practitioners; practice agreements.

Summary as passed:

Nurse practitioners; practice agreements. Eliminates the requirement for a practice agreement with a patient care team physician for a licensed nurse practitioner who has completed the equivalent of at least five years of full-time clinical experience and submitted an attestation from his patient care team physician stating (i) that the patient care team physician has served as a patient care team physician on a patient care team with the nurse practitioner pursuant to a practice agreement; (ii) that while a party to such practice agreement, the patient care team physician routinely practiced with a patient population and in a practice area included within the category for which the nurse practitioner was certified and licensed; and (iii) the period of time for which the patient care team physician practiced with the nurse practitioner under such a practice agreement. The bill requires that a nurse practitioner authorized to practice without a practice agreement (a) only practice within the scope of his clinical and professional training and limits of his knowledge and experience and consistent with the applicable standards of care, (b)

consult and collaborate with other health care providers based on the clinical conditions of the patient to whom health care is provided, and (c) establish a plan for referral of complex medical cases and emergencies to physicians or other appropriate health care providers. The bill requires (1) the Boards of Medicine and Nursing to jointly promulgate regulations governing the practice of nurse practitioners without a practice agreement; (2) the Department of Health Professions, by November 1, 2020, to report to the General Assembly a process by which nurse practitioners who practice without a practice agreement may be included in the online Practitioner Profile maintained by the Department of Health Professions; and (3) the Boards of Medicine and Nursing to report information related to the practice of nurse practitioners without a practice agreement that includes certain data, complaints and disciplinary actions, and recommended modifications to the provisions of this bill to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health and the Chairman of the Joint Commission on Health Care by November 1, 2021.

HB 842 Controlled paraphernalia; possession or distribution, hypodermic needles and syringes, naloxone.

Summary as passed House:

Possession or distribution of controlled paraphernalia; hypodermic needles and syringes; naloxone. Provides that a person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for use in opioid overdose 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 and that has obtained a controlled substances registration from the Board of Pharmacy may dispense or distribute hypodermic needles and syringes in conjunction with such dispensing of naloxone and that a person to whom naloxone has been distributed by such individual may possess hypodermic needles and syringes in conjunction with such possession of naloxone. The bill also allows the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone. The bill contains an emergency clause.

EMERGENCY

HB 875 Veterinarians; compounding of drugs.

Summary as introduced:

Veterinarians; compounding of drugs. Increases the quantity, from a 72-hour supply to a seven-day supply, of a compounded drug that a veterinarian may dispense to the owner of a companion animal for which the veterinarian is providing treatment.

HB 878 Schedule VI; delivery of prescription devices on behalf of medical equipment supplier.

Summary as passed:

Delivery of Schedule VI prescription devices. Provides that a permitted manufacturer, wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider or registered nonresident manufacturer or nonresident wholesale distributor (the provider) may deliver a Schedule VI prescription device directly to an ultimate user or consumer, provided that the provider is delivering on behalf of and has entered into an agreement with (i) a medical equipment supplier that has received a valid order from a prescriber authorizing the dispensing of the Schedule VI prescription device or (ii) a medical director of a home health agency, nursing home, assisted living facility, or hospice who has requested the distribution of the Schedule VI prescription device to be administered by persons authorized to administer such devices. The bill directs the Board of Pharmacy to promulgate regulations to implement the provisions of the measure within 280 days. This bill is identical to SB 413.

HB 883 Regulatory reduction pilot program; Department of Planning and Budget to implement, report.

Summary as passed House:

Department of Planning and Budget; regulatory reduction pilot program; report. Directs the Department of Planning and Budget (the Department), under the supervision of the Secretary of Finance (the Secretary), to administer a three-year regulatory reduction pilot program aimed at reducing by 25 percent the regulations and regulatory requirements, as defined in the bill, of the Department of Professional and Occupational Regulation and the Department of Criminal Justice Services by July 1, 2021. The bill requires the Secretary to report annually to the Speaker of the House and the Chairman of the Senate Rules Committee no later than October 1, 2019, and October 1, 2020, on the progress of the regulatory reduction pilot program. The bill also requires the Secretary to report by August 15, 2021, to the Speaker of the House and the Chairman of the Senate Rules Committee (i) the progress toward identifying the 25 percent reduction goal, (ii) recommendations for expanding the program to other agencies, and (iii) any additional information the Secretary determines may be helpful to support the General Assembly's regulatory reduction and reform efforts. The bill provides that if, by October 1, 2021, the program has achieved less than a 25 percent total reduction in regulations and regulatory requirements across both pilot agencies, the Secretary shall report on the feasibility and effectiveness of implementing a 2-for-1 regulatory budget providing that for every one new regulatory requirement, two existing regulatory requirements of equivalent or greater burden must be streamlined, repealed, or replaced for a period not to exceed three years. Lastly, the bill directs all executive branch agencies subject to the Administrative Process Act (§ 2.2-4000 et seq.) to develop a baseline regulatory catalog and report such catalog data to the Department, which shall then track and report on the extent to which agencies comply with existing requirements to periodically review all regulations every four years. This bill is identical to SB 20.

HB 1173 Controlled substances; limits on prescriptions containing opioids.

Summary as introduced:

Limits on prescription of controlled substances containing opioids. Eliminates the surgical or invasive procedure treatment exception to the requirement that a prescriber request certain information from the Prescription Monitoring Program (PMP) when initiating a new course of treatment that includes prescribing opioids for a human patient to last more than seven days. Under current law, a prescriber is not required to request certain information from the PMP for opioid prescriptions of up to 14 days to a patient as part of treatment for a surgical or invasive procedure. The bill has an expiration date of July 1, 2022. This bill is identical to SB 632.

HB 1177 Health insurance; contracts with pharmacies and pharmacists, etc.

Summary as passed House:

Pharmacists and pharmacy practices. Provides that no provider contract between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent shall contain a provision (i) authorizing the carrier or its pharmacy benefits manager to charge, (ii) requiring the pharmacy or pharmacist to collect, or (iii) requiring an enrollee to make, a copayment for a covered prescription drug in an amount that exceeds the least of the applicable copayment for the prescription drug that would be payable in the absence of this section or the cash price the enrollee would pay for the prescription drug if the enrollee purchased the prescription drug without using the enrollee's health plan. The measure requires provider contracts between a health carrier or its pharmacy benefits manager and a pharmacy or its contracting agent to contain specific provisions that allow a pharmacy to (a) disclose to an enrollee information relating to the provisions of this section and the availability of a more affordable therapeutically equivalent prescription drug; (b) sell a more affordable therapeutically equivalent prescription drug to an enrollee if one is available; and (c) offer and provide direct and limited delivery services to an enrollee as an ancillary service of the pharmacy. The measure applies to provider contracts entered into, amended, extended, or renewed on or after January 1, 2019. This bill is identical to SB 933.

HB 1194 Schedule I controlled substances; adds various drugs to list.

Summary as introduced:
Schedule I controlled substances. Adds drugs to the list of Schedule I controlled substances.

HB 1251 CBD oil and THC-A oil; certification for use, dispensing.

Summary as passed:

CBD oil and THC-A oil; certification for use; dispensing. Provides that a practitioner may issue a written certification for the use of cannabidiol (CBD) oil or THC-A oil for the treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use. Under current law, a practitioner may only issue such certification for the treatment or to alleviate the symptoms of intractable epilepsy. The bill increases the supply of CBD oil or THC-A oil a pharmaceutical processor may dispense from a 30-day supply to a 90-day supply. The bill reduces the minimum amount of cannabidiol or tetrahydrocannabinol acid per milliliter for a dilution of the Cannabis plant to fall under the definition of CBD oil or THC-

A oil, respectively. As introduced, this bill was a recommendation of the Joint Commission on Health Care. The bill contains an emergency clause. This bill is identical to SB 726.

EMERGENCY

HB 1303 Prescribing controlled substances; veterinarian-client-patient relationship.

Summary as passed House:

Prescribing controlled substances; veterinarian-client-patient relationship. Provides that a veterinarian shall not prescribe medication unless a bona fide veterinarian-client-patient relationship exists and establishes the requirements for a bona fide veterinarian-client-patient relationship.

HB 1377 Epinephrine; possession and administration at outdoor educational programs.

Summary as passed:

Possession and administration of epinephrine; outdoor educational programs. Provides that an employee of an organization that provides outdoor educational experiences or programs for youth who is authorized by a prescriber and trained in the administration of epinephrine may possess and administer epinephrine and provides liability protection for such employees.

HB 1440 Schedule I and Schedule II drugs; adds various drugs to lists.

Summary as introduced:

Schedule I and Schedule II drugs. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I of the Drug Control Act and Dronabinol [(-)-delta-9-*trans* tetrahydrocannabinol] in an oral solution in a drug product approved for marketing by the U.S. Food and Drug Administration to Schedule II of the Drug Control Act and removes naldemedine from Schedule II of the Drug Control Act.

HB 1556 Prescription Monitoring Program; adds controlled substances included in Schedule V and naloxone.

Summary as introduced:

Prescription Monitoring Program; covered substances. Adds controlled substances included in Schedule V for which a prescription is required and naloxone to the list of covered substances the dispensing of which must be reported to the Prescription Monitoring Program. This bill is identical to SB 832.

SB 226 Prescription Monitoring Program; veterinarians.

Summary as passed Senate:

Prescription Monitoring Program; veterinarians. Requires veterinarians who dispense controlled substances to report certain information about the animal and the owner of the animal to the Prescription Monitoring Program (PMP). The bill requires veterinarians to register with the PMP and, when issuing a prescription to an animal for opiates that will last more than seven days, to request certain information from the Director of the Department of Health Professions regarding both the animal and the owner of the animal.

SB 330 THC-A oil; dispensing, tetrahydrocannabinol levels.

Summary as passed Senate:

CBD and THC-A oil. Adds cannabidiol oil (CBD oil) or THC-A oil to the list of covered substances the dispensing of which must be reported to the Prescription Monitoring Program. The bill requires a practitioner who issues a written certification for CBD oil or THC-A oil to request information from the Director of the Department of Health Professions for the purpose of determining what other covered substances have been dispensed to the patient.

The bill requires the Board of Pharmacy to promulgate regulations that include requirements for (i) a process for registering a CBD oil and THC-A oil product; and (ii) a requirement for an applicant for a pharmaceutical processor permit to have a criminal background check through the Central Criminal Records Exchange to the Federal Bureau of Investigation. The bill requires a pharmacist or pharmacy technician, prior to the initial dispensing of each written certification to (a) make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible, (b) view a current photo identification of the patient, parent, or legal guardian, and (c) verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian. The bill requires that prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent to view the current written certification, a current photo identification of the patient, parent, or legal guardian, and the current board registration issued to the patient, parent, or legal guardian.

Finally, the bill requires a pharmaceutical processor to (i) ensure the percentage of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and to establish a stability testing schedule of THC-A oil.

EMERGENCY

SB 544 Prescription drugs; donation of used medicines.

Summary as passed Senate:

Prescription drug donation program. Requires that the existing prescription drug donation program regulated by the Board of Pharmacy accept eligible prescription drugs from individuals, including those residing in nursing homes, assisted living facilities, or intermediate care facilities established for individuals with intellectual disability (ICF/IID), licensed hospitals, any facility

operated by the Department of Behavioral Health and Developmental Services, from an agent pursuant to a power of attorney, a decedent's personal representative, a legal guardian of an incapacitated person, and a guardian ad litem donated on behalf of the represented individual. The bill also provides liability protection for those who donate, accept, and dispense such unused drugs.

SB 882 Prescription refill; protocol.

Summary as passed Senate:

Prescription refill; approval. Provides that a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to current law and regulations of the Board of Pharmacy.

SB 918 Professional and occupational regulation; authority to suspend or revoke licenses, certificates.

Summary as passed:

Professional and occupational regulation; authority to suspend or revoke licenses, certificates, registrations, or permits; default or delinquency of education loan or scholarship. Provides that the Board of Education, the Board of Accountancy, and regulatory boards within the Department of Professional and Occupational Regulation and the Department of Health Professions shall not be authorized to suspend or revoke the license, certificate, registration, permit, or authority issued to any person who is in default or delinquent in the payment of a federal-guaranteed or state-guaranteed educational loan or work-conditional scholarship solely on the basis of such default or delinquency.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia, relating to dispensing of THC-A oil; tetrahydrocannabinol levels and stability testing.

[S 330]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2519, 54.1-2521, 54.1-2522.1, as it is currently effective and as it shall become effective, 54.1-3442.6, and 54.1-3442.7 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2519. Definitions.

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

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

"Bureau" means the Virginia Department of State Police, Bureau of Criminal Investigation, Drug Diversion Unit.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act, Chapter 34 (§ 54.1-3400 et seq.) of this title.

"Covered substance" means all controlled substances included in Schedules II, III, and IV and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter. *"Covered substance" also includes cannabidiol oil or THC-A oil dispensed by a pharmaceutical processor in Virginia.*

"Department" means the Virginia Department of Health Professions.

"Director" means the Director of the Virginia Department of Health Professions.

"Dispense" means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for that delivery.

"Dispenser" means a person or entity that (i) is authorized by law to dispense a covered substance or to maintain a stock of covered substances for the purpose of dispensing, and (ii) dispenses the covered substance to a citizen of the Commonwealth regardless of the location of the dispenser, or who dispenses such covered substance from a location in Virginia regardless of the location of the recipient.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

"Prescriber" means a practitioner licensed in the Commonwealth who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance or a practitioner licensed in another state to so issue a prescription for a covered substance.

"Recipient" means a person who receives a covered substance from a dispenser.

"Relevant health regulatory board" means any such board that licenses persons or entities with the authority to prescribe or dispense covered substances, including, but not limited to, the Board of Dentistry, the Board of Medicine, and the Board of Pharmacy.

§ 54.1-2521. Reporting requirements.

A. The failure by any person subject to the reporting requirements set forth in this section and the Department's regulations to report the dispensing of covered substances shall constitute grounds for disciplinary action by the relevant health regulatory board.

B. Upon dispensing a covered substance, a dispenser of such covered substance shall report the following information:

1. The recipient's name and address.
2. The recipient's date of birth.
3. The covered substance that was dispensed to the recipient.
4. The quantity of the covered substance that was dispensed.
5. The date of the dispensing.
6. The prescriber's identifier number *and, in cases in which the covered substance is cannabidiol oil or THC-A oil, the expiration date of the written certification.*

7. The dispenser's identifier number.

8. The method of payment for the prescription.

9. Any other non-clinical information that is designated by the Director as necessary for the implementation of this chapter in accordance with the Department's regulations.

10. Any other information specified in regulations promulgated by the Director as required in order for the Prescription Monitoring Program to be eligible to receive federal funds.

C. The reports required herein shall be made to the Department or its agent within 24 hours or the dispenser's next business day, whichever comes later, and shall be made and transmitted in such manner and format and according to the standards and schedule established in the Department's regulations.

§ 54.1-2522.1. (Effective until July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. A prescriber registered with the Prescription Monitoring Program or a person to whom he has delegated authority to access information in the possession of the Prescription Monitoring Program pursuant to § 54.1-2523.2 shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of opioids anticipated at the onset of treatment to last more than seven consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. A prescriber shall not be required to meet the provisions of subsection B if:

1. The opioid is prescribed to a patient currently receiving hospice or palliative care;

2. The opioid is prescribed to a patient as part of treatment for a surgical or invasive procedure and such prescription is for no more than 14 consecutive days;

3. The opioid is prescribed to a patient during an inpatient hospital admission or at discharge;

4. The opioid is prescribed to a patient in a nursing home or a patient in an assisted living facility that uses a sole source pharmacy;

5. The Prescription Monitoring Program is not operational or available due to temporary technological or electrical failure or natural disaster; or

6. The prescriber is unable to access the Prescription Monitoring Program due to emergency or disaster and documents such circumstances in the patient's medical record.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-2522.1. (Effective July 1, 2022) Requirements of practitioners.

A. Any prescriber who is licensed in the Commonwealth to treat human patients and is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription for a covered substance shall be registered with the Prescription Monitoring Program by the Department of Health Professions.

B. Prescribers registered with the Prescription Monitoring Program shall, at the time of initiating a new course of treatment to a human patient that includes the prescribing of benzodiazepine or an opiate anticipated at the onset of treatment to last more than 90 consecutive days, request information from the Director for the purpose of determining what, if any, other covered substances are currently prescribed to the patient. In addition, any prescriber who holds a special identification number from the Drug Enforcement Administration authorizing the prescribing of controlled substances approved for use in opioid addiction therapy shall, prior to or as a part of execution of a treatment agreement with the patient, request information from the Director for the purpose of determining what, if any, other covered substances the patient is currently being prescribed. Nothing in this section shall prohibit prescribers from making additional periodic requests for information from the Director as may be required by routine prescribing practices.

C. The Secretary of Health and Human Resources may identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients. Prescribers who prescribe such identified benzodiazepines or opiates shall not be required to meet the provisions of subsection B. In addition, a prescriber shall not be required to meet the provisions of subsection B if the course of treatment arises from pain management relating to dialysis or cancer treatments.

D. Prior to issuing a written certification for the use of cannabidiol oil or THC-A oil in accordance with § 54.1-3408.3, a practitioner shall request information from the Director for the purpose of

determining what, if any, other covered substances have been dispensed to the patient.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; ~~and~~ (x) the secure disposal of plant remains*; and (xi) a process for registering a cannabidiol oil and THC-A oil product.*

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor.

E. *The Board shall require an applicant for a pharmaceutical processor permit to submit to fingerprinting and provide personal descriptive information to be forwarded along with his fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search shall be paid by the applicant. The Central Criminal Records Exchange shall forward the results of the criminal history background check to the Board or its designee, which shall be a governmental entity.*

F. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1 et seq.) of Chapter 7 of Title 18.2 shall be employed by or act as an agent of a pharmaceutical processor.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to *the initial* dispensing *of each written certification*, the *pharmacist or pharmacy technician at the location of the* pharmaceutical processor shall ~~verify that the practitioner issuing the written certification, the patient, and, if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board~~ *make and maintain for two years a paper or electronic copy of the written certification that provides an exact image of the document that is clearly legible; shall view a current photo identification of the patient, parent, or legal guardian; and shall verify current board registration of the practitioner and the corresponding patient, parent, or legal guardian. Prior to any subsequent dispensing of each written certification, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification; a current photo identification of the patient, parent, or legal guardian; and the current board registration issued to the patient, parent, or legal guardian.* No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

D. A pharmaceutical processor shall ensure that the concentration of tetrahydrocannabinol in any THC-A oil on site is within 10 percent of the level of tetrahydrocannabinol measured for labeling and shall establish a stability testing schedule of THC-A oil.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this

act to be effective within 280 days of its enactment.
3. That an emergency exists and this act is in force from its passage.

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

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* *Comment closed: 12/13/17*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] NOIRA - *Register Date: 1/8/18* *Comment closed: 2/7/18*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] NOIRA - *At Secretary's Office for 76 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Controlled substances registration for naloxone and teleprescribing [Action 4789] Proposed - *At Secretary's Office for 84 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] Proposed - *AT Attorney General's Office for 82 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Secretary's Office for 329 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Response to petitions for rulemaking [Action 4694] Final - *At Secretary's Office for 77 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Chemicals in Schedule I [Action 4969] Final - *Register Date: 1/22/18* *Effective: 2/21/18*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	New regulations [Action 4695] Emergency/NOIRA - *Register Date: 8/7/17* *Expiration of emergency: 2/6/19* *Comment on NOIRA closed: 9/6/17*

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

Scheduling Chemicals in Schedule I - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing listing chemicals to be scheduled

Amendment to regulation: 18VAC110-20-322

Staff Note:

A public hearing was conducted before the meeting this morning.

Action is exempt from the provisions of the Administrative Process Act in accordance with § 2.2-4006.

Board action:

Adoption of final regulation

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VIRGINIA REGULATORY TOWN HALL

Logged in as
Elaine J. Yeatts

Agency **Department of Health Professions**

Board **Board of Pharmacy**

General Notice

Edit Notice

Scheduling of chemicals in Schedule I of the Drug Control Act

Date Posted: 1/17/2018

Expiration Date: 3/29/2018

Submitted to Registrar for publication: YES

71 Day Comment Forum is underway. Began on 1/17/2018 and will end on 3/29/2018

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 **9:05 a.m. on March 29, 2018** 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 Virginia Department of Forensic Science (DFS) has identified seven (7) compounds for recommended inclusion into the Code of Virginia.

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-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine)**, 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. **3,4-methylenedioxy-N-tert-butylcathinone**, 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. **4-fluoro-N-ethylamphetamine**, 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. **beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B)**, 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.

1. **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl 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.
2. **2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754)**, 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.
3. **N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl)**, 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.

Contact Information

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

Project 5437 - none

BOARD OF PHARMACY

Scheduling of chemicals 3-18

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

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

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

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

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

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

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

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

7. 4-methyl-alpha-ethylaminopentiophenone; and

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

The placement of drugs listed in this subsection shall remain in effect until August 22, 2018, unless enacted into law in the Drug Control Act.

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

1. 6-ethyl-6-nor-lysergic acid diethylamide (other name: ETH-LAD), its optical, position, and geometric isomers, salts, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation;

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

3. Synthetic opioids:

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

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

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

4. Cannabimimetic agents:

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

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

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

The placement of drugs listed in this subsection shall remain in effect until December 13, 2018, unless enacted into law in the Drug Control Act.

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

1. 4-Bromo-2,5-dimethoxy-N-[(2-hydroxyphenyl)methyl]-benzeneethanamine (25B-NBOH), its optical, position, and geometric isomers, salts and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

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

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

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

1. 5-methoxy-N,N-dimethyltryptamine (5-MeO-DMT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

3. 4-hydroxy-N,N-diisopropyltryptamine (4-OH-DIPT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

5. 3,4-tetramethylene-alpha-pyrrolidinovalerophenone (TH-PVP), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

6. 4-chloro-alpha-methylamino-valerophenone (4-chloropentedrone), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

7. Synthetic opioids:

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

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

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

The placement of drugs listed in this subsection shall remain in effect until June 12, 2019, unless enacted into law in the Drug Control Act.

E. 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.

8. Central nervous system stimulants:

a. Methyl 2-(4-fluorophenyl)-2-(2-piperidinyl)acetate (other name: 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 August 21, 2019, unless enacted into law in the Drug Control Act.

F. 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. Research chemicals.

a. 2-(ethylamino)-2-phenyl-cyclohexanone (other name: deschloro-N-ethyl-ketamine), 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.

b. 3,4-methylenedioxy-N-tert-butylcathinone, 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.

c. 4-fluoro-N-ethylamphetamine, 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.

d. beta-keto-4-bromo-2,5-dimethoxyphenethylamine (other name: bk-2C-B), 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. Synthetic opioids.

a. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide (other name: Crotonyl 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. 2-(3,4-dichlorophenyl)-N-[2-(dimethylamino)cyclohexyl]-N-methylacetamide (other name: U-51754), 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. N-phenyl-N-[4-phenyl-1-(2-phenylethyl)-4-piperidinyl]-propanamide (other name: 4-phenylfentanyl), 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 (18 months after the effective date of this regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Petition for rulemaking:

Included in your package are:

Copy of petition from Judy Dietrick

Copy of Notice of Comment

Board action – choose one option:

1) Accept the petitioner's request and initiate rulemaking; or

2) Deny the request and state reasons for denial.

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,)		
Judy Lifland Dietrick		
Street Address	**Area Code and Telephone Number**	
9611 Podium Dr	703 938 4384	
City	**State**	**Zip Code**
Vienna	VA	22182
Email Address (optional)	**Fax (optional)**	
LIFLANDJ @ yahoo.com		

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. 18 VA 110-20-240 Manner of maintaining records, prescriptions, inventory records

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Doctors are required to keep records for 10 years. I tried to get info on pneumonia vaccines given to me at Safeway and Walgreens and I was told they do not keep records after 2 years.
I think law should be changed so records are kept 10 years as they would be in a doctor's office.
Vaccines are part of a patient's medical records and should be available longer than 2 years.

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. 54.1-2400

Signature: Judy Lifland Dietrick Date: 2/1/2018

July 2002

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 02/02/2018

Petitioner Judy Lifland Dietrick

Petitioner's Request
To amend the requirement for retention of records beyond two years, to include records of vaccine administration

Agency Plan
In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on March 5, 2018. 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 March 27, 2018. 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 March 29, 2018.

Publication Date 03/05/2018 *(comment period will also begin on this date)*

Comment End Date 03/27/2018

Agenda Item: Adoption of Proposed Regulations – e-profile number

Included in your agenda package are:

A copy of the NOIRA background document

There were no comments on the Notice of Intended Regulatory Action.

A copy of proposed regulation

Board action:

Adoption of proposed regulation as included in agenda package or adoption of different amended language

VIRGINIA
REGULATORY TOWN HALL

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	Requirement for e-profile ID number
Date this document prepared	9/11/17

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 require an applicant as a pharmacist, a pharmacy intern, or a pharmacy technician to obtain an e-profile ID number that may be utilized by the applicant and the Board to track discipline, exam scores, and continuing education. There is no cost to applicants to obtain the number, and there is no cost to the Board for using an e-profile ID number to get information from the National Association of Boards of Pharmacy (NABP).

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:

1. To establish the qualifications for registration, certification, licensure, permit, or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification, licensure, or registration. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license, or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, permit, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification, permitting, or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions, and the health regulatory boards.

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.).

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 streamline the licensure process and expedite NABP reporting of demographic information, examination scores, licensure status in all states, disciplinary history, and continuing education. By having real time information, the Board will have greater assurance that there are no grounds for denial of an initial or reinstatement application for a pharmacist, a pharmacy intern, or a pharmacy technician. The e-profile 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.

Sections relating to initial application for licensure or registration as a pharmacist, pharmacy intern, or pharmacy technician or for renewal of any of such license or registration will be amended to include a requirement for each such person to report an e-profile ID number obtained from NABP.

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.

Most pharmacists, pharmacy technicians, and pharmacy interns already possess an e-profile ID since it is assigned anytime someone uses an NABP service, such as applying to sit for an examination, monitoring of continuing education, verifying licensure for endorsement, etc. Further there is no cost for obtaining the e-profile ID number or for utilizing it by the Board. Therefore, the Board does not believe the requirement is burdensome for applicants and may decrease its administrative burden for communications with NABP for licensure or examination information.

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.

The amended language will be very straight-forward, so a Regulatory Advisory Panel is not necessary for development of regulatory changes.

Project 5278 - NOIRA

BOARD OF PHARMACY

Requirement for applicants to have an e-profile ID number

18VAC110-20-22. Application to include e-profile number.

An application for licensure as a pharmacist by examination or endorsement or for registration as a pharmacy intern or pharmacy technician shall include an e-profile number issued by NABP.

Guidance document: 110-45

Protocol for the Prescribing of Naloxone and Dispensing by Trainers

Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone for opioid overdose reversal shall follow this protocol when dispensing naloxone, and the hypodermic needles and syringes required for injecting such naloxone, to a person, without charge or compensation, for administration to another person believed to be experiencing or about to experience a life-threatening opioid overdose as authorized in ~~subsection Y of~~ § 54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C).

1) **Controlled Substances Registration:** An organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal on whose behalf an authorized trainer may dispense naloxone pursuant to a standing order shall apply for a controlled substances registration certificate from the Board of Pharmacy. The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration certificate.

2) **Standing Order:** An authorized trainer may dispense naloxone, and the hypodermic needles and syringes required for injecting such naloxone, pursuant to a standing order. The standing order must be issued by an individual prescriber to the organization on whose behalf the authorized trainer is acting. The standing order authorizes a trainer to dispense one or more of the specified naloxone formulations, and may authorize the dispensing of hypodermic needles and syringes for injecting such naloxone, to any person seeking to obtain naloxone following completion of a training program on the administration of naloxone for opioid overdose reversal approved by the Department of Behavioral Health and Developmental Services. A standing order is valid for no more than two years from the date of issuance and must contain the following information at a minimum:
   a. Name of organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and that has obtained a controlled substances registration from the Board of Pharmacy on whose behalf the authorized trainer may dispense naloxone pursuant to the standing order;
   b. ~~Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration~~ Drug name, strength, quantity of naloxone to be dipsensed, ~~to include quantity of drug~~ and directions for administration. If hypodermic needles and syringes are to be dispensed for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the "Kit Contents" in part 3 of this protocol;
   c. Prescriber's signature; and
   d. Date of issuance.

Adopted: June 27, 2017; Revised: March 29, 2018

3) Kit Contents for Intranasal, ~~or~~ Auto-Injector, or Injectable Administration:

Intranasal	Auto-Injector	Intranasal	Injection
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. No kit is required. Product is commercially available.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. No kit is required. Product is commercially available.	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Kit must contain 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.

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

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

4) Storage, Labeling, Dispensing, and Recordkeeping:

A. Persons authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone, and hypodermic needles and syringes for injecting such naloxone, for opioid overdose reversal pursuant to ~~subsection Y of~~ §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) shall maintain the following records:

1. The prescriber's standing order issued in accordance with ~~subsection Y of~~ §54.1-3408(Y), §54.1-3466(F), and §54.1-3467(C) authorizing the trained individual to dispense naloxone, and hypodermic needles and syringes for injecting such naloxone.
2. Invoices or other records showing receipts of naloxone, hypodermic needles, and syringes must be maintained, but may be stored in an electronic database or record as an electronic image that provides an exact, clearly legible, image of the document or in secured storage either on or off site. All records in off-site storage or database shall be retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.
3. A manual or electronic log indicating the name, strength, lot, expiration date, and quantity of naloxone, description and quantity of hypodermic needles, and syringes transferred to and from the controlled substances registration location to the off-site training location, along with date of transfer, name of trained individual approved by the Department of Behavioral Health and Developmental Services.
4. Record of dispensing indicating name of person receiving naloxone, address or contact information if available, date of dispensing, drug name, strength, quantity, lot number, expiration date, description and quantity of hypodermic needles and syringes, if dispensed, and name of trained individual approved by the Department of Behavioral Health and Developmental Services to dispense naloxone.

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

C. The trainer shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf

D. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

E. In the event of a manufacturer recall, the supervising practitioner or responsible party associated with the controlled substances registration certificate must ensure compliance with any recall procedures as issued by the manufacturer, United States Food and Drug Administration, or Board to ensure affected drug is transferred to a person or entity authorized to possess the drug for return or destruction.

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

Resources:

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

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3466 and 54.1-3467 of the Code of Virginia, relating to possession or distribution of controlled paraphernalia; hypodermic needles and syringes; naloxone.

[H 842]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3466 and 54.1-3467 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3466. Possession or distribution of controlled paraphernalia; meaning of controlled paraphernalia; evidence; exceptions.

A. For purposes of this chapter, "controlled paraphernalia" means (i) a hypodermic syringe, needle, or other instrument or implement or combination thereof adapted for the administration of controlled dangerous substances by hypodermic injections under circumstances that reasonably indicate an intention to use such controlled paraphernalia for purposes of illegally administering any controlled drug or (ii) gelatin capsules, glassine envelopes, or any other container suitable for the packaging of individual quantities of controlled drugs in sufficient quantity to and under circumstances that reasonably indicate an intention to use any such item for the illegal manufacture, distribution, or dispensing of any such controlled drug. Evidence of such circumstances shall include, but not be limited to, close proximity of any such controlled paraphernalia to any adulterants or equipment commonly used in the illegal manufacture and distribution of controlled drugs including, but not limited to, scales, sieves, strainers, measuring spoons, staples and staplers, or procaine hydrochloride, mannitol, lactose, quinine, or any controlled drug, or any machine, equipment, instrument, implement, device, or combination thereof that is adapted for the production of controlled drugs under circumstances that reasonably indicate an intention to use such item or combination thereof to produce, sell, or dispense any controlled drug in violation of the provisions of this chapter.

B. Except as authorized in this chapter, it is unlawful for any person to possess controlled paraphernalia.

C. Except as authorized in this chapter, it is unlawful for any person to distribute controlled paraphernalia.

D. A violation of this section is a Class 1 misdemeanor.

E. The provisions of this section shall not apply to persons who have acquired possession and control of controlled paraphernalia in accordance with the provisions of this article or to any person who owns or is engaged in breeding or raising livestock, poultry, or other animals to which hypodermic injections are customarily given in the interest of health, safety, or good husbandry; or to hospitals, physicians, pharmacists, dentists, podiatrists, veterinarians, funeral directors and embalmers, persons to whom a permit has been issued, manufacturers, wholesalers, or their authorized agents or employees when in the usual course of their business, if the controlled paraphernalia lawfully obtained continue to be used for the legitimate purposes for which they were obtained.

F. The provisions of this section and of § 18.2-265.3 shall not apply to (i) a person who dispenses naloxone in accordance with the provisions of subsection Y of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes hypodermic needles and syringes for injecting such naloxone or (ii) a person who possesses naloxone that has been dispensed in accordance with the provisions of subsection Y of § 54.1-3408 and possesses hypodermic needles and syringes for injecting such naloxone in conjunction with such possession of naloxone.

§ 54.1-3467. Distribution of hypodermic needles or syringes, gelatin capsules, quinine or any of its salts.

A. Distribution by any method, of any hypodermic needles or syringes, gelatin capsules, quinine or any of its salts, in excess of one-fourth ounce shall be restricted to licensed pharmacists or to others who have received a license or a permit from the Board.

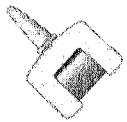
B. (Expires July 1, 2020) Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized by the State Health Commissioner pursuant to a comprehensive harm reduction program established pursuant to § 32.1-45.4 who are acting in accordance with the standards and protocols of such program for the duration of the declared public health emergency.

C. Nothing in this section shall prohibit the dispensing or distributing of hypodermic needles and syringes by persons authorized to dispense naloxone in accordance with the provisions of subsection Y of § 54.1-3408 and who, in conjunction with such dispensing of naloxone, dispenses or distributes

hypodermic needles and syringes.

2. That an emergency exists and this act is in force from its passage.

Naloxone Product Comparison

	Injectable (and intranasal-IN) generic	Intranasal branded		Injectable generic[1]		Auto-injector branded	
Brand name		Narcan Nasal Spray				Evzio Auto-Injector	
Product comparison							
			(Product not yet released[2])			(yellow & purple)  (Formulation to be discontinued[3])	(blue & purple) 
FDA approved Labeling includes instructions for layperson use	X (for IV, IM, SC)	X X		X		X X	
Assembly required	X			X			
Fragile	X						
Can titrate dose	X			X			
Strength	1 mg/mL	4 mg/0.1 mL	2mg/0.1mL	0.4 mg/mL	4 mg/10 mL	0.4 mg/0.4mL	2 mg/0.4mL
Storage requirements (All protect from light)	Store at 59-86 °F Fragile: Glass.	Store at 59-77 °F Excursions from 39-104 °F		Store at 68-77 °F Breakable: Glass.		Store at 59-77 °F Excursions from 39-104 °F	
Cost/kit[4]	$$	$$		$		$$$	
Prescription variation							
Refills	Two	Two		Two		Two	
Rx and quantity	#2 2 mL Luer-Jet™ Luer-Lock needleless syringe plus #2 mucosal atomizer devices (MAD-300)	#1 two-pack of two 4 mg/0.1 mL intranasal devices	#1 four-pack of four 2 mg/0.1 mL intranasal devices	#2 single-use 1 mL vials PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#1 10mL multidose vial PLUS #2 3 mL syringe w/ 23-25 gauge 1-1.5 inch IM needles	#1 two-pack of two 0.4 mg/0.4 mL prefilled auto-injector devices	#1 two-pack of two 2 mg/0.4 mL prefilled auto-injector devices

Naloxone Product Comparison

	Injectable (and intranasal-IN) generic		Intranasal branded		Injectable generic[1]		Auto-injector branded	
Sig. (for suspected opioid overdose)	Spray 1 ml (1/2 of syringe) into each nostril. Repeat after 2-3 minutes if no or minimal response.		Spray 0.1 mL into one nostril. Repeat with second device into other nostril after 2-3 minutes if no or minimal response.		Inject 1 mL in shoulder or thigh. Repeat after 2-3 minutes if no or minimal response.		Inject into outer thigh as directed by English voice-prompt system. Place black side firmly on outer thigh and depress and hold for 5 seconds. Repeat with second device in 2-3 minutes if no or minimal response.	
Ordering information								
How supplied	Box of 10 Luer-Jet™ prefilled glass syringes		Two-pack of single use intranasal devices		Box of 10 or package of 25 single-dose fliptop vials (1 ml)	Case of 25 multi-dose fliptop vials (10 ml)	Two pack of single use auto-injectors + 1 trainer	
Manufacturer	IMS/ Amphastar	Teleflex (off-label IN adapter)	Adapt Pharma		Pfizer, Mylan and West-Ward Pharmaceuticals	Pfizer	kaléo	
Web address	Amphastar.com	Teleflex. com	Narcannasalspray.com		Pfizerinjectables.com Mylan.com West-ward.com	Pfizerinjectables.com	Evzio.com	
Customer service	800-423-4136	866-246-6990	844-462-7226		877-946-7747 (P) 724-514-1800 (M) 800-631-2174 (W)	877-946-7747 (P)	855-773-8946	
NDC	76329-3369-01	DME- no NDC	69547-353-02	69547-212-04	00409-1215-01 (P) 67457-0292-02 (M) 0641-6132-25 (W)	00409-1219-01	60842-030-01	60842-051-01

[1] Pfizer acquired Hospira in 2015. Pfizer has an additional naloxone product, which is ***not recommended*** for layperson and take-home naloxone use because it is complicated to assemble. (Naloxone Hydrochloride Injection, USP, 0.4 mg/mL Carpuject™ Luer Lock Glass Syringe (no needle) NDC# 0409-1782-69)
[2] This product concentration is not yet currently available. As a result, some of the content is left blank.
[3] EVZIO 2 mg is now available. As of February 2017, EVZIO 0.4 mg will no longer be manufactured, but is still currently available and effective.
[4] There is considerable price variance for each product- local pharmacists are able to provide specific local pricing.
Image development supported by 1R01DA038082-01 Friedmann/Rich

(DRAFT)
Virginia Board of Pharmacy
Theft or Loss of Drugs

Virginia law requires the reporting of any theft or unusual loss of any Schedule I – V controlled substances to the Board of Pharmacy, as follows:

from Code of Virginia, Drug Control Act
§54.1-3404

...

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs. Within thirty days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

...

Board guidance on reporting theft or unusual loss

The Drug Control Act in §54.1-3404 requires a registrant or licensee who discovers a theft or any other unusual loss of a drug in Schedules II, III, IV, or V to immediately report the theft or loss to the Board. Similarly, Title 21 Code of Federal Regulations (CFR) §1301.74 states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss." In addition to the notification requirement, a registrant or licensee must furnish the Board with a listing of the kind, quantity, and strength of such drugs lost within 30 days after the discovery of the loss. Submission of a copy of Drug Enforcement Administration (DEA) Form 106 is acceptable for complying with the Board's reporting requirement.

While it is clear that a "theft" of any quantity of drug in Schedules II-V must be reported to the Board and DEA, there is occasionally confusion regarding the reporting requirements for a loss when it is unclear whether the loss constitutes an "unusual" or "significant" loss. While the terms "unusual loss" as used in the Drug Control Act and "significant loss" as used in the federal regulation are not defined in state or federal rules, DEA does offer guidance in rule and the *Pharmacist's Manual* for determining if a loss constitutes a "significant loss." It is suggested that pharmacists and pharmacy technicians follow DEA's guidance for satisfying the state and federal reporting requirements for both unusual and significant drug losses. To determine whether a loss is "significant," Title 21 CFR §1301.74 states:

> . . . a registrant should consider, among others, the following factors:
> 1. The actual quantity of controlled substances lost in relation to the type of business;
> 2. The specific controlled substances lost;
> 3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
> 4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
> 5. Whether the specific controlled substances are likely candidates for diversion;
> 6. Local trends and other indicators of the diversion potential of the missing controlled substance.

Furthermore, DEA's 2010 edition of the *Pharmacist's Manual* states:

> Although the [Controlled Substances Act] regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer. Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

In accordance with §54.1-3404 of the Drug Control Act, if the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he or she shall immediately make a complete inventory of all Schedule II-V drugs. Also, if after the initial notification of a theft or loss to the Board or DEA the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, then a complete listing and the DEA Form 106 is not required to be filed. However, the licensee or registrant should notify the Board and DEA in writing of this fact in order to resolve the initial report.

If it is determined that a loss occurred, but it is not significant, DEA indicates in the *Pharmacist's Manual* that " . . . the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion." Lastly, as indicated in the *Pharmacist's Manual* and supported by the Board, if there is a question as to whether a theft has occurred or a loss is significant, a licensee or registrant should err on the side of caution and report it to DEA and the Board.

Procedure for reporting a theft or loss

Please use DEA 106 form for the complete reporting of theft or loss of drugs. The form may be found on DEA's website as follows:
http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html

If, after a breaking or suspected loss of drugs, it is determined that no drugs were taken, the above form does not need to be completed.

Distribute copies and keep a copy as follows:

1 Copy: Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, VA 23233
804/367-4456

2 Copies: Drug Enforcement Administration*
Techworld Plaza
ATTN: Drug Diversion
800 K Street, N.W., Suite 500
Washington, DC 20001
202/305-8888

1 Copy: To be maintained at location of drug stock for your records

***You may submit your DEA form via the online submission process on DEA's website. You will need to print a copy for your records and the Board of Pharmacy**

Guidance document: 110-47

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.
- **Drug deactivation or disposal pouches** – pharmacists are encouraged to educate patients on the use of drug deactivation or disposal pouches and how to obtain them for purchase or free of charge for disposing of unwanted medications. The unwanted medications are placed in the pouch which deactivates the medication and renders the drug safe for landfills.
- **Home disposal** - if an authorized collection site or take-back program is not available, home Disposal is a viable option despite the risk of diversion and environmental contamination
    - **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.

Adopted: December 11, 2017; Revised March 29, 2018

- **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/

Virginia Board of Pharmacy

503B Outsourcing Facility Inspections & Risk Assessments

By

Gates Healthcare Associates, Inc.

About Gates Healthcare Associates

Gates Healthcare Associates is a pharmaceutical consulting firm that provides extensive clinical and regulatory knowledge and insight to pharmaceutical organizations.

- Operating since 1994
- 22 Expert Consultants located across the United States and Canada
- Operating in 47 out of 50 States as well as Ontario and Alberta, Canada
- Expertise and Effective Solutions in: USP, FDA, DEA, BOP, PCAB, ACHC, NABP, and NAPRA Compliance

Team of Experts

Leadership
Ernest P. Gates Jr. RPh, FASCP, FIACP, FACA, President & CEO
Kenneth Speidel, RPh., BS Pharm, PharmD, FACA, FIACP, Vice President

Senior Associates
Adèle D. Audet, RPh., Senior Associate
Carlos Aquino, Senior Associate
Lori A. Bassinger, RPh., J.D., Senior Associate
Joe Cabaleiro, RPh, FACA, Senior Associate
Donna Horn, RPh., D.Ph, Senior Associate
Kenneth Latta, RPh., BS Pharm., FACA, FIACP, Senior Associate
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Leah Tolliver, PharmD, RPh, Senior Associate
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Robert Falkum, Associate, HEPA Filtration Specialist
Denise Frank, RPh, FACA, Associate
John Herr, RPh., FIACP, Associate
Lloyd Jessen, RPh, JD
Paul O'Connor, RPh, MBA, Associate
Patrice Ann Shook, CPhT, Associate

FDA Section 503B/cGMP Compliance Services

Gates Healthcare Associates FDA Section 503B and cGMP Compliance Services contain:

FDA Section 503B (Outsourcing Facility) Mock Inspection

Inspection criteria (including all six systems the outsourcing facility utilizes):

- "Front Door" Operations – Receiving
- Inventory Controls
- Product Shelf Life
- Beyond Use Dating
- Analytical Testing
- Microbial Contaminants
- Facility & Labs
- Recall Process
- Quality Assurance/Sterility Assurance
- Policies and Procedures
- CQI

FDA Form 483 (or Warning Letter) Remediation

- In-Depth Letter Analysis
- FDA Findings Interpretation/Explanation
- Response Recommendations
- Root Cause Analysis with Remediation Support

FDA Section 503B/cGMP Leading Expert

Jeffrey Watson, Senior Associate, Team Leader

FDA Background: Consumer Safety Officer in the FDA's San Francisco District Office, overseeing sterile and non-sterile dosage forms of therapeutic biologics and pharmaceutical drugs, and completing more than 200 inspections for cGMPs, recalls, seizures, new drug applications, pre-approval inspections, adverse drug events, and other issues.

503B Facility Background: Previously served as Vice President of Quality Assurance at Leiter's Compounding in California, a full-service compounding pharmacy and FDA-registered 503B Outsourcing Facility in San Jose, Calif. Oversaw all sterile and non-sterile operations and led a team of 14 quality assurance employees.

Additional Service Offerings

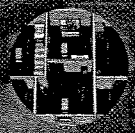
Gates Healthcare Associates, Inc. specialty is tailoring our services specifically towards the pharmacy's needs in conjunction to the requirements of their respective State Board of Pharmacy and federal regulations.

Accreditation Support

DEA Compliance

Staff Training & Competency

3rd Party Assessments & Compliance



Pharmacy Lab Design Services


Thank You
Questions?
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www.gateshealthcareassociates.com

Gates Healthcare Associates, Inc.

Innovative Pharmacy Solutions & Expertise

FDA Section 503B Expert Solutions

Gates Healthcare Associates, Inc.

1 Central Street, Suite 201
Middleton, MA 01949

Phone: 978-646-0091

Web: www.gateshealthcareassociates.com

Firm History

Gates Healthcare Associates, Inc. is a pharmaceutical consulting firm that specializes in regulation compliance. Our firm was founded in 1994 by President and CEO, Ernest P. Gates Jr., after successfully operating the largest fertility compounding pharmacy in the United States.

Since its inception, Gates Healthcare Associates, Inc. has provided strategic advice, counsel, and compliance support to a broad cross-section of health care organizations including: compounding pharmacies, retails pharmacies, specialty pharmacies, hospital pharmacies, infusion centers, specialty clinics, wholesale distributors, and pharmaceutical manufacturers. It is our mission to support our clients for improved clinical practices, ultimately leading to better patient care.

Timeline Overview: Compliance Services & Expansion

1994 - Founded Gates Healthcare Associates, Inc. (operated locally in New England)

2012 - Compounding Compliance Services expanded across entire United States (i.e. Accreditation Support, USP <795> & <797> Compliance Support, Competency Training, etc.)

2014 - Compounding Compliance Services expanded into Canada

2014 - Compounding Pharmacy Credentialing Program Developed for Distribution Network

2014 - Compounding Pharmacy Inspection Training to State Boards of Pharmacies

2014 - DEA Compliance expert compliance services

2015 - Risk Mitigation through Compliance Monitoring with State Boards of Pharmacies added to List of Service

2016 - USP <800> Compliance expert compliance services

2016 - FDA Section 503B and cGMP expert compliance services

2016 - PBM Compliance Services expert compliance services

2017 - Community Pharmacy Support and NABP expert compliance services

2017 - Long Term Care Facility Compliance expert compliance services

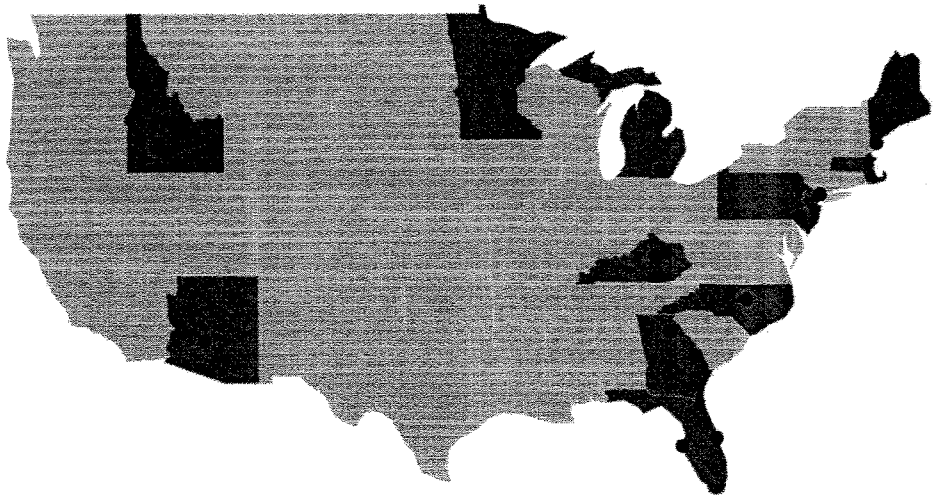
Location

Gates Healthcare Associates, Inc. central headquarters is located in Middleton, Massachusetts with satellite offices of our team of experts located nationally and in Canada. Please review map below:

Satellite Offices of Expert Consultants:

Gates Healthcare Associates, Inc. Expert Consultants: 22

- Middleton, MA - *HQ*
- Jefferson, GA
- Ridgewood, NJ
- Surprise, AZ
- Lexington, KY
- Media, PA
- Cary, NC
- Indian Shores, FL
- Manchester, MI
- Rockledge, FL
- Kennebunk, ME
- Princeton, MN
- Boise, ID
- Manitoba, Canada



Geographic Service Coverage

Geographic Area

Gates Healthcare Associates, Inc. inspections and consulting services cover the entire United States and Canada. Gates Healthcare Associates has serviced clients in 47 out of 50 states and operated in both Alberta and Ontario, Canada. Due to our extensive number of experts and satellite locations, Gates Healthcare has virtually no limits for travel restrictions to inspect and consult with pharmacies.

Team of Experts

Leadership

Ernest P. Gates Jr. RPh, FASCP, FIACP, FACA, President & CEO

Kenneth Speidel, RPh, BS Pharm, PharmD, FACA, FIACP, Vice President

Senior Associates

Adèle D. Audet, RPh, Senior Associate

Carlos Aquino, Senior Associate

Lori A. Bassinger, RPh, J.D., Senior Associate

Joe Cabaleiro, RPh, FACA, Senior Associate

Donna Horn, RPh, D.Ph, Senior Associate

Kenneth Latta, RPh, BS Pharm., FACA, FIACP, Senior Associate

William A. Mixon, RPh, MS, FIACP, D.Ph, Senior Associate

Neil A. Petry, MS, RPh, BCNP, FAPhA, Senior Associate

Leah Tolliver, PharmD, RPh, Senior Associate

Jeffrey Watson, Senior Associate

Associates

Verne Betlach, RPh, FIACP, Associate

Larry Braden, RPh, D.Sc., Associate

Dale Coker, RPh, FIACP, Associate

John M. Consoletti, RPh, Associate

Quinton Didyk, B. Sc (Gen), B. Sc. (Pharm), RPEBC, Associate

Robert Falkum, Associate, HEPA Filtration Specialist

Denise Frank, RPh, FACA, Associate

John Herr, R.Ph., FIACP, Associate

Lloyd Jessen, RPh, JD, Associate

Paul O'Connor, RPh, MBA, Associate

Patrice Ann Shook, CPhT, Associate

FDA Section 503B and cGMP Compliance Services

The Drug Quality and Security Act, signed into law on November 27, 2013, created a new section 503B in the FDCA.

Under section 503B, a compounder can become an "outsourcing facility."

Outsourcing facilities:

- must comply with cGMP requirements;
- will be inspected by FDA according to a risk-based schedule; and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

Gates Healthcare Associates FDA Section 503B and cGMP Compliance Services include:

FDA Section 503B (Outsourcing Facility) Mock Inspection

Inspection criteria:

- "Front Door" Operations – Receiving
- Inventory Controls
- Product Shelf Life
- Beyond Use Dating
- Analytical Testing
- Microbial Contaminants
- Facility & Labs
- Recall Process
- Quality Assurance/Sterility Assurance
- Policies and Procedures
- CQI

FDA Form 483 (or Warning Letter) Remediation

- In-Depth Letter Analysis
- FDA Findings Interpretation/Explanation
- Response Recommendations
- Root Cause Analysis with Remediation Support

503B and cGMP Team of Experts:

Jeffrey Watson, Senior Associate - *Team Leader*

Kenneth Speidel, RPh, BS Pharm, PharmD, FACA, FIACP, Vice President

Joe Cabaleiro, RPh, FACA, Senior Associate

Kenneth Latta, RPh, BS Pharm., FACA, FIACP, Senior Associate

FDA Expert Bio

Jeffrey M. Watson, FDA 503B Compliance Team Leader

Jeffrey M. Watson, a Senior Associate with Gates Healthcare Associates, has more than a quarter-century of experience with the U.S. Food and Drug Administration (FDA) and advanced training and expertise in sterile and non-sterile pharmaceutical manufacturing as well as current Good Manufacturing Practices (cGMP).

Mr. Watson previously served as Vice President of Quality Assurance at Leiter's Compounding, a full-service compounding pharmacy and FDA-registered 503B Outsourcing Facility in San Jose, Calif. He oversaw all sterile and non-sterile operations and led a team of 14 quality assurance employees.

Prior to Leiter's, Mr. Watson was the Consumer Safety Officer in the FDA's San Francisco District Office, overseeing sterile and non-sterile dosage forms of therapeutic biologics and pharmaceutical drugs, and completing more than 200 inspections for cGMPs, recalls, seizures, new drug applications, pre-approval inspections, adverse drug events, and other issues.

He began his 23-year tenure with the FDA as a microbiologist specializing in sterility and endotoxin analyses of drugs and devices, facilities and equipment, and procedures and documentation. He has been recognized for his leadership and communications skills.

He authored the FDA District Office microbiology laboratory's Cleanroom SOP and co-authored an FDA sterility analytical manual for the Department of Health and Human Services' Public Health Service.

Mr. Watson earned a bachelor's degree in biology, with an emphasis in microbiology, from the University of San Francisco. He completed graduate courses for regulatory affairs in the biotechnology, pharmaceutical and medical device industries through San Diego State University, as well as graduate courses in biomanufacturing principles through North Carolina State University.

Additional Compliance Service Offerings

Gates Healthcare Associates, Inc. specialty is tailoring our services specifically towards the pharmacy's needs in conjunction to the requirements of their respective State Board of Pharmacy and federal regulations.

Our innovative and personalized consulting methods allow our clients to incorporate best practice techniques into everyday operations while being in compliance with the latest compounding laws and regulations.

The following is a summary list of compliance services offered to pharmacies by Gates Healthcare Associates, Inc.

3rd Party Pharmacy Compliance Assessment

- Applicable USP (<795>, <797>, and <800>) Standards
- Applicable State BOP Regulations
- Facility/Lab(s)
- Staff Competency/Training
- Policies and Procedures
- Quality Assurance & Continuous Quality Improvement
- Proper Documentation
- Testing Requirements

Accreditation Facilitation

- PCAB
- ACHC Specialty
- DMEPOS
- VAWD
- VIPPS
- Center for Pharmacy Practice Accreditation (CPPA)

Compliance Remediation from Regulatory Inspection

- Corrective Action Planning & Implementation
- Month-by-Month Progress Monitoring
- Status Reports to State BOP

Continuous Quality Improvement/ Performance Improvement

- Quality Indicator Trending and Benchmarking
    - Compounding Records
    - Formulation Records
    - Recall Process Verification
    - Environmental Monitoring
    - Personnel Competency
    - Labeling
    - Packaging and Shipping

Controlled Substance Monitoring

- Controlled Substance Risk Assessment
- Monthly Monitoring

DEA Compliance

- Application/Registration Support
- How to Handle DEA Inspections Training
- DEA Mock Audits

Policies & Procedures

- Supplementation of core Standard Operating Procedures
- Customization towards specific facility and operations conducted at Licensee's location

Staff Competency Training

- Didactic Training on Understanding Regulation Requirements
- Observational Checklists/Hands-On Learning
- Webinars Available
- Certificates of Competency (CE's Available)

Virginia Board of Pharmacy
Inspection Report
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Licenses Issued

	9/1/16-11/30/16	12/1/16-2/28/17	3/1/17-5/31/17	6/1/17-8/31/17	9/1/17-11/30/17	12/1/17-2/28/18	License Count 3/1/2018
Business CSR	21	16	38	34	40	81	1,212
CE Courses	0	0	1	0	1	0	9
Limited Use Pharmacy Technician	1	0	0	0	1	0	17
Medical Equipment Supplier	12	2	9	3	3	2	208
Nonresident Manufacturer					13	92	102
Nonresident Medical Equipment Supplier					19	12	208
Non-resident Outsourcing Facility		279	40	17	3	1	28
Non-resident Pharmacy	2	25	9	4	38	32	750
Non-resident Wholesale Distributor	24	14	40	42	8	13	578
Non-restricted Manufacturer	14	1	18	10	0	1	27
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	163	130	166	438	251	142	11,449
Pharmacist Volunteer Registration	1	0	0	4	1	0	0
Pharmacy	16	15	18	24	17	3	1,850
Pharmacy Intern	187	148	107	140	204	148	1,738
Pharmacy Technician	390	475	513	621	387	357	13,171
Pharmacy Technician Training Program	4	1	5	4	5	5	143
Physician Selling Controlled Substances	29	30	26	44	30	22	642
Physician Selling Drugs Location	10	3	5	5	5	1	141
Pilot Programs	0	0	0	2	0	2	11
Repackaging Training Program	1	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	1	0	56
Third Party Logistics Provider					2	3	4
Warehouser	1	0	1	1	0	39	79
Wholesale Distributor	0	1	2	3	5	1	77
Total	**876**	**1,140**	**998**	**1,396**	**1,034**	**957**	**32,502**

Virginia Board of Pharmacy
Inspection Report
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Inspections Completed

	9/1/16-11/30/16		12/1/16-2/28/17		3/1/17-5/31/17		6/1/17-8/31/17		9/1/17-11/30/17		12/1/17-2/28/18	
License Type												
Controlled Substances Registration	87		109		149		133		131		163	
Medical Equipment Supplier	19		16		25		18		32		22	
Non-restricted Manufacturer	1		1		2		1		1		1	
Permitted Physician	2		0		0		0		0		0	
Physician Selling Drugs Location	36		17		18		32		39		23	
Restricted Manufacturer	0		0		1		1		3		0	
Third Party Logistics Provider									2		1	
Warehouse	3		1		5		3		6		11	
Wholesale Distributor	3		12		12		20		13		6	
Pharmacy	294		262		281		313		293		272	
Pilot	6		2		1		2		1		0	
Total	**451**		**420**		**494**		**523**		**521**		**499**	
Pharmacy (0201) Inspections												
Change of Location	4		3		4		3		3		4	
New	16		14		17		21		13		3	
Reinspection	3		15		9		8		14		2	
Remodel	51		30		48		45		55		31	
Routine	219		197		184		232		206		232	
Focus	1		3		3		4		0		0	
Federal Agency	0		0		15		0		0		0	
Compliance	0		0		1		0		2		0	
Pilot	0		0		0		0		0		0	
Total	**294**		**262**		**281**		**313**		**293**		**272**	
Pharmacy Routine Inspections												
No Deficiency	57	26%	50	25%	37	20%	52	23%	43	21%	77	33%
Deficiency	87	40%	74	38%	79	43%	100	43%	66	32%	77	33%
Deficiency & IPHCO	75	34%	73	37%	68	37%	80	34%	97	47%	78	34%
Total	**219**		**197**		**184**		**232**	*	**206**		**232**	

* Corrected 12/11/17

Virginia Board of Pharmacy
March 29, 2018
Frequently Cited Deficiencies
September 2016 - February 2018

Deficiencies Numbered Less Than 100	Cumulative Total
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	150
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	62
14. No incoming change of Pharmacist-in-Charge inventory , inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	60
20a. Pharmacist not documenting final verification of non-sterile compounding	45
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	43
20. Pharmacist not checking and documenting repackaging or bulk packaging	38
7. Change of location or remodel of pharmacy without submitting application or Board approval	37
12. Storage of prescription drugs not in the prescription department	35
20b. Pharmacist not documenting final verification of sterile compounding	35
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	34

Virginia Board of Pharmacy
March 29, 2018
Frequently Cited Deficiencies
September 2016 - February 2018

Deficiencies Numbered Greater Than 100	Cumulative Total
113. 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.	281
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	280
127. Repackaging records and labeling not kept as required or in compliance	237
130a. Compounded products not properly labeled	236
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	174
124. Labels do not include all required information	88
108. Emergency access alarm code/key not maintained in compliance	87
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	70
122. Engaging in alternate delivery not in compliance	69
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	56

Virginia Board of Pharmacy
Inspection Report
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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
Routine Inspections Completed	219	197	184	232	206	232	1270	Repeat	Repeat
Total Deficiencies	124	112	117	131	158	127	769	12	172
Average Deficiencies per Inspection	0.6	0.6	0.6	0.6	0.8	0.5	0.6		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	2	3	0	2	3	2	12		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	3	4	2	2	0	5	16		1
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	4	6	0	2	2	4	18		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	1	0	0	0	1	2		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	2	3	1	1	2	10		
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	0	0	0	0	0	0	0		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	10	5	3	5	10	4	37		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	4	3	2	0	2	1	12		1
9. Alarm not operational or not being set	0	2	1	5	3	0	11		
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (12/12/13 New Minor 44 if no drug loss)	2	0	0	1	2	1	6		1

Virginia Board of Pharmacy
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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	1	2	1	8	7	1	20		
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	0	1	1	0	0	3		
12. Storage of prescription drugs not in the prescription department	8	0	3	5	7	12	35	1	8
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (12/12/13 New Minor 46 if no drug loss)	0	0	4	0	1	0	5		3
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	8	3	3	2	6	0	22		2
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V (12/12/13 Cite Minor 13 if only expired drugs not included)	11	10	10	15	8	6	60		8
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18	19	28	25	29	31	150	8	87
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	2	4	6	7	9	6	34		2
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	0	0	0	0	2	0	2		
18. Records of dispensing not maintained as required	3	2	1	6	15	7	34		

Virginia Board of Pharmacy
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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	1	0	1	2	7	2	13		1
20. Pharmacist not checking and documenting repackaging or bulk packaging	6	4	4	9	10	5	38		14
20a. Pharmacist not documenting final verification of non-sterile compounding	7	10	7	8	7	6	45		3
20b. Pharmacist not documenting final verification of sterile compounding	7	8	5	5	4	6	35	2	6
21. No clean room	0	0	0	0	1	0	1		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	1	3	0	0	0	4		
22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed	2	0	0	1	0	0	3		
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	1	0	1	1	1	0	4		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	0	2	2		
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	0	2	0	2		1
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounding of sterile preparations.	0	0	0	0	0	0	0		1

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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
25b. . High-risk compounded sterile preparations intended for use are improperly stored	0	0	0	0	0	0	0		
25c. Documentation that a person who failed a media-fill test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	0	0	0	0	0		
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	13	9	7	6	2	6	43	1	23
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	2	2	0	2	0	6		
27. Compounding using ingredients in violation of 54.1-3410.2.	0	0	0	0	0	0	0		1
28. Compounding copies of commercially available products	0	0	1	1	2	3	7		
29. Unlawful compounding for further distribution by other entities	0	0	1	2	0	3	6		
30. Security of after-hours stock not in compliance	0	0	0	0	0	0	0		
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	0	0	0	0	0	0	0		
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	7	11	14	8	12	10	62		4
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	1	0	1	1	1	0	4		1
34. Combined with Minor 42 – 12/2013.	0	0	0	0	0	0	0		
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	1	1	2	0	0	1	5		1

Virginia Board of Pharmacy
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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
Routine Inspections Completed	219	197	184	232	206	232	1270	Repeat	Repeat
Total Deficiencies	265	265	275	317	338	302	1460	20	204
Average Deficiencies per Inspection	1.2	1.3	1.5	1.4	1.6	1.3	1.1		
101. Repealed 6/2011	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
102. Special/limited-use scope being exceeded without approval	0	0	1	0	0	0	1		
103. Repealed 12/12/2013 - Decreased hours of operation without public/Board notice	0	0	0	0	0	0	0		
104. Sink with hot and cold running water not available within the prescription department.	10	9	4	3	4	7	37	2	5
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	5	5	9	1	5	4	29	1	7
106. Prescription department substantially not clean and sanitary and in good repair	1	3	2	0	2	1	9		2
107. Current dispensing reference not maintained	2	2	6	1	6	4	21	1	8
108. Emergency access alarm code/key not maintained in compliance	16	16	8	13	16	18	87	2	12
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	24	28	35	33	33	27	180		24
110. Storage of paraphernalia/Rx devices not in compliance	0	0	0	2	0	0	2		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	3	0	1	5	1	2	12		1
112. Biennial taken late but within 30 days	0	7	0	1	2	1	11		
113. 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.	24	30	26	37	25	40	182	5	38

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Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	0	0	3	5	9	10	27		
115. Other records of distributions not maintained as required	0	0	3	3	3	0	9		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	0	0	5	3	4	4	16		0
117. Minor 17 combined with Minor 16 – 6/2011	0	0	0	0	0	0	0		
118. Schedule II emergency oral prescriptions not dispensed in compliance	0	0	0	1	0	1	2		
119. Not properly documenting partial filling of prescriptions	10	6	5	5	6	10	42		23
120. Offer to counsel not made as required	0	0	7	7	2	2	18		
121. Prospective drug review not performed as required	0	0	1	0	1	0	2		
122. Engaging in alternate delivery not in compliance	3	6	9	19	18	14	69	1	4
123. Engaging in remote processing not in compliance	2	0	10	3	5	9	29		
124. Labels do not include all required information	13	14	16	15	15	15	88		10
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	2	7	4	6	8	5	32		4
126. Special packaging not used or no documentation of request for non-special packaging	0	0	2	0	1	0	3		3
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	8	11	18	26	41	33	137	1	18
128. Unit dose procedures or records not in compliance	0	0	0	0	0	0	0		
129. Robotic pharmacy systems not in compliance	0	1	0	1	0	0	2		
130. Required compounding/dispensing/distribution records not complete and properly maintained	10	10	6	9	10	5	50		9
130a. Compounded products not properly labeled	49	37	30	60	42	18	236	1	8

Virginia Board of Pharmacy
Inspection Report
March 29, 2018

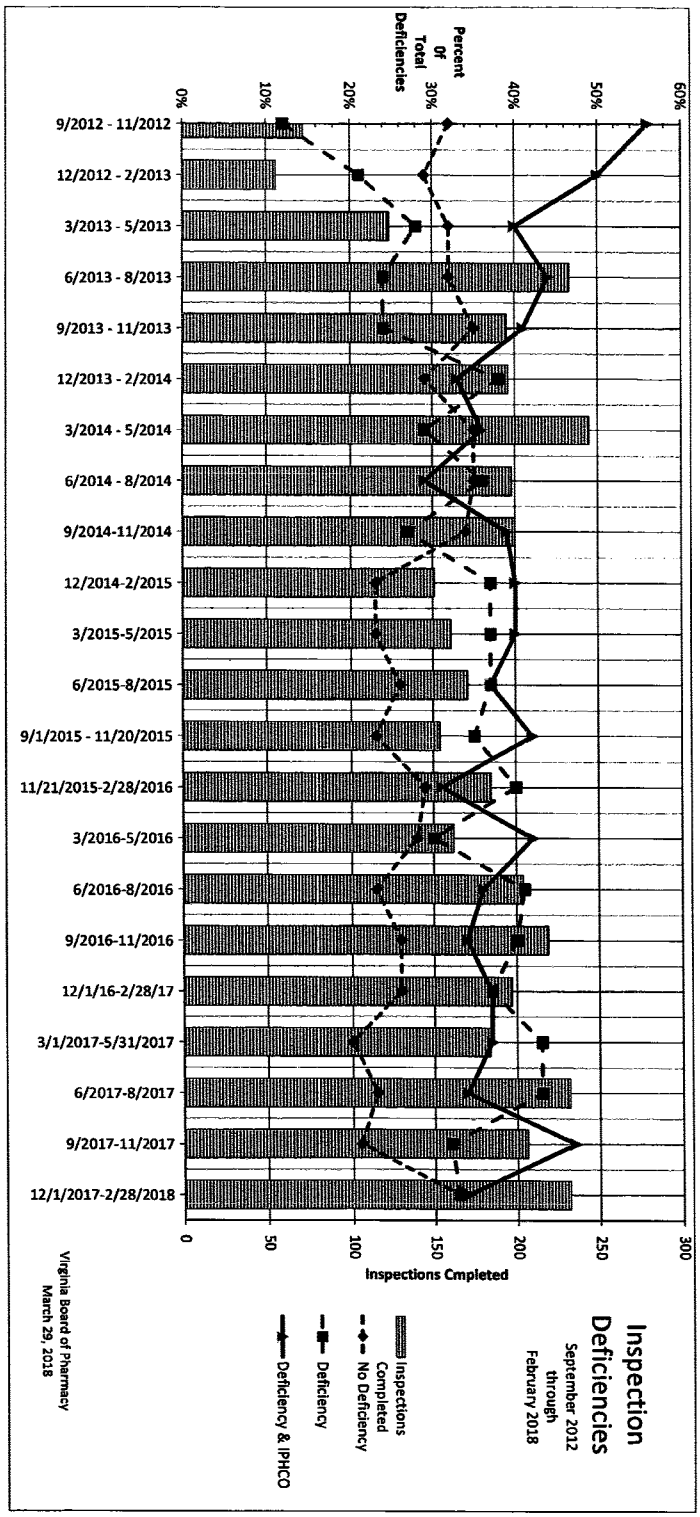
Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	0	0	3	3	6	0	12		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	3	7	15	9	14	8	56		1
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	3	3	0	6		
Hospital specific or long-term care specific:						0			
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	0	0	0	0	0		0		
135. Policies and procedures for drug therapy reviews not maintained or followed	0	0	0	0	0	0	0		
136. After hours access to a supply of drugs or records not in compliance	0	0	0	0	0	0	0		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	0	0	0	1	0	1	2		
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	3	2	2	0	0	1	8		
139. Emergency medical services procedures or records not in compliance	2	1	3	1	3	3	13	1	4
140. Emergency kit or stat-drug box procedures or records not in compliance	1	3	0	0	3	3	10	2	6
141. Maintaining floor stock in a long-term care facility when not authorized	0	0	0	0	0	0	0		
142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance	56	40	22	15	24	17	174	1	4
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	2	1	1	0	0	4		

Virginia Board of Pharmacy
Inspection Report
March 29, 2018

Deficiencies

	9/16-11/16	12/16-2/17	3/17-5/17	6/17-8/17	9/17-11/17	12/17-2/18	Total	12/17-2/18	Cumulative
144. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated. (Added 12/12/13)	13	13	6	15	14	9	70		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	3	2	0	3	2	0	10		3
146. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe. (Added 12/12/13)	0	2	4	4	9	14	33	1	1
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	2	1	8	3	1	16	31	1	3


Inspection Deficiencies
September 2012 through February 2018
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
Inspections Cmpleted
Percent Of Total Deficiencies
0%
10%
20%
30%
40%
50%
60%
0
50
100
150
200
250
300
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/1/2017-5/31/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
Virginia Board of Pharmacy
March 29, 2018

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times: Quarterly Performance Measurement, Q2 2014 - Q2 2018

David E. Brown, D.C.
Director

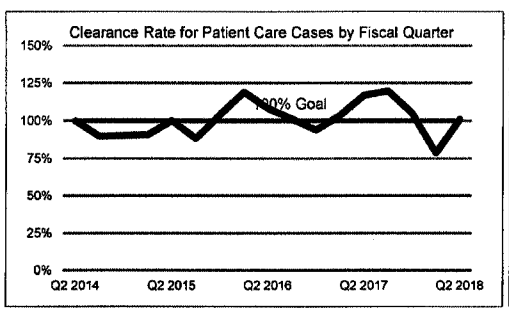
"To ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public."
DHP Mission Statement

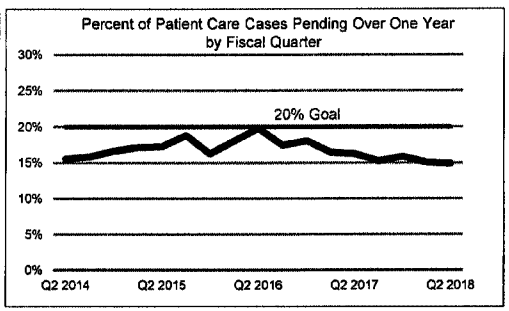
In order to uphold its mission relating to discipline, DHP continually assesses and reports on performance. Extensive trend information is provided on the DHP website, in biennial reports, and, most recently, on Virginia Performs through Key Performance Measures (KPMs). KPMs offer a concise, balanced, and data-based way to measure disciplinary case processing. These three measures, taken together, enable staff to identify and focus on areas of greatest importance in managing the disciplinary caseload; Clearance Rate, Age of Pending Caseload and Time to Disposition uphold the objectives of the DHP mission statement. The following pages show the KPMs by board, listed in order by caseload volume; volume is defined as the number of cases received during the previous 4 quarters. In addition, readers should be aware that vertical scales on the line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation. This report includes the number of days the case was in the continuance activity.

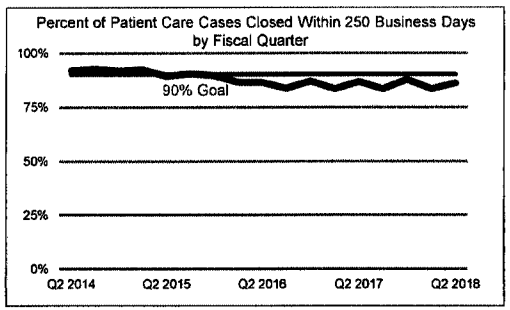
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct. The current quarter's clearance rate is **101%**, with **955** patient care cases received and **965** closed.

Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 250 business days at no more than 20%. The current quarter shows **15%** patient care cases pending over 250 business days with **2689** patient care cases pending and **400** pending over 250 business days.

Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 250 business days. The current quarter shows **86%** percent of patient care cases being resolved within 250 business days with **965** cases closed and **830** closed within 250 business days.





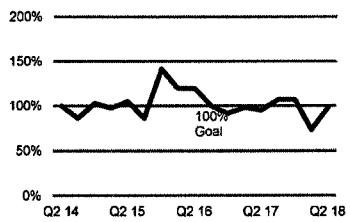


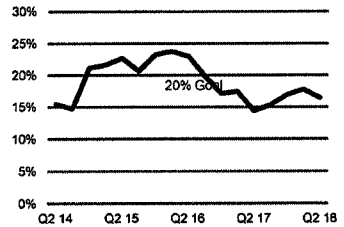
Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times, by Board

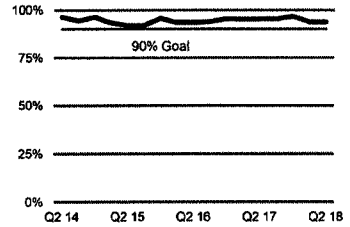
Clearance Rate | **Age of Pending Caseload** (percent of cases pending over one year) | **Percent Closed in 250 Business Days**

Medicine - In Q2 2018, the clearance rate was **98%**, the Pending Caseload older than 250 business days was **16%** and the percent closed within 250 business days was **94%**.

Q2 2018 Caseloads:
Received = **341** , Closed = **335**
Pending over 250 days = **112**
Closed within 250 days = **314**

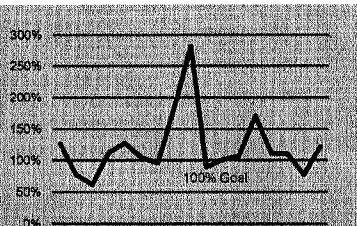


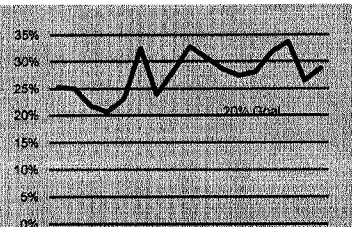


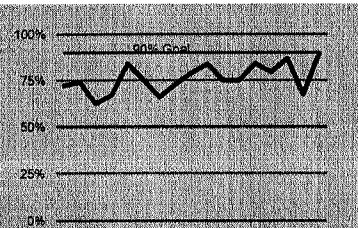


Dentistry - In Q2 2018, the clearance rate was **122%**, the Pending Caseload older than 250 business days was **29%** and the percent closed within 250 business days was **90%**.

Q2 2018 Caseloads:
Received= **64**, Closed = **78**
Pending over 250 days = **51**
Closed within 250 days = **70**

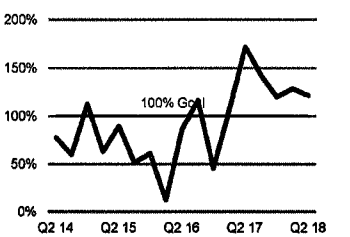


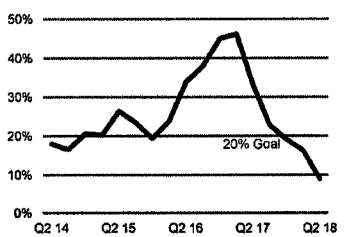


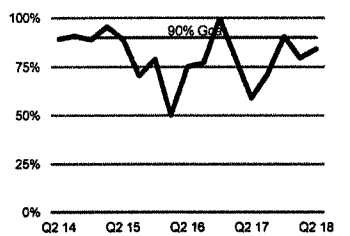


Pharmacy - In Q2 2018, the clearance rate was **121%**, the Pending Caseload older than 250 business days was **9%** and the percent closed within 250 business days was **84%**.

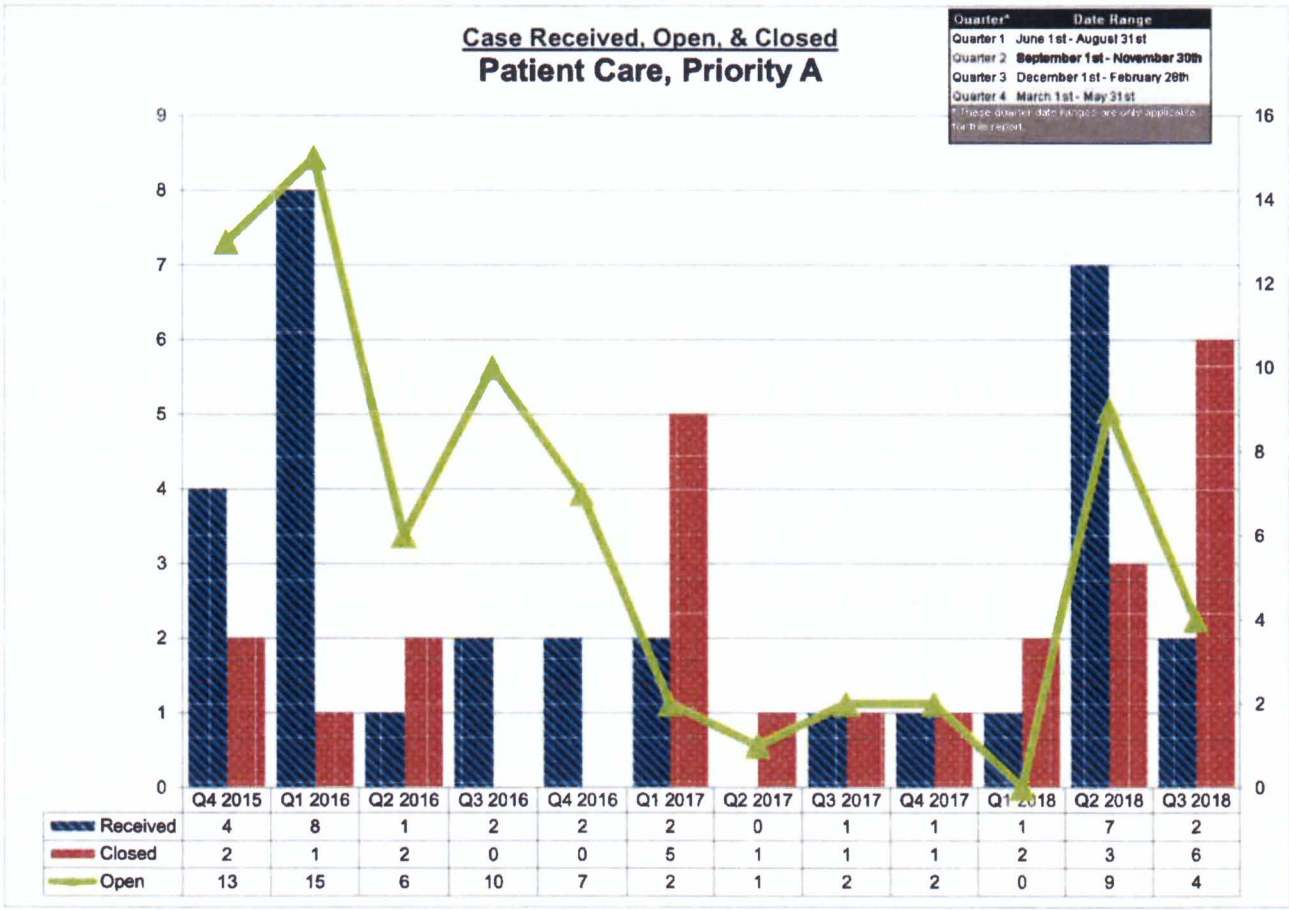
Q2 2018 Caseloads:
Received = **42** , Closed = **51**
Pending over 250 days = **9**
Closed within 250 days = **43**



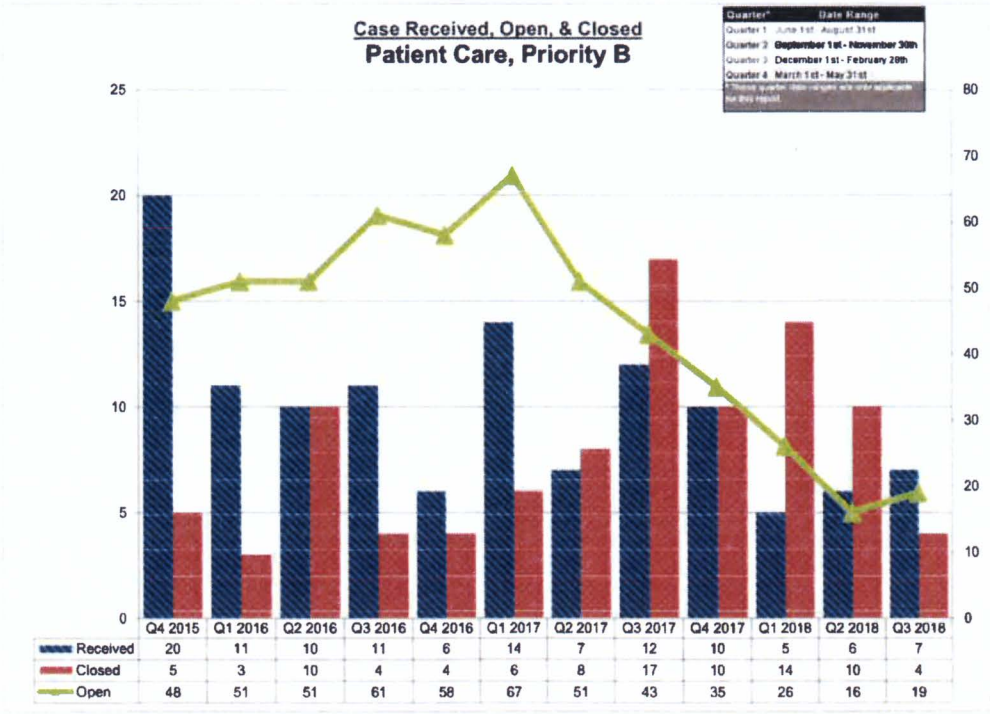




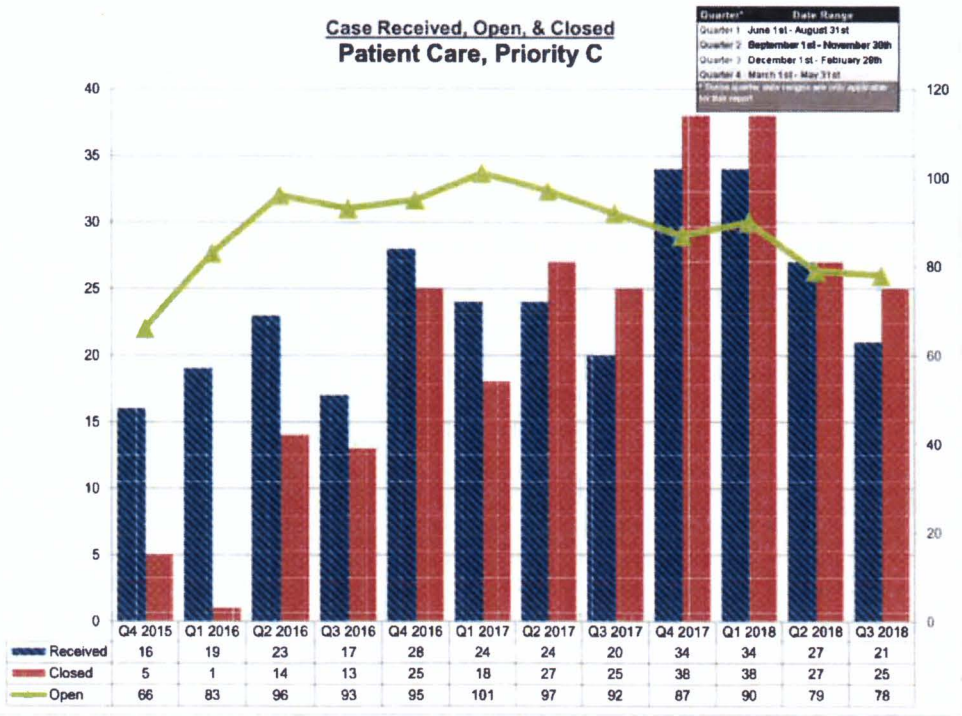
Note: Vertical scales on line charts change, both across boards and measures, in order to accommodate varying degrees of data fluctuation.

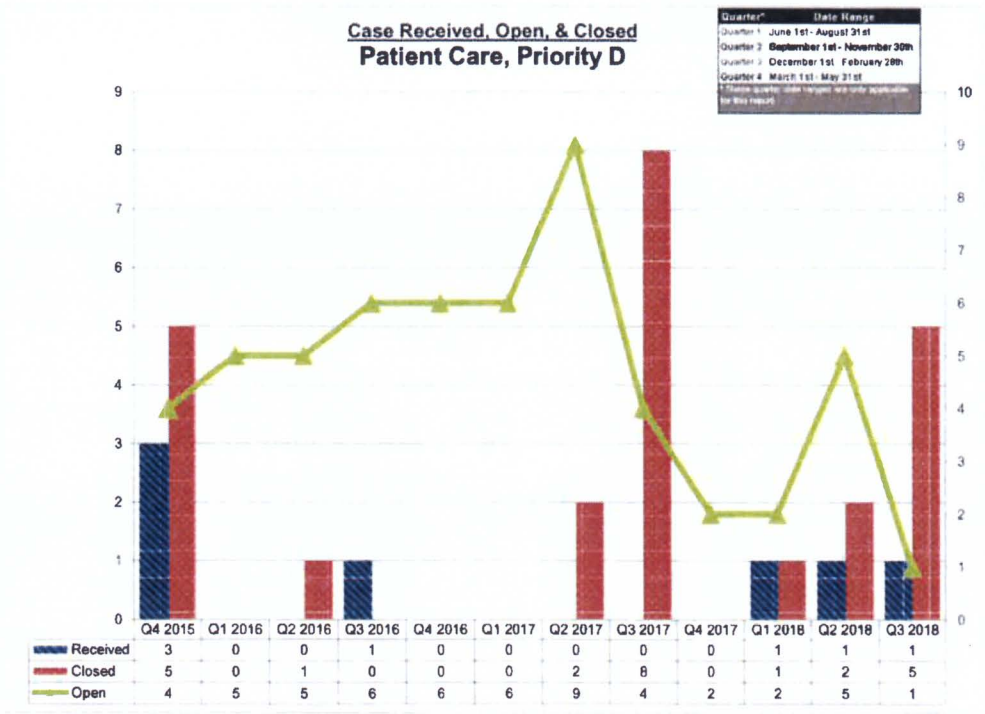


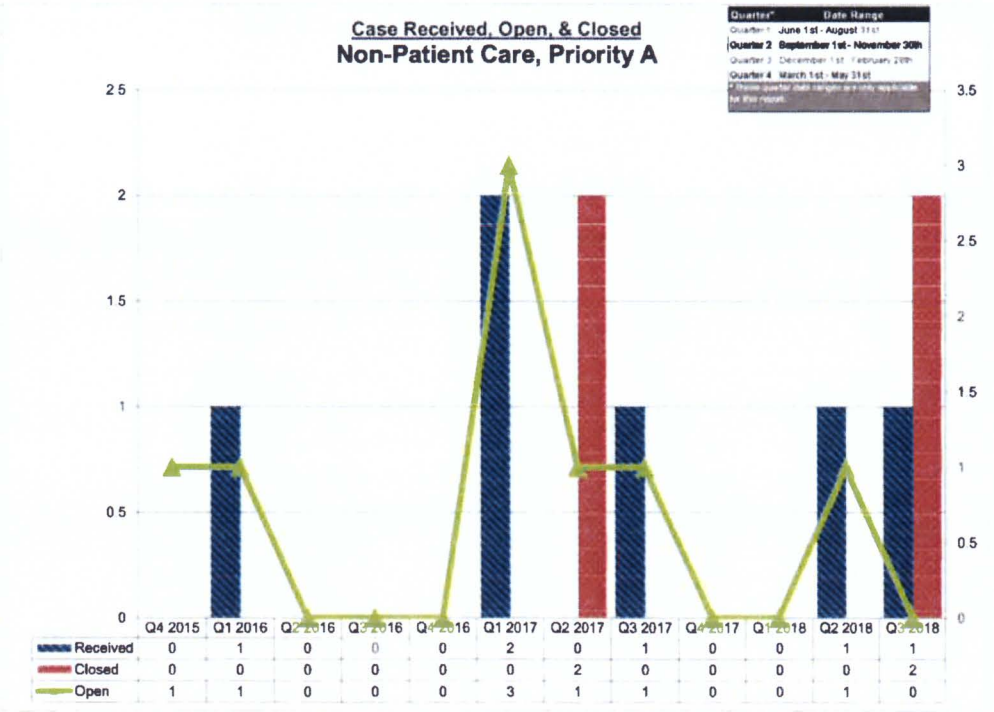
	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Received	4	8	1	2	2	2	0	1	1	1	7	2
Closed	2	1	2	0	0	5	1	1	1	2	3	6
Open	13	15	6	10	7	2	1	2	2	0	9	4

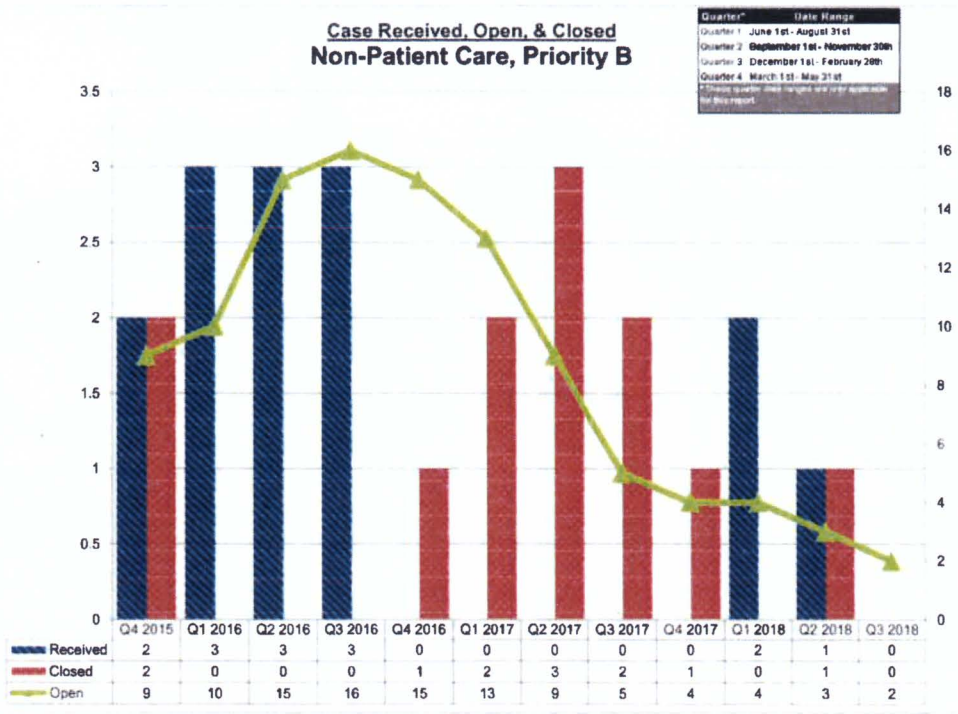


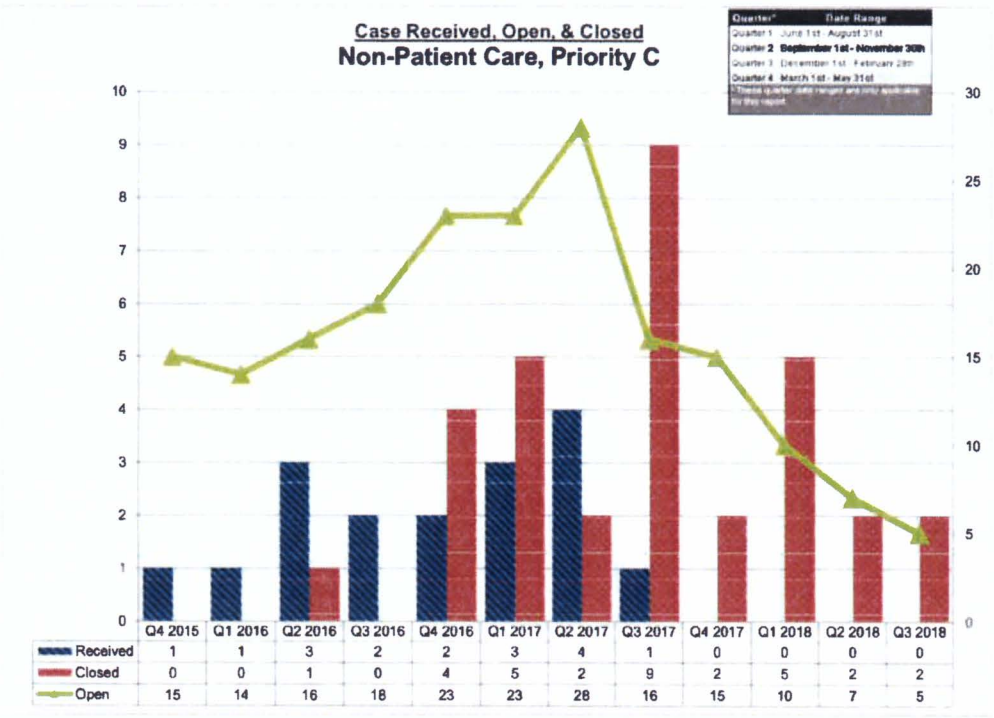
	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Received	20	11	10	11	6	14	7	12	10	5	6	7
Closed	5	3	10	4	4	6	8	17	10	14	10	4
Open	48	51	51	61	58	67	51	43	35	26	16	19


Case Received, Open, & Closed
Patient Care, Priority C
Quarter* Date Range
Quarter 1 June 1st - August 31st
Quarter 2 September 1st - November 30th
Quarter 3 December 1st - February 28th
Quarter 4 March 1st - May 31st
40
35
30
25
20
15
10
5
0
120
100
80
60
40
20
0
Q4 2015 Q1 2016 Q2 2016 Q3 2016 Q4 2016 Q1 2017 Q2 2017 Q3 2017 Q4 2017 Q1 2018 Q2 2018 Q3 2018
Received 16 19 23 17 28 24 24 20 34 34 27 21
Closed 5 1 14 13 25 18 27 25 38 38 27 25
Open 66 83 96 93 95 101 97 92 87 90 79 78

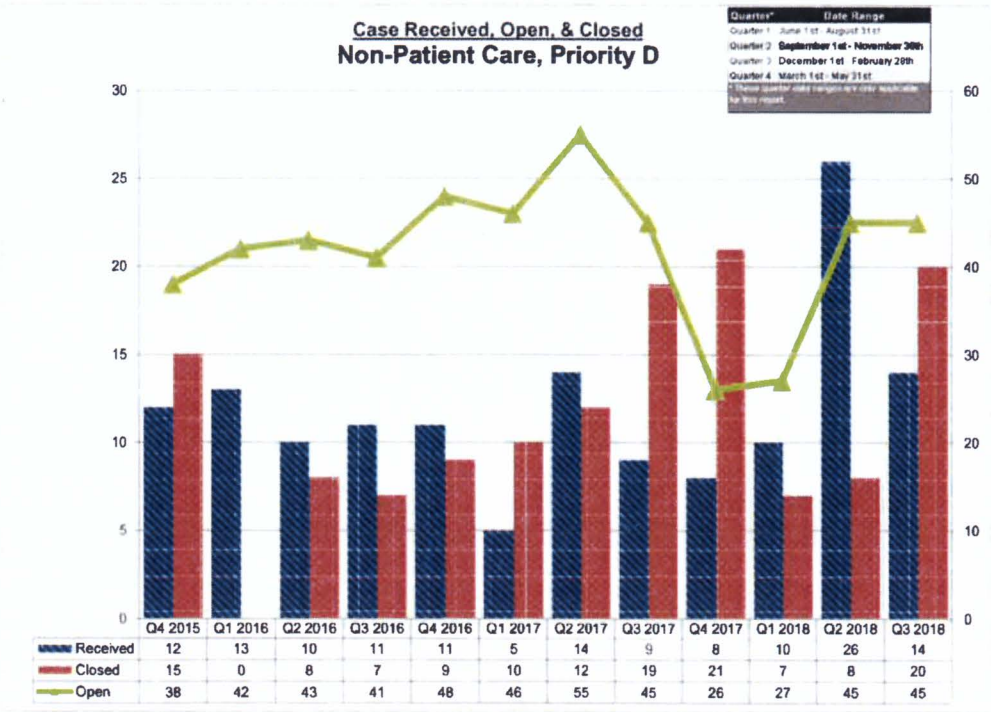

Case Received, Open, & Closed
Patient Care, Priority D
Quarter* Date Range
Quarter 1 June 1st - August 31st
Quarter 2 September 1st - November 30th
Quarter 3 December 1st February 28th
Quarter 4 March 1st - May 31st
Q4 2015 Q1 2016 Q2 2016 Q3 2016 Q4 2016 Q1 2017 Q2 2017 Q3 2017 Q4 2017 Q1 2018 Q2 2018 Q3 2018
Received 3 0 0 1 0 0 0 0 0 1 1 1
Closed 5 0 1 0 0 0 2 8 0 1 2 5
Open 4 5 5 6 6 6 9 4 2 2 5 1


Case Received, Open, & Closed
Non-Patient Care, Priority A
Quarter* Date Range
Quarter 1 June 1st - August 31st
Quarter 2 September 1st - November 30th
Quarter 3 December 1st - February 28th
Quarter 4 March 1st - May 31st
2.5
2
1.5
1
0.5
0
3.5
3
2.5
2
1.5
1
0.5
0
Q4 2015 Q1 2016 Q2 2016 Q3 2016 Q4 2016 Q1 2017 Q2 2017 Q3 2017 Q4 2017 Q1 2018 Q2 2018 Q3 2018
Received 0 1 0 0 0 2 0 1 0 0 1 1
Closed 0 0 0 0 0 0 2 0 0 0 0 2
Open 1 1 0 0 0 3 1 1 0 0 1 0

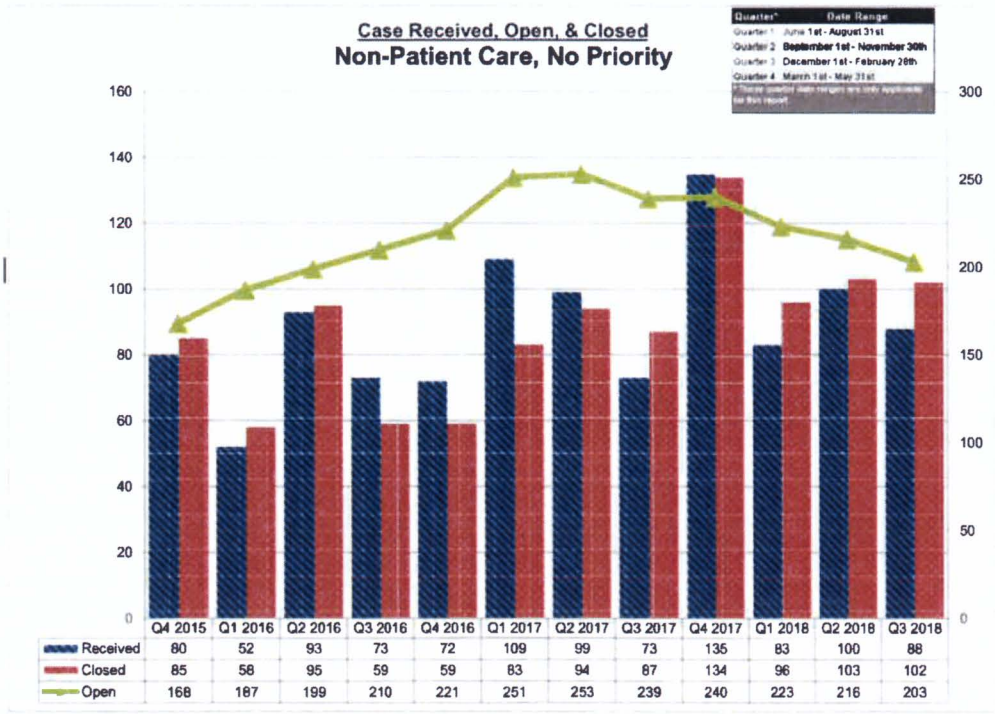

Case Received, Open, & Closed
Non-Patient Care, Priority B
Quarter* Date Range
Quarter 1 June 1st - August 31st
Quarter 2 September 1st - November 30th
Quarter 3 December 1st - February 28th
Quarter 4 March 1st - May 31st
3.5
3
2.5
2
1.5
1
0.5
0
18
16
14
12
10
8
6
4
2
0
Q4 2015 Q1 2016 Q2 2016 Q3 2016 Q4 2016 Q1 2017 Q2 2017 Q3 2017 Q4 2017 Q1 2018 Q2 2018 Q3 2018
Received 2 3 3 3 0 0 0 0 0 2 1 0
Closed 2 0 0 0 1 2 3 2 1 0 1 0
Open 9 10 15 16 15 13 9 5 4 4 3 2



	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Received	1	1	3	2	2	3	4	1	0	0	0	0
Closed	0	0	1	0	4	5	2	9	2	5	2	2
Open	15	14	16	18	23	23	28	16	15	10	7	5



	Q4 2015	Q1 2016	Q2 2016	Q3 2016	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018
Received	12	13	10	11	11	5	14	9	8	10	26	14
Closed	15	0	8	7	9	10	12	19	21	7	8	20
Open	38	42	43	41	48	46	55	45	26	27	45	45


Case Received, Open, & Closed
Non-Patient Care, No Priority
Quarter* Date Range
Quarter 1 June 1st - August 31st
Quarter 2 September 1st - November 30th
Quarter 3 December 1st - February 28th
Quarter 4 March 1st - May 31st
160
140
120
100
80
60
40
20
0
300
250
200
150
100
50
0
Q4 2015 Q1 2016 Q2 2016 Q3 2016 Q4 2016 Q1 2017 Q2 2017 Q3 2017 Q4 2017 Q1 2018 Q2 2018 Q3 2018
Received 80 52 93 73 72 109 99 73 135 83 100 88
Closed 85 58 95 59 59 83 94 87 134 96 103 102
Open 168 187 199 210 221 251 253 239 240 223 216 203

Executive Director's Report – March 29, 2018

Recent or Ongoing Projects:

- Implementation of oversight for pharmaceutical processors, RFA
- Amending routine pharmacy inspection report to include USP Chapter <800>
- Review of current routine pharmacy inspection process

Upcoming Meetings:

- 3/29/18 – Formal Hearings
- 4/18/18 – Special Conference Committee
- 4/24/18 – 9am Regulation Committee, 1pm Formal Hearings
- 4/25/18 – Tentative meeting for innovative pilot programs
- 5/17/18 – Formal Hearings
- 5/24/18 - Special Conference Committee
- 6/05/18 – Special Conference Committee
- 6/20/18 – Inspection Special Conference Committee
- 6/21/18 – Full Board Meeting with Formal Hearings
- Ad Hoc Committee to review routine pharmacy inspection process – TBD, summer
- E-prescribing Workgroup – TBD, summer (HB2165)

Recent or Upcoming Presentations/Meetings:

- DEA Meeting – December 2017
- VACDS Meeting – January 2018
- NABP Executive Committee – February 2018
- VCU School of Pharmacy – February 2018

Staffing:

- New position - Ellen Shinaberry, Deputy Executive Director started 2/2018
- Vacancies – deputy executive director (discipline), executive assistant