COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearings and Full Board Meeting
May 18, 2020 Virtual Meeting
9:00AM

*******Refer to the Third Page of Agenda for Meeting Access Information*******

- Adoption of Exempt Regulation to Conform Drug Schedules to Actions Taken by DEA 71-83
- Adoption of Final Regulations for Delivery of Prescription Devices 84-88
- Adoption of Final Regulations for Delivery of Dispensed Prescriptions, Labeling 89-93
- Adoption of Proposed Regulations for Pharmaceutical Processors 94-125
- Adoption of Final Regulations for White Bagging and Brown Bagging 126-136
- Adoption of Regulatory Amendments for Handling Fee for Returned Check 137-149

New Business:

- Consideration of certification from a substantially similar program approved by the Board for nonresident pharmacies (§ 54.1-3434.1(A)(4)) 150-156

Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – Beth O'Halloran 157
- Report on Inspection Program – Sammy Johnson 158-168
- Report on Pharmaceutical Processors – Annette Kelley 169
- Report on Disciplinary Program – Ellen B. Shinaberry 170-175
- Executive Director's Report – Caroline D. Juran 176

Adjourn

Virginia Board of Pharmacy

Instructions for Accessing May 18, 2020 Virtual Full Board Meeting and Providing Public Comment

- **Access:** Perimeter Center building access is closed to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Disregard any reference to the Board of Dentistry as a shared subscription to WebEx is being utilized. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the public hearings and during the full board meeting from those persons who have submitted an email to caroline.juran@dhp.virginia.gov **no later than 8am on May 18, 2020** indicating that they wish to offer comment. Be sure to specify if the comment is associated with the public hearing or the full board meeting. Comment may be offered by these individuals when their names are announced by the chairman. Comments must be restricted to 3-5 minutes each.
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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, December 4, 2019
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 9:31 am.
PRESIDING:	Patricia Richards-Spruill, Committee Chair
MEMBERS PRESENT:	Glen Bolyard, Committee Member
STAFF PRESENT:	Ellen B. Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jess Kelley, DHP Adjudication Specialist
Brenda L. Epps 0202-005189 Pharmacist Reinstatement Applicant	Brenda L. Epps, pharmacist, appeared to consider her application for the reinstatement of her pharmacy license and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 24, 2019 Notice. She was represented by Crystal L. Bailey, Esq. Dr. Leonard Edloe testified in person on behalf of Ms. Epps.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Brenda L. Epps. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order approving Ms. Epps' application for reinstatement of her license under certain terms and conditions.
CVS/Pharmacy #1404 Permit No. 0201-000652	No representative of CVS/Pharmacy #1404 appeared to discuss allegations that the pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the October 22, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 CVS/Pharmacy #1404. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to enter an Order for a monetary penalty.
Tiffany Nguyen Registration No. 0230-018251	Tiffany Nquyen, pharmacy technician, appeared on her own behalf to discuss allegations that she may have violated certain laws and regulations

governing the practice of pharmacy as stated in the October 31, 2019 Notice.

Closed Meeting:

Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Tiffany Nguyen. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously issue an Order for a Reprimand.

Jane Binas
Registration No. 0230-011846

Jane Binas, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 31, 2019 Notice.

Closed Meeting:

Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Jane Binas. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for a monetary penalty and a Reprimand.

Il Hyung Jeong
Registration No. 0230-031420

Il Hyung Jeong, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 31, 2019 Notice.

Closed Meeting:

Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Il Hyung Jeong. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for a Reprimand.

Rozelle West
Registration No. 0230-009096

Rozelle West, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 31, 2019 Notice.

Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Rozelle West. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for a Reprimand.
Jordan Hunter Registration No. 0230-026523	Jordan Hunter, pharmacy technician, did not appear to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 31, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Jordan Hunter. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for a Reprimand.
Bailey Pritchard Registration No. 0230-027802	Bailey Pritchard, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the October 31, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Bailey Pritchard. Additionally, he moved that Ellen Shinaberry, Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for a Reprimand.
ADJOURNED:	11:51 am

_____
Patricia Richards-Spruill, Chair

_____
Ellen B. Shinaberry
Deputy Executive Director

_____
Date

_____
Date

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

December 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: The meeting of the Board of Pharmacy was called to order at 9:14 AM.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Kristopher S. Ratliff, Vice Chairman
Glen Bolyard
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill
Rebecca Thornbury

MEMBERS ABSENT: William Lee

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
James Johnson, Deputy Executive Director
Annette Kelley, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP (Departed 9:51 AM)
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

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

APPROVAL OF AGENDA: Ms. Warriner informed the board that an amended agenda had been provided as a handout that included the following new agenda items: Approval of 11-21-2019 Regulation Committee minutes. She added that the agenda item "Consideration of Interpretation of the term "New" Prescription as it related to Requiring an offer to Counsel" was stricken from the agenda as the OAG is no longer in need of assistance, and the honoring of Mr. Saenz had been stricken as the plaque was not received in time. She indicated the board will plan to

honor Mr. Saenz at the March board meeting.

MOTION: **The amended agenda was adopted unanimously as presented. (motion by Nelson , seconded by Boone)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The following corrections were noted: 9/25/19 formal hearing minutes – change Rafael Saenz to Kris Ratliff; 11/22/19 Regulation Committee minutes – correct spelling of "the".

MOTION:

The Board voted unanimously to adopt the minutes as presented and amended for the following meetings:

- **September 20, 2019, Special Conference Committee**
- **September 24, 2019, Informal Conference Committee**
- **September 25, 2019, Full Board Meeting**
- **September 25, 2019, Public Hearing Scheduling Chemicals**
- **September 25, 2019, Formal Hearing**
- **October 9, 2019, Telephone Conference Call**
- **October 23, 2019, Special Conference Committee**
- **October 31, 2019, Telephone Conference Call**
- **November 21, 2019, Regulation Committee**

(motion by Jenkins , seconded by Richards-Spruill)

PUBLIC COMMENTS:

Katie Hellebush, Executive Director for Virginia Medical Cannabis Coalition, offered comment related to the draft guidance document for pharmaceutical processor sample size testing. She urged the board to confer with stakeholders to determine a sample size requirement that is sufficiently large enough, but not excessive and wasteful.

Cindy Williams, Vice President, Riverside Health Systems and member of VSHP, provided comment on the draft regulatory action to incorporate allowances for RFID and carousel technology. Ms. Williams offered support to the board for the adoption of the draft amendments to 18VAC110-20-425 and new section 18VAC110-20-505 related to medication carousels and use of RFID technology in provision of floor stock. She added that both technologies are currently in use at Riverside Regional Medical Center via innovative pilot programs. Ms. Williams offered support to the board for publication of a NOIRA to solicit feedback on the draft language.

Christina Barrille, Executive Director, Virginia Pharmacists Association, echoed support provided by Katie Hellebush regarding pharmaceutical processor sample size requirements. She also informed the board that VPhA intends to have legislation introduced regarding pharmacy benefit managers. She referenced the Mercer report provided to DMAS that identified $29 million in waste related to the current PBM practices. She also expressed appreciation to the board for compiling information related to pharmacy closings.

Hunter Jamerson, Esq., Regulatory Counsel for pharmaceutical processors Dalitso and Greenleaf, requested that the board not adopt Guidance Document 110-14 *Statically Valid Sample Size for Pharmaceutical Processors* as written and re-refer to the Regulation Committee for further study. He stated USP chapter <561> is not a standard in many states and that it appears unnecessary and unfeasible. He provided a handout of written comments as well.

Aaron Lopez, representing Dalitso LLC, expressed concern for the sample testing guidance as written. He listed concerns regarding the cost of testing, the backlog of product that the testing may create, potential diversion, and waste.

DHP DIRECTOR'S REPORT:

Dr. Brown shared comment on success rating of the board member training conducted by DHP on October 7, 2019. He encouraged board members to attend future trainings, if possible. Dr. Brown also provided updates regarding new security processes being implemented at DHP. Dr. Brown also offered praise to Ms. O' Halloran for her work in identifying a fraudulent application, Ms. Kelley for her participation at the Cannabiz Summit, Ms. Shinaberry for her work with disciplinary cases, and Ms. Juran for her work at the national level through NABP. He indicated it will likely be a busy legislative session

LEGISLATIVE/ REGULATORY/ GUIDANCE UPDATE

Update on Regulatory/Policy Actions

Ms. Yeatts reviewed the Chart of Regulatory Actions found on page 40 in the agenda packet.

Report from Regulation Committee

Mr. Ratliff addressed documents requiring review, reaffirmation or adoption.

Recommendations for Guidance Documents

Reaffirmation of 110-18

The board reviewed the proposed documents provided in the agenda packet on

Interpretation of "administer" to include preparation for administration and 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide*

pages 41-52.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to reaffirm guidance document 110-18 *Interpretation of "administer" to include preparation for administration.* (motion by Nelson, seconded by Thornbury)

The board had some discussion related to the penalty amount for the line 26 Major Penalty found in Guidance Document 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide.*

MOTION:

The board voted unanimously to insert a $1000.00 penalty into line 26 of guidance document 110-23 *Practitioner of Healing Arts Inspection Deficiency Monetary Penalty Guide* and to reaffirm guidance document 110-23 as amended. (motion by Boone, Seconded by Richards-Spruill)

Revision of 110-15 *Delegation of Authority for Disciplinary Matters*

Ms. Juran shared with the board that staff identified two actions that could be delegated to staff to expedite the handling of certain matters such as:

- The offering of a pre-hearing consent order for the voluntary surrender of a license or regulation for a reason not related to disciplinary action.
- Authorizing the Executive Director to issue an advisory letter to the person who was the subject of a complaint pursuant to §54.1-2400.2(G), when it is determined that the proceeding will not be instituted.

Ms. Juran further added that staff receives approximately 1-2 calls each year from pharmacist requesting to voluntarily surrender their license.

MOTION:

The board voted unanimously to accept the Regulation Committee's recommendation to adopt revisions of 110-15 *Delegation of Authority for Disciplinary Matters* proposed by staff as presented.

Revision of 110-27 *PIC Responsibilities*

Ms. Juran reviewed the proposed revisions as show on pages 56-58 of the agenda packet.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt revisions to guidance document 110-27 *PIC Responsibilities* as presented.

Revision of 110-34 *Manufacturer, Wholesale Distributor Licensure Guidance*

Ms. Juran shared suggestions offered by Mr. Johnson and Ms. O' Halloran as shown on page 60 of the agenda packet.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt guidance 110-34 as presented.

Adoption of 110-13 *Guidance on Collaborative Practice Agreements*

During a Joint Commission on Health Care study, it was reported to the researcher by various stakeholders that confusion exists regarding whether a collaborative practice agreement is required for each patient to participate. The researcher inquired if the board would consider adopting guidance on this subject to clarify the Board's position. Ms. Yeatts added that once a guidance document is adopted, public comment would be open for 30 days.

MOTION:

The board voted unanimously to accept the recommendation from the Regulation Committee to adopt guidance document 110-13 as presented.

Adoption of 110-14 *Statistically Valid Sample Size for Pharmaceutical Processors*

Regulation 18VAC110-60-300 stated the sample size should be a statically valid sample size determined by the board.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt guidance document 110-14 as presented.

Recommendation of Emergency Action Prohibiting Vitamin E Acetate in CBD and THC-A Oil Vaping Formulations

The Regulation Committee voted 5:1 to recommend to the full board that it promulgate an emergency regulation to prohibit CBD or THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate and to recommend to the Health Commissioner that he also consider taking a more immediate action to prohibit these products from containing Vitamin E acetate.

MOTION:

The board voted 8:1 to accept the recommendation of the Regulation Committee to adopt an emergency regulation as presented to prohibit CBD or THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate. (Warriner Abstained)

MOTION:

The board voted unanimously to adopt the Regulation Committee's recommendation to send a recommendation to the Health Commissioner that he also consider taking a more immediate action to prohibit CBD or

THC-A formulations intended to be vaped or inhaled from containing Vitamin E acetate.

Consideration of Amendments to Incorporate Changes Currently in Approved Innovation Pilots

Mr. Johnson provided an overview to the board of the Medication Carousel and Radio Frequency Identification (RFID) technologies currently in use in certain hospital pharmacies via innovative pilot programs. The Regulation Committee voted unanimously to recommend to the board to amend the language in 18VAC110-20-425(C)(2) to allow for these technologies.

MOTION:

The board voted unanimously to accept the recommendation of the Regulation Committee to adopt a NOIRA to allow for the use of medication carousels and RFID technology in hospital pharmacies.

Discussion of Immunization Records

Mr. Ratliff shared some background on his experience using the Virginia Immunization Information System (VIIS) database.

ACTION ITEM:

The board requested staff to reach out to VDH to determine if an immunization coalition is being formed that would possibly be discussing immunization administration recordkeeping, how a hospital pharmacist would report to the database since the pharmacist may not know if the vaccine was truly administered or if a template exists for hospitals to report immunization administrations, and if the database could potentially support increased usage via mandatory reporting from pharmacists or all health care providers. The board also requested that staff educate pharmacists on the VIIS database in an upcoming board e-newsletter.

OLD BUSINESS:

Review Pharmacy Closing Statistics

Ms. Juran provided a review of pages 104-115 of agenda packet regarding the number of pharmacy permits issued and closed during recent years. She also provide the board with a map indicating the location of current pharmacies in Virginia. She reminded the board that there is only one type of pharmacy permit and that staff could not easily distinguish the type of pharmacy services being provided at each pharmacy location.

NEW BUSINESS:

Discuss Request from VPhA to Require CE for Statewide Standing Order for Dispensing Naloxone

Ms. Juran shared that she is not aware of a current CE program specifically developed on the use of the Virginia Health Commissioner's standing order for naloxone. She also stated that the board is not currently in a position to develop such a program. She reminded the board that the board can require pharmacists to complete up to two hours of CE on a specific subject, but that they must notify licensees prior to January 1. There was some discussion regarding whether to require CE on the general subject of naloxone.

ACTION ITEM:

The board decided to table the discussion of whether to require CE in a particular subject to the March board meeting.

Discuss request from VPhA to Review Recommendations from National Consensus Conference on *Enhancing Well-Being and Resilience Among the Pharmacist Workforce*

Ms. Juran provided a summary of actions taken by the board in 2012/2013 regarding workplace conditions, which were included in the agenda packet. She also stated that organizations such as NABP would like to review the recommendations resulting from the Consensus Conference to ensure the boards can support such recommendations prior to the meeting's final report being published. NABP is currently waiting to receive information from APhA. The board received the information and did not take any action at this time.

Prescription Monitoring Program Update

Ashley Carter, Deputy Director, PMP, provided a presentation to the board as an update on the Prescription Monitoring Program.

REPORTS

Chairman's Report

Ms. Warriner began her report by acknowledging the request received from VSHP during the public comment period at the last meeting. She stated the board would not be forming a Compounding Committee at this time since the USP chapters are currently under appeal. She also thanked staff for the quick turnaround of information from the Regulation Committee meeting. Ms. Warinner shared that she will attend the NABP Member Interactive Forum in January and plans to provide an overview of this event at the March board meeting.

Report on Board of Health Professions

Mr. Logan provided updates on topics shared at the December Board of Health Professions meeting that included updates to the DHP website, enhancements to DHP security at the Perimeter Center, budget, and licensee statistics.

Report on Inspection and Licensure Program

Mr. Johnson reviewed the licensure and inspection report provided in the agenda packet.

Report on Pharmaceutical Processors

Ms. Kelley provided overview of the pharmaceutical processor report provided in the agenda packet.

Report on Disciplinary Program

Ms. Shinaberry reviewed the disciplinary report provided in agenda packet and provided a handout that included quarterly statistics regarding the number of cases received and closed.

Executive Director's Report

Ms. Juran shared news that Carmen Catizone, NABP CEO/Secretary announced his retirement that will take place in December 2020. She also offered that the NABP award nomination deadline is December 31, 2019, and encouraged the board to submit nominations to her if interested. Ms. Juran indicated that she is planning to attend the NABP Annual Meeting this year, taking place in Maryland, and encourages board member attendance.

ADJOURN: With all business concluded, the meeting adjourned at 12:38 PM.

Cynthia Warriner, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

PUBLIC HEARING FOR DELIVERY OF SCHEDULE VI DEVICES AND WHITE BAGGING/BROWN BAGGING

December 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

CALL TO ORDER: The public hearing was called to order at 9:08 a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Kristopher S. Ratliff, Vice Chairman
Glen Bolyard
Melvin L. Boone, Sr.
James L. Jenkins, Jr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill
Rebecca Thornbury

MEMBERS ABSENT: William Lee

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
Annette Kelley, Deputy Executive Director
James Johnson, Deputy Executive Director
Beth O' Halloran, Deputy Executive Director
Elaine Yeatts, Senior Policy Analyst, DHP
David E. Brown, D.C., Director, DHP
James Rutkowski, Assistant Attorney General
Kiara Christian, Executive Assistant

CALL FOR PUBLIC COMMENT: Ms. Warriner called for public comment to consider delivery of Schedule VI devices.

PUBLIC COMMENT: There was no public comment offered during the public hearing.

The Board is promulgating regulations in accordance with provisions of § 54.1-3415.1 of the Code of Virginia as amended by Chapter 241 of the 2018 Acts of the Assembly. Proposed regulations replace emergency regulations currently in effect. A new section, 18VAC110-50-55, sets out the requirements for delivery of Schedule VI devices directly to an ultimate user or consumer on behalf of a medical equipment supplier upon a valid order from a prescriber or upon request from the medical director of home health agency, nursing home, assisted living facility or

hospice.

Ms. Warriner stated that the public comment period for this topic will close on December 13, 2019.

CALL FOR PUBLIC COMMENT:

Ms. Warriner called for public comment to consider regulations for white bagging/brown bagging.

PUBLIC COMMENT:

There was no public comment offered during the public hearing.

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

Ms. Warriner stated that the public comment period for this topic will close January 10, 2020.

ADJOURN:

The public hearing adjourned at 9:14 am.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

December 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

Call to Order: A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 1:20 p.m.

Presiding: Kristopher S. Ratliff, Vice Chairman

Members Present:
Glen Bolyard
James L. Jenkins, Jr.
Ryan Logan
Cheryl H. Nelson
Patricia Richards-Spruill

Staff Present:
Caroline Juran, Executive Director
James Rutkowski, Assistant Attorney General
James Schliessmann, Sr. Assistant Attorney General
Jessica Kelley, Adjudication Specialist, APD
Kiara Christian, Executive Assistant (exited 4:40 p.m.)

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

FORMAL HEARING

Lansdowne Pharmacy
Permit #: 0230-004204

A formal hearing was held in the matter of Lansdowne Pharmacy, to discuss allegations that it may have violated certain laws and regulations governing the practice of pharmacy in Virginia as stated in their October 8, 2019 notice.

James Schliessmann, Senior Assistant Attorney General, presented a summary of the evidence to the board, with assistance from Jessica Kelley, DHP Adjudication Specialist.

Lansdowne Pharmacy was represented by Nathan

	Mortier, and Pascale M. El Hayek, pharmacist-in-charge, testified on behalf of Lansdowne Pharmacy. Vicki Gwaltney Garrison, former DHP Investigator, and Majorie Smith, DEA Investigator, testified on behalf of the Commonwealth.
Closed Meeting:	Upon a motion by Ms. Nelson, and duly seconded by Mr. Bolyard, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Lansdowne Pharmacy. Additionally, he moved that Caroline Juran and Jim Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Nelson, Second by Jenkins)
Proposed Finding of Facts:	Upon a motion by Mr. Bolyard and duly seconded by Ms. Richards-Spruill, the Board unanimously voted to accept the proposed findings of facts as amended by the board.
Decision:	Upon a motion by Mr. Jenkins, duly seconded by Ms. Nelson, the board voted 5:1 (Logan opposed) to revoke the permit issued to Lansdowne Pharmacy and impose a monetary penalty.
ADJOURNED	With all business concluded, the meeting adjourned at 5:50 pm.

Kristopher Ratliff, Chairman	Caroline Juran, Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

December 9, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

Call to Order: A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 6:00 p.m.

Presiding: Cynthia Warriner, Chair

Members Present:
Kristopher Ratliff, Vice Chair
Melvin Boone
James L. Jenkins, Jr.
Ryan Logan
Cheryl H. Nelson

Staff Present:
Caroline Juran, Executive Director
James Rutkowski, Assistant Attorney General
Jessica Kelley, Adjudication Specialist, APD
Wayne Halblieb, Sr. Assistant Attorney General

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

FORMAL HEARING

Gihan W. Seraka
License #: 0202-204419

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

Wayne Halblieb, Senior Assistant Attorney, presented the case.

Gihan W. Seraka, was represented by Lindsey Sessa.

Karen Book, Senior Investigator, DHP, testified in person on behalf of the Commonwealth.

	Rose Dematteo, DHP Compliance Case Manager, testified in person on behalf of the Commonwealth. Dr. Leslie Pickens, prescribing physician, testified in person on behalf of the Commonwealth.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Nelson, the panel voted 6-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the matter of Gihan W. Seraka. Additionally, he moved that Caroline Juran and Jim Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Ratliff, Second by Nelson)
Proposed Finding of Facts:	Upon a motion by Ms. Nelson and duly seconded by Mr. Logan, the Board voted unanimously to accept the proposed findings of facts as amended by the board.
Decision:	Upon a motion by Mr. Jenkins, duly seconded by Mr. Boone, the board voted unanimously to suspend the Pharmacy license of Gihan W. Seraka for a period of no less than one year.
ADJOURNED	With all business concluded, the meeting adjourned at 10:14 pm.

Cynthia Warriner, Chair	Caroline Juran, Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

December 10, 2019
Commonwealth Conference Center
Second Floor
Board Room 4

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

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

Call to Order: A meeting of a quorum of the Board of Pharmacy ("Board") was called to order at 9:08 a.m.

Presiding: Cynthia Warriner, Chair

Members Present:
Kristopher Ratliff
Cheryl Nelson
Patricia Richards-Spruill
Melvin Boone

Staff Present:
Ellen Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Jessica Kelley, Adjudication Specialist, APD
Ileita Redd, Disciplinary Program Specialist

Quorum: With six (5) members of the Board present, a panel was established.

FORMAL HEARING

Paulette G. Toller
Registration #: 0230-004204

A formal hearing was held in the matter of Paulette G. Toller, Pharmacy Technician, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy in Virginia.

Ms. Toller was not present for the hearing and was not represented by legal counsel.

Jessica Kelley, DHP Adjudication Specialist, presented the case.

Laura Pezzulo, Senior Investigator, DHP, testified by telephone on behalf of the Commonwealth.

Reconvene:	Sherri Francisco, Director of Pharmacy, SOVAH Danville, testified by telephone on behalf of the Commonwealth.
Closed Meeting:	Upon a motion by Mr. Ratliff, and duly seconded by Ms. Richards-Spruill, 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 Paulette G. Toller. Additionally, he moved that Ileita Redd, Ellen Shinaberry, and Jim Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened an open meeting and announced the decision. (Motion by Ratliff, Second by Richards-Spruill)
Proposed Finding of Facts:	Upon a motion by Ms. Nelson and duly seconded by Mr. Boone, the Board unanimously voted to accept the proposed findings of facts as amended by the board.
Decision:	Upon a motion by Ms. Richards-Spruill, duly seconded by Ms. Nelson, the board unanimously voted to revoke the Pharmacy Technician registration of Paulette G. Toller.
ADJOURNED	With all business concluded, the meeting adjourned at 10:18 am.

Cynthia Warriner, Chair	Ellen Shinaberry, Deputy Executive Director
Date	Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Friday, February 14, 2020

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 February 14, 2020, at 2:00 p.m., to consider the summary suspension of the registration of Justin Agloro to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Cindy Warriner, Chair

MEMBERS PRESENT:
Glenn Bolyard
Melvin Boone
James Jenkins
William Lee
Cheryl Nelson
Kristopher Ratliff
Patricia Richards-Spruill
Rebecca Thornbury

STAFF PRESENT:
Caroline D. Juran, Executive Director
Mykl D. Egan, Discipline Case Manager
Ellen Shinaberry, Deputy Executive Director
Jess Kelley, DHP Adjudication Specialist
James Rutkowski, Senior Assistant Attorney General
Sean J. Murphy, 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 a possible summary suspension case. The Board members stated that they would not have been able to attend.

With nine (9) members participating and one (1) member unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

JUSTIN AGLORO
Permit No. 0230-015349

Sean J. Murphy, Assistant Attorney General, presented a summary of the evidence in this case.

DECISION:

Upon a motion by Mr. Ratliff and duly seconded by Mr. Boone, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Justin Agloro poses a substantial danger to the public; and therefore, the registration of Mr. Agloro shall be summarily suspended. Further, upon a motion by Mr. Ratliff and duly seconded by Mr. Boone, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Mr. Agloro for the revocation of his registration.

ADJOURN:

With all business concluded, the meeting adjourned at 2:19 p.m.

Cindy Warriner, Chair

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday February 18, 2020
Commonwealth Conference Center
Second Floor
Board Room 2

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 9:12 am.
PRESIDING:	Kris Ratliff, Committee Chair
MEMBERS PRESENT:	Melvin Boone, Committee Member
STAFF PRESENT:	Mykl Egan, Discipline Case Manager Ileita Redd, Discipline Program Specialist Jess Kelley, DHP Adjudication Specialist
IMMANUEL WATKINS License No. 0202-207784	Immanuel Watkins, pharmacist, appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 16, 2020 Notice.
Closed Meeting:	Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, 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 Immanuel Watkins. Additionally, he moved that Mykl Egan and Ileita Redd 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 by Mr. Ratliff, the Committee voted unanimously enter an Order for a reprimand, continuing

education and other terms and conditions.

LAFAYETTE PHARMACY
Permit No. 0201-002357

James Fitzgerald, Pharmacist-in-Charge of Lafayette Pharmacy, appeared to discuss allegations that Lafayette Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 6, 2020 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, 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 Lafayette Pharmacy. Additionally, he moved that Mykl Egan and Ileita Redd 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 by Mr. Ratliff, the Committee voted unanimously to assess a monetary penalty against Lafayette Pharmacy.

JAMES FITZGERALD
License No. 0202-005319

James Fitzgerald, pharmacist, appeared on his own behalf to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 6, 2020 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, the Committee unanimously voted to convene a closed meeting pursuant to Virginia Code § 2.2-3711(A)(27) for the purpose of deliberation to reach a decision in the matter of James Fitzgerald. Additionally, he moved that

Mykl Egan and Ileita Redd 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 by Mr. Ratliff, the Committee voted unanimously enter an Order to issue a monetary penalty and require the completion of two hours of continuing education.

SERIOUSLY WEIGHT LOSS
Permit No. 0224-000213

Jennifer F. Pagador, M.D., Owner of Seriously Weight Loss, and Butch Pagador, Office Manager for Seriously Weight Loss, appeared to discuss allegations that Seriously Weight Loss may have violated certain laws and regulations governing the permit to sell controlled substances, and to rule on its request for a waiver of the regulations regarding equipment as stated in the December 4, 2019 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, 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 Seriously Weight Loss. Additionally, he moved that Mykl Egan and Ileita Redd 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

by Mr. Ratliff, the Committee voted unanimously to assess a monetary penalty and to grant the waiver under certain terms and conditions.

JENNIFER VAN GORDER
Registration No. 0230-0019550

Jennifer Van Gorder, pharmacy technician, did not appear and was not represented at the informal conference to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the December 20, 2019 Notice.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Ratliff, 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 Jennifer Van Gorder. Additionally, he moved that Mykl Egan and Ileita Redd 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 by Mr. Ratliff, the Committee unanimously voted to refer the matter to a Formal Administrative Hearing, and to offer a Consent Order for the revocation of Ms. Van Gorder's right to renew her registration.

ADJOURNED:

6:45 pm

Kris Ratliff, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, March 10, 2020
Commonwealth Conference Center
Second Floor
Board Room 4

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 9:29 am.

PRESIDING: Patricia Richards-Spruill, Committee Chair

MEMBERS PRESENT: Glen Bolyard, Committee Member

STAFF PRESENT: Mykl Egan, Discipline Case Manager
Ileita Redd, Discipline Program Specialist
Jess Kelley, DHP Adjudication Specialist

MOYATU HELEN MOSERY
Registration No. 0230-027719

Moyatu H. Mosery, pharmacy technician, appeared on her own behalf to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the October 31, 2019 Notice.

Closed Meeting: Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Moyatu H. Mosery. Additionally, he moved that Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for no sanction against Ms. Moseray's registration.
ELIZABETH S. MURRAY Registration No. 0230-002946	Elizabeth S. Murray, pharmacy technician, did not appear to discuss allegations that she may have violated certain laws and regulations governing her practice as a pharmacy technician as stated in the January 22, 2020 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Elizabeth Murray. Additionally, he moved that Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee unanimously voted to order that Ms. Murray shall be issued a reprimand and shall take continuing education classes.
PATIENT'S CHOICE DISCOUNT PHARMACY Permit No. 0201-004571	Preston R. Grobes, Pharmacist-in-Charge of Patient's Choice Discount Pharmacy, appeared to discuss allegations that Patient's Choice Discount Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 6, 2019 Notice. The pharmacy was represented by Robert H. Gibbs Esq. and William S. Daisley, Esq.

Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Patient's Choice Discount Pharmacy. Additionally, he moved that Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order to issue a monetary penalty to Patient's Choice and to order it to cease compounding certain drugs.
ADVANCED SPINE AND PAIN CENTERS - STAFFORD Permit No. 0224-00478	Christopher Haycock, an employee of Advanced Spine and Pain, appeared to discuss allegations that Advanced Spine and Pain Centers - Stafford may have violated certain laws and regulations governing its permit of a location of a physician selling controlled substances as stated in the December 19, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Advanced Spine and Pain Centers - Stafford, he moved that Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order to issue a monetary penalty to Advanced Spine and Pain Centers - Stafford.
ST. THEODORE LLC D/B/A/ TED PHARMACY Permit No. 0201-004844	Ehab Tadrous, Pharmacy Manager of St. Theodore LLC, d/b/a/ Ted Pharmacy, appeared to discuss allegations that Ted Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 19, 2019 Notice.
Closed Meeting:	Upon a motion by Mr. Bolyard, and duly seconded by Ms. Richards-Spruill, 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 Ted Pharmacy. Additionally, he moved that Mykl Egan, and Ileita Redd 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. Bolyard and duly seconded by Ms. Richards-Spruill, the Committee voted unanimously enter an Order for no sanction against Ted Pharmacy's permit.
ADJOURNED:	3:40 pm

Patricia Richards-Spruill, Chair

Ellen B. Shinaberry
Deputy Executive Director

Date

Date

Board of Pharmacy

Report of the 2020 General Assembly

HB 347 Commonwealth's medical cannabis program; SHHR to convene work group to review & make recommendation.

Chief patron: Davis

Summary as passed House:

Tetrahydrocannabinol products; permits to process and dispense cannabidiol oil and THC-A oil. Directs the Secretary of Health and Human Resources to convene a work group to review the Commonwealth's medical cannabis program and issues of critical importance to the medical cannabis industry and patients, including expansion of the medical cannabis program and the medical use of cannabis flowers, and to report its findings and recommendations, including any legislative recommendations, to the Governor, the Attorney General, and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than October 1, 2020.

HB 471 Health professionals; unprofessional conduct, reporting.

Chief patron: Collins

Summary as passed House:

Health professionals; unprofessional conduct; reporting. Requires the chief executive officer and the chief of staff of every hospital or other health care institution in the Commonwealth, the director of every licensed home health or hospice organization, the director of every accredited home health organization exempt from licensure, the administrator of every licensed assisted living facility, and the administrator of every provider licensed by the Department of Behavioral Health and Developmental Services in the Commonwealth to report to the Department of Health Professions any information of which he may become aware in his professional capacity that indicates a reasonable belief that a health care provider is in need of treatment or has been admitted as a patient for treatment of substance abuse or psychiatric illness that may render the health professional a danger to himself, the public or his patients, or that he determines, following review and any necessary investigation or consultation with the appropriate internal boards or committees authorized to impose disciplinary action on a health professional, indicates that there is a reasonable probability that such health professional may have engaged in unethical, fraudulent, or unprofessional conduct. Current law requires information to be reported if the information indicates, after reasonable investigation and consultation with the appropriate internal boards or committees authorized to impose disciplinary action on a health professional, a reasonable probability that such health professional may have engaged in unethical, fraudulent, or unprofessional conduct. This bill is identical to SB 540.

HB 517 Collaborative practice agreements; adds nurse practitioners and physician assistants to list.

Chief patron: Bulova

Summary as passed House:

Collaborative practice agreements; nurse practitioners; physician assistants. Adds nurse practitioners and physician assistants to the list of health care practitioners who shall not be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists. As introduced, this bill is a recommendation of the Joint Commission on Healthcare. This bill is identical to SB 565.

HB 648 Prescription Monitoring Program; information disclosed to Emergency Department Information.

Chief patron: Hurst

Summary as introduced:

Prescription Monitoring Program; information disclosed to the Emergency Department Information Exchange; redisclosure. Provides for the mutual exchange of information between the Prescription Monitoring Program and the Emergency Department Information Exchange and clarifies that nothing shall prohibit the redisclosure of confidential information from the Prescription Monitoring Program or any data or reports produced by the Prescription Monitoring Program disclosed to the Emergency Department Information Exchange to a prescriber in an electronic report generated by the Emergency Department Information Exchange so long as the electronic report complies with relevant federal law and regulations governing privacy of health information.

HB 908 Naloxone; possession and administration, employee or person acting on behalf of a public place.

Chief patron: Hayes

Summary as passed House:

Naloxone; possession and administration; employee or person acting on behalf of a public place. Authorizes an employee or other person acting on behalf of a public place, as defined in the bill, who has completed a training program on the administration of naloxone or other opioid antagonist to possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. The bill also provides that a person who is not otherwise authorized to administer naloxone or other opioid antagonist used for overdose reversal may administer

naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. The bill provides immunity from civil liability for a person who, in good faith, administers naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose, unless such act or omission was the result of gross negligence or willful and wanton misconduct. This bill incorporates HB 650, HB 1465 and HB 1466.

HB 967 Military service members and veterans; expediting the issuance of credentials to spouses.

Chief patron: Willett

Summary as passed House:

Professions and occupations; expediting the issuance of credentials to spouses of military service members. Provides for the expedited issuance of credentials to the spouses of military service members who are (i) ordered to federal active duty under Title 10 of the United States Code or (ii) veterans who have left active duty service within one year of the submission of an application to a board if the spouse accompanies the service member to the Commonwealth or an adjoining state or the District of Columbia. Under current law, the expedited review is provided more generally for active duty members of the military who are the subject of a military transfer to the Commonwealth. The bill also authorizes a regulatory board within the Department of Professional and Occupational Regulation or the Department of Health Professions or any other board in Title 54.1 (Professions and Occupations) to waive any requirement relating to experience if the board determines that the documentation provided by the applicant supports such waiver. This bill incorporates HB 930.

HB 1000 Prescription drugs; expedited partner therapy, labels.

Chief patron: Hope

Summary as introduced:

Prescription drugs; expedited partner therapy; labels. Eliminates the requirement that a bona fide practitioner-patient relationship exist with a contact patient for a practitioner to prescribe expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention. A pharmacist dispensing a Schedule III through VI drug to a contact patient whose name and address are unavailable shall affix "Expedited Partner Therapy" or "EPT" to the written prescription and the label. The bill repeals the July 1, 2020, sunset on the provision that allows practitioners employed by the Department of Health to prescribe antibiotic therapy to the sexual partner of a patient diagnosed with a sexually transmitted disease without the physical examination normally required.

HB 1059 Certified registered nurse anesthetists; prescriptive authority.

Chief patron: Adams, D.M.

Summary as passed House:

Certified registered nurse anesthetists; prescriptive authority. Authorizes certified registered nurse anesthetists to prescribe Schedule II through Schedule VI controlled substances and devices to a patient requiring anesthesia as part of the periprocedural care of the patient, provided that such prescribing is in accordance with requirements for practice by certified registered nurse anesthetists and is done under the supervision of a doctor of medicine, osteopathy, podiatry, or dentistry. This bill is identical to SB 264.

HB 1147 Epinephrine; certain public places may make available for administration.

Chief patron: Keam

Summary as passed House:

Epinephrine permitted in certain public places. Allows public places to make epinephrine available for administration. The bill allows employees of such public places who are authorized by a prescriber and trained in the administration of epinephrine to possess and administer epinephrine to a person present in such public place believed in good faith to be having an anaphylactic reaction. The bill also provides that an employee of such public place who is authorized by a prescriber and trained in the administration of epinephrine and who administers or assists in the administration of epinephrine to a person present in the public place believed in good faith to be having an anaphylactic reaction, or is the prescriber of the epinephrine, shall not be liable for any civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment.

HB 1174 Inhaled asthma medications; school nurse, etc., may administer to a student.

Chief patron: Lopez

Summary as passed:

Professional use by practitioners; administration of inhaled asthma medication. Provides that, pursuant to an order or standing protocol issued by the prescriber within the course of his professional practice, any school nurse, school board employee, employee of a local governing body, employee of a local health department, employee of a school for students with disabilities, or employee of an accredited private school who is authorized by a prescriber and trained in the administration of albuterol inhalers or nebulized albuterol may possess or administer an albuterol inhaler or nebulized albuterol to a student diagnosed with a condition requiring an albuterol inhaler or nebulized albuterol when the student is believed to be experiencing or about to experience an asthmatic crisis. The bill also provides that a school nurse, employee of a school board, employee of a local governing body, or employee of a local health department who is authorized by a prescriber and trained in the administration of albuterol inhalers or nebulized albuterol who provides, administers, or assists in the administration of an albuterol inhaler or

nebulized albuterol for a student believed in good faith to be in need of such medication, or is the prescriber of such medication, is not liable for civil damages for ordinary negligence in acts or omissions resulting from the rendering of such treatment. This bill is identical to HB 860.

HB 1263 Drug Control Act; adds certain chemicals to Schedule 1 of Act.

Chief patron: Hodges

Summary as introduced:

Drug Control Act; Schedule I. Adds certain chemicals to Schedule I of the Drug Control Act. The Board of Pharmacy has added these substances to Schedule I in an expedited regulatory process. A substance added via this process is removed from the schedule after 18 months unless a general law is enacted adding the substance to the schedule. This bill is identical to SB 538.

HB 1304 Pharmacy technicians and pharmacy technician trainees; registration.

Chief patron: Hodges

Summary as passed House:

Pharmacy technicians and pharmacy technician trainees; registration. Amends eligibility criteria for registration as a pharmacy technician to include a requirement that the individual has (i) successfully completed or was enrolled in a Board of Pharmacy-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board of Pharmacy but did not complete a Board-approved pharmacy technician training program. The bill also directs the Board to establish requirements for the issuance of a registration as a pharmacy technician to a person who (a) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (b) has passed a national certification examination required by the Board. The bill defines "pharmacy technician trainee" and sets out requirements for registration as a pharmacy technician trainee. The bill also directs the Board to convene a workgroup composed of stakeholders deemed appropriate by the Board to develop recommendations related to the addition of duties that a pharmacy technician registered by the Board may perform. This bill is identical to SB 830.

HB 1460 Cannabidiol oil and THC-A oil; certification for use of oil.

Chief patron: O'Quinn

Summary as passed House:

Dispensing cannabidiol oil and THC-A oil; non-Virginia residents. Removes the requirement that a person be a Virginia resident to obtain a certification for cannabidiol oil and THC-A oil in Virginia. The bill also makes clear that a practitioner who issues a written certification for cannabidiol oil must use his professional judgment to determine the manner and frequency of

patient care and evaluation and authorizes such practitioner to utilize telemedicine, consistent with federal requirements for the prescribing of Schedule II through V controlled substances.

HB 1506 Pharmacists; initiating of treatment with and dispensing and administering of controlled substances.

Chief patron: Sickles

Summary as passed House:

Pharmacists; prescribing, dispensing, and administration of controlled substances. Allows a pharmacist to initiate treatment with and dispense and administer certain drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board of Pharmacy in collaboration with the Board of Medicine and the Department of Health. The bill directs the Board of Pharmacy to establish such protocols by November 1, 2020, and to convene a workgroup to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering of additional drugs and devices for persons 18 years of age and older. The bill also clarifies that an accident and sickness insurance policy that provides reimbursement for a service that may be legally performed by a licensed pharmacist shall provide reimbursement for the initiating of treatment with and dispensing and administration of controlled substances by a pharmacist when such initiating of treatment with or dispensing or administration is in accordance with regulations of the Board of Pharmacy.

HB 1531 Drug disposal; Bd. of Pharmacy to develop public awareness of proper methods.

Chief patron: Jenkins

Summary as passed House:

Prescription drug disposal program; methods to enhance public awareness. Directs the Board of Pharmacy to enhance public awareness of proper drug disposal methods by assembling a group of stakeholders to develop strategies to increase the number of permissible drug disposal sites and options for the legal disposal of drugs, including requirements that pharmacies, or in-house pharmacies of hospitals or clinics, provide such information to customers. The bill directs the Board to report its findings and recommendations to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than November 15, 2020.

HB 1654 Schedule VI controlled substances and hypodermic syringes and needles; limited-use license.

Chief patron: Helmer

Summary as introduced:
Schedule VI controlled substances; hypodermic syringes and needles; limited-use license. Allows the Board of Pharmacy to issue a limited-use license for the purpose of dispensing

Schedule VI controlled substances and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. The bill requires such nonprofit facilities to obtain a limited-use permit from the Board and comply with regulations for such a permit.

HB 1670 Pharmaceutical processors; cannabidiol oil, permit to operate processor.

Chief patron: O'Quinn

Summary as passed House:

Board of Pharmacy; pharmaceutical processors; cannabis oil. Allows pharmaceutical processors to acquire industrial hemp grown and processed in Virginia from a registered industrial hemp dealer or processor and allows a pharmaceutical processor to process and formulate industrial hemp with cannabis plant extract into an allowable dosage.

HJ 52 Prescription drugs; SHHR to convene work group to address cost to Virginians, etc.

Chief patron: Guzman

Summary as passed House:

Secretary of Health and Human Resources; pharmaceutical distribution payment system; report. Requests the Secretary of Health and Human Resources to convene a work group to examine the pharmaceutical distribution payment system in the Commonwealth and innovative solutions to address the cost of prescription drugs to Virginians at the point of sale.

SB 270 Pharmacy; practice, regulation by Board of Pharmacy, report.

Chief patron: Bell

Summary as passed Senate:

Practice of pharmacy; regulation by Board of Pharmacy; report. Provides that compounding of drugs provided to the Department of Corrections for the purpose of carrying out an execution by lethal injection shall constitute the practice of pharmacy and be subject to the requirements of the Drug Control Act and the jurisdiction of the Board of Pharmacy. The bill provides that only outsourcing facilities may compound such drugs; currently, both pharmacies and outsourcing facilities may compound such drugs. The bill requires the Board of Pharmacy to report annually by December 1 to the Chairmen of the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions on (i) the number of pharmacies and outsourcing facilities permitted or registered by the Board that perform sterile compounding in Virginia or ship sterile compounded drugs into Virginia and (ii) the name of any pharmacies or outsourcing facilities that received disciplinary action for a violation of law or regulation related to compounding.

SB 530 Epinephrine; possession and administration by a restaurant employee.

Chief patron: Edwards

Summary as introduced:

Possession and administration of epinephrine; restaurant employee. Authorizes any employee of a licensed restaurant to possess and administer epinephrine, provided that such employee is authorized by a prescriber and trained in the administration of epinephrine. The bill also requires the Department of Health, in conjunction with the Department of Health Professions, to develop policies and guidelines for the recognition and treatment of anaphylaxis in restaurants.

SB 646 Tetrahydrocannabinol concentration; definition.

Chief patron: Surovell

Summary as passed Senate:

Tetrahydrocannabinol concentration; definition. Clarifies that certain uses of "tetrahydrocannabinol concentration" refer to delta-9-tetrahydrocannabinol. The bill contains an emergency clause.

EMERGENCY

SB 885 Performance of laboratory analysis; cannabidiol oil, THC-A oil, tetrahydrocannabinol.

Chief patron: Marsden

Summary as passed Senate:

Performance of laboratory analysis; cannabidiol oil; THC-A oil; tetrahydrocannabinol. Provides that no person employed by an analytical laboratory to retrieve, deliver, or possess cannabidiol oil, THC-A oil or industrial hemp samples from a permitted pharmaceutical processor, a licensed industrial hemp grower, or a licensed industrial hemp processor for the purpose of performing required testing shall be prosecuted for the possession or distribution of cannabidiol oil, THC-A oil, or industrial hemp, or for storing cannabidiol oil, THC-A oil, or industrial hemp for testing purposes in accordance with regulations promulgated by the Board of Pharmacy and the Board of Agriculture and Consumer Services.

EMERGENCY

SB 976 Pharmaceutical processors; operation of cannabis dispensing facilities.

Chief patron: Marsden

Summary as passed Senate:

Board of Pharmacy; pharmaceutical processors; cannabis dispensing facilities. Defines "cannabis dispensing facilities" and allows the Board of Pharmacy to issue up to five permits for cannabis dispensing facilities per health service area. The bill requires the Board to establish a ratio of one pharmacist for every six pharmacy interns, technicians, and technician trainees for pharmaceutical processors and cannabis dispensing facilities. The bill directs the Board of Pharmacy to require that, after processing and before dispensing cannabidiol oil and THC-A oil, a pharmaceutical processor make a sample available from each homogenized batch of product for testing at an independent laboratory located in Virginia that meets board requirements. The bill requires that the Board promulgate regulations that include an allowance for the sale of devices for administration of dispensed products and an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification. The bill also requires the Board to adopt regulations for pharmaceutical processors that include requirements for (i) processes for safely and securely cultivating cannabis plants intended for producing cannabidiol oil or THC-A oil; (ii) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (iii) the secure disposal of plant remains; (iv) dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; and (v) a process for registering cannabidiol oil and THC-A oil products. The bill requires the Board of Pharmacy to promulgate required regulations with 280 days.

SB 1045 Cannabidiol oil and THC-A oil; sample testing.

Chief patron: Hashmi

Summary as passed Senate:

Cannabidiol oil and THC-A oil; sample testing. Directs the Board of Pharmacy to require that, after processing and before dispensing cannabidiol oil and THC-A oil, a pharmaceutical processor make a homogenized batch of product for testing at an independent laboratory located in Virginia.

Post Session Studies/Reports

1. Request from Joint Commission – Workgroup on expansion of statewide standing orders for drugs that may be dispensed without prescription
2. Request from Joint Commission – Information with renewal on availability of naloxone
3. HB1531 – Stakeholder group to develop strategies to increase drug disposal sites
4. HB1304/SB830 – Stakeholder group to develop recommendations related to duties of pharmacy techs
5. HB1304/SB830 – Adoption of emergency regulations for pharmacy technician training programs/registration
6. HB1654/SB1074 – Adoption of emergency regulations for issuance of limited-use permit for dispensing of certain CVI drugs and devices
7. SB976 – Adoption of emergency regulations for 5 dispensing facilities, etc.
8. HB1460 and HB1670 – Adoption of exempt regulations for conformity (pharmaceutical processors)
9. HB1506 – Adoption of emergency regulations; protocol for pharmacists initiating treatment by November 1; convening workgroup to recommend protocols for other conditions with report to Gov. and GA by November 1.
10. Code Commission – rewrite of 54.1-3408
11. SB270 - Annual report to House and Senate on outsourcing facilities that have a contract with Corrections to compound drugs for lethal injections

Joint Commission on Health Care

Senator George L. Barker, Interim Chair

February 10, 2020

David E. Brown, D.C., Director
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Dear Director Brown:

On behalf of the Joint Commission on Health Care, I respectfully request that the Board of Pharmacy and the Board of Medicine convene a work group of expert stakeholders to develop recommendations regarding the expansion of statewide standing orders to include additional conditions for which CLIA Waiver tests exist and drugs, (e.g., antiviral drugs, hormonal birth control and smoking cessation drugs) that may be dispensed by a licensed pharmacist without a practitioner prescription. Recommendations should include whether, and if so what, additional training is required in order for a licensed pharmacist to dispense any new drug added to a statewide standing order and whether, and if so what, other requirements may be needed to ensure that new dispensing authorities will pose no risk to individual or public health.

The work group should include members from the Virginia Boards of Pharmacy and Medicine and may include other expert stakeholders, such as representatives from the Virginia Department of Health, the Virginia Department of Medical Assistance Services and the Office of the Secretary of Health and Human Resources. The work group shall provide recommendations to the Joint Commission on Health Care by October 1, 2020 and may reconvene periodically thereafter to address any additions and/or changes to statewide standing orders. Recommendations from additional meetings shall be provided to the Commission as they are determined.

Thank you for your consideration of this request. Michele Chesser and Paula Margolis are happy to discuss any questions or concerns you or your staff may have. They may be reached at mchesser@jchc.virginia.gov, pmargolis@jchc.virginia.gov, and 804-786-5445.

Sincerely,

George L. Barker

Michele L. Chesser, Ph.D., Executive Director
Joint Commission on Health Care
P.O. Box 1322 / Richmond, Virginia 23218 / 804-786-5445

Joint Commission on Health Care

Senator George L. Barker, Interim Chair

February 10, 2020

David E. Brown, D.C., Dircctor
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Dear Director Brown:

On behalf of the Joint Commission on Health Care, I respectfully request that the Board of Pharmacy include in its next pharmacy profession license renewal communication information about Virginia laws and regulations making naloxone available without a patient-specific prescription.

During the 2019 study "Naloxone Public Access and Storage," JCHC staff documented that some pharmacies still provide members of the public incorrect information on Virginia laws and regulations regarding the dispensing of naloxone. Specifically, in a statewide survey based on a representative sample of over 300 community retail pharmacies, almost one-quarter of respondents (23%) did not accurately indicate that a patient-specific prescription is *not* a requirement for an individual to purchase naloxone. Also significant, only 50 percent of respondents from independent pharmacies provided accurate information on obtaining naloxone without a patient-specific prescription, compared to 87 percent of chain pharmacies. In the upcoming license renewal communication, a clear statement of Virginia laws and regulations regarding pharmacy-based dispensing of naloxone would help ensure that all Board-regulated pharmacists have up-to-date and accurate information that they also can share with pharmacy staff.

Thank you for your consideration of this request. Michele Chesser and Andrew Mitchell are happy to discuss any questions or concerns you or your staff may have. They may be reached at mchesser@jchc.virginia.gov, amitchell@jchc.virginia.gov, and 804-786-5445.

Sincerely,

George L. Barker

Michele L. Chesser, Ph.D., Executive Director
Joint Commission on Health Care
P.O. Box 1322 / Richmond, Virginia 23218 / 804-786-5445

20107102D

HOUSE BILL NO. 1531

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on February 4, 2020)

(Patron Prior to Substitute—Delegate Jenkins)

A BILL to require the Board of Pharmacy to develop public awareness of proper methods of drug disposal.

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy shall determine methods to enhance public awareness of proper drug disposal methods, which may include requirements for pharmacies or hospitals or clinics with an on-site pharmacy to provide such information to customers and the public through the provision of informative pamphlets, the posting of signs in public areas of the pharmacy, and the posting of information on public-facing websites. The Board of Pharmacy shall also assemble a group of stakeholders to develop strategies to increase the number of permissible drug disposal sites and options for the legal disposal of drugs, including pharmacies and hospitals and clinics with an on-site pharmacy that are authorized collectors and other sites legally permitted for drug disposal, and the legal return of unused drugs by mail. Such stakeholders shall include the Virginia Pharmacists Association, the Virginia Association of Free Clinics, the Virginia Hospital and Healthcare Association, the Virginia Society of Health System Pharmacists, the Virginia Association of Drug Stores, and any other relevant stakeholders. Strategies developed by the Board of Pharmacy and stakeholders shall take into account the geographic proximity and availability of drug disposal sites in localities across the Commonwealth and existing resources. The Board shall report its findings and recommendations to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health no later than November 15, 2020.*

20105913D

HOUSE BILL NO. 1304

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the House Committee on Health, Welfare and Institutions
on January 28, 2020)
(Patron Prior to Substitute—Delegate Hodges)

A BILL to amend and reenact §§ 54.1-3300 and 54.1-3321 of the Code of Virginia, relating to pharmacy technicians and pharmacy technician trainees; registration.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3321 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

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

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Pharmacy technician trainee" means a person registered with the Board for the purpose of performing duties restricted to a pharmacy technician as part of a pharmacy technician training program in accordance with the provisions of subsection G of § 54.1-3321.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit ~~satisfactory evidence~~:

1. An application and fee specified in regulations of the Board;

2. Evidence that he ~~is of good moral character and~~ has ~~satisfactorily~~ *successfully* completed a training program *that is (i) an accredited training program, including an accredited training program operated through the Department of Education's Career and Technical Education program or approved by the Board, or (ii) operated through a federal agency or branch of the military;* and

3. Evidence that he has successfully passed a national certification examination ~~that meet the criteria approved by the Board in regulation or that he holds current certification from~~ *administered by* the Pharmacy Technician Certification Board *or the National Healthcareer Association.*

C. ~~A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.~~

~~D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.~~

~~E.~~ The Board shall promulgate regulations establishing requirements for ~~evidence~~:

1. Issuance of a registration as a pharmacy technician to a person who, prior to the effective date of such regulations, (i) successfully completed or was enrolled in a Board-approved pharmacy technician training program or (ii) passed a national certification examination required by the Board but did not complete a Board-approved pharmacy technician training program;

2. Issuance of a registration as a pharmacy technician to a person who (i) has previously practiced as a pharmacy technician in another U.S. jurisdiction and (ii) has passed a national certification examination required by the Board; and

3. Evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

~~F.~~ *D.* The Board shall waive the initial registration fee ~~and the first examination fee for the Board-approved examination~~ for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. ~~If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination.~~ A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

E. Any person registered as a pharmacy technician prior to the effective date of regulations implementing the provisions of this section shall not be required to comply with the requirements of subsection B in order to maintain or renew registration as a pharmacy technician.

F. A pharmacy technician trainee enrolled in a training program for pharmacy technicians described in subdivision B 2 may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for completion of the training program, so long as such activities are directly monitored by a supervising pharmacist.

G. To be registered as a pharmacy technician trainee, a person shall submit an application and a fee specified in regulations of the Board. Such registration shall only be valid while the person is enrolled in a pharmacy technician training program described in subsection B and actively progressing toward completion of such program. A registration card issued pursuant to this section shall be invalid and shall be returned to the Board if such person fails to enroll in a pharmacy technician training program described in subsection B.

H. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A

when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

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. However, the provisions of subsection B 2 of § 54.1-3321 of the Code of Virginia, as amended by this act, requiring accreditation of a pharmacy technician training program shall become effective July 1, 2022.

3. The Board of Pharmacy shall convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform. The workgroup shall report its recommendations to the Secretary of Health and Human Resources and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2021.

2020 SESSION

INTRODUCED

20105315D

HOUSE BILL NO. 1654

Offered January 17, 2020

A BILL to amend and reenact §§ 54.1-3304.1 and 54.1-3467 of the Code of Virginia, relating to Schedule VI controlled substances; hypodermic syringes and needles; limited-use license.

Patrons—Helmer, Ayala, Subramanyam, Sullivan, Tran and Willett

Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3304.1 and 54.1-3467 of the Code of Virginia are amended and reenacted as follows:

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

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

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

C. The Board of Pharmacy may issue a limited-use license for the purpose of dispensing Schedule VI controlled substances and hypodermic syringes and needles for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.

excluding the combination of misoprostol + methotrexate,

§ 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. *Nothing in this section shall prohibit the dispensing of hypodermic needles and syringes for the administration of prescribed drugs by prescribers licensed to dispense Schedule VI controlled substances at a nonprofit facility pursuant to § 54.1-3304.1.*

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.

INTRODUCED

HB1654

2/12/20 10:31

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20107275D

SENATE BILL NO. 976

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on February 6, 2020)
(Patron Prior to Substitute—Senator Marsden)

A BILL to amend and reenact §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia, relating to pharmaceutical processors; cannabis dispensing facilities.

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3408.3 and 54.1-3442.5 through 54.1-3442.8 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil for treatment.

A. As used in this section:

"Cannabidiol oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of cannabidiol per dose but not more than five percent tetrahydrocannabinol. "Cannabidiol oil" does not include industrial hemp, as defined in § 3.2-4112, that is grown, dealt, or processed in compliance with state or federal law.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine, or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing.

"Registered agent" means an individual designated by a patient who has been issued a written certification, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, designated by such patient's parent or legal guardian, and registered with the Board pursuant to subsection G.

"THC-A oil" means any formulation of processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least five milligrams of tetrahydrocannabinol acid per dose but not more than five percent tetrahydrocannabinol.

B. A practitioner in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's diagnosed condition or disease pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

F. A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.

G. A 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, may designate an individual to act as his registered agent for the purposes of receiving cannabidiol oil or THC-A oil pursuant to a valid written certification. Such designated individual shall register with the Board. The Board may set a limit on the number patients for whom any individual is authorized to act as a registered agent.

H. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, his registered agent, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a

prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

I. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House ~~and Senate Committees~~ *Committee* for Courts of Justice *and the Senate Committee on the Judiciary*, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed ~~physicians~~ *practitioners* or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor *or cannabis dispensing facility* involved in the treatment of a registered patient, or (v) a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

§ 54.1-3442.5. Definitions.

As used in this article:

"Cannabidiol oil" has the same meaning as specified in § 54.1-3408.3.

"Cannabis dispensing facility" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3442.6; (ii) is owned, at least in part, by a pharmaceutical processor; and (iii) dispenses cannabidiol oil or THC-A oil produced by a pharmaceutical processor to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient, his registered agent, or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"Registered agent" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.6. Permit to operate pharmaceutical processor *or cannabis dispensing facility*.

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 *or cannabis dispensing facility*. 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 *pharmaceutical processor and up to five cannabis dispensing facilities* 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 *and cannabis dispensing facility*.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors *and cannabis dispensing facilities*. 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, his registered agent, 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; (x) the secure disposal of plant remains; (xi) a process for registering a cannabidiol oil and THC-A oil product; (xii)~~ dosage limitations, which shall provide that each dispensed dose of cannabidiol oil or THC-A not exceed 10 milligrams of tetrahydrocannabinol; ~~and (xiii)~~ *(x)* a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors *and between a pharmaceutical processor and a cannabis dispensing facility; (xi) an allowance for the sale of devices for administration of dispensed products; and (xii) an allowance for the use and distribution of inert product samples containing no cannabinoids for patient demonstration exclusively at the pharmaceutical processor or cannabis dispensing facility, and not for further distribution or sale, without the need for a written certification. The Board shall also adopt regulations for pharmaceutical processors that include requirements for (a) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil or THC-A oil; (b) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; (c) the secure disposal of plant remains; and (d) a process for registering cannabidiol oil and THC-A oil products.*

D. The Board shall require that after processing and before dispensing cannabidiol oil and THC-A

oil, a pharmaceutical processor shall make a sample available from each homogenized batch of product for testing by an independent laboratory located in Virginia meeting Board requirements. A valid sample size for testing shall be determined by each laboratory and may vary due to sample matrix, analytical method, and laboratory-specific procedures. A minimum sample size of 0.5 percent of individual units for dispensing or distribution from each homogenized batch is required to achieve a representative sample for analysis.

E. A laboratory testing samples for a pharmaceutical processor shall obtain a controlled substances registration certificate pursuant to § 54.1-3423 and shall comply with quality standards established by the Board in regulation.

~~D.~~ *F.* Every pharmaceutical processor *or cannabis dispensing facility* shall be under the personal supervision of a licensed pharmacist on the premises of the pharmaceutical processor *or cannabis dispensing facility. A pharmacist in charge of a pharmaceutical processor may authorize certain employee access to secured areas designated for cultivation and other areas approved by the Board. No pharmacist shall be required to be on the premises during such authorized access. The pharmacist-in-charge shall ensure security measures are adequate to protect the cannabis from diversion at all times.*

~~E.~~ *G.* The Board shall require an applicant for a pharmaceutical processor *and cannabis dispensing facility* 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.~~ *H.* In addition to other employees authorized by the Board, a pharmaceutical processor may employ individuals who may have less than two years of experience (i) to perform cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the Board or who has at least two years of experience cultivating plants and (ii) to perform extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

I. A pharmaceutical processor to whom a permit has been issued by the Board may establish up to five cannabis dispensing facilities for the dispensing of cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. Each cannabis dispensing facility shall be located within the same health service area as the pharmaceutical processor.

~~G.~~ *J.* No person who has been convicted of (i) a felony under the laws of the Commonwealth or another jurisdiction or (ii) within the last five years, 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 or a substantially similar offense under the laws of another jurisdiction shall be employed by or act as an agent of a pharmaceutical processor *or cannabis dispensing facility.*

~~H.~~ *K.* Every pharmaceutical processor *and cannabis dispensing facility* shall adopt policies for pre-employment drug screening and regular, ongoing, random drug screening of employees.

L. A pharmacist at the pharmaceutical processor and the cannabis dispensing facility shall determine the number of pharmacy interns, pharmacy technicians and pharmacy technician trainees who can be safely and competently supervised at one time; however, no pharmacist shall supervise more than six persons performing the duties of a pharmacy technician at one time.

M. Any person who proposes to use an automated process or procedure during the production of cannabidiol oil or THC-A oil that is not otherwise authorized in law or regulation or at a time when a pharmacist will not be on-site may apply to the Board for approval to use such process or procedure pursuant to subsections B through E of § 54.1-3307.2.

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

A. A pharmaceutical processor *or cannabis dispensing facility* shall dispense or deliver cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident *or temporarily resides in Virginia as made evident to the Board,* has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3, (ii) such patient's registered agent, or (iii) 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 *or temporarily resides in Virginia as made evident to the Board* 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 *or cannabis dispensing facility* shall 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, registered agent, parent, or legal guardian; and shall verify current

board registration of the practitioner and the corresponding patient, registered agent, 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, registered agent, parent, or legal guardian; and the current board registration issued to the patient, registered agent, parent, or legal guardian. No pharmaceutical processor *or cannabis dispensing facility* shall dispense more than a 90-day supply for any patient during any 90-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 90-day supply to treat or alleviate the symptoms of a patient's diagnosed condition or disease.

B. A pharmaceutical processor *or cannabis dispensing facility* shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of a pharmaceutical processor permitted by the Board. A pharmaceutical processor may begin cultivation upon being issued a permit by the Board.

C. The Board shall report annually by December 1 to the Chairmen of the House ~~and Senate~~ ~~Committees~~ *Committee* for Courts of Justice *and the Senate Committee on the Judiciary* on the operation of pharmaceutical processors *and cannabis dispensing facilities* issued a permit by the Board, including the number of practitioners, patients, registered agents, 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. The concentration of tetrahydrocannabinol in any THC-A oil on site may be up to 10 percent greater than or less than the level of tetrahydrocannabinol measured for labeling. A pharmaceutical processor *and cannabis dispensing facility* shall ensure that such concentration in any THC-A onsite is within such range ~~and~~. *A pharmaceutical processor producing THC-A oil* shall establish a stability testing schedule of THC-A oil.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor *or cannabis dispensing facility* under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor *or cannabis dispensing facility* pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

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.

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HOUSE BILL NO. 1506

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Joint Conference Committee
on March 7, 2020)
(Patron Prior to Substitute—Delegate Sickles)

A BILL to amend and reenact §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3303.1, relating to pharmacists; initiating treatment with and dispensing and administering of controlled substances.

Be it enacted by the General Assembly of Virginia:

1. That §§ 38.2-3408, 54.1-3300, and 54.1-3300.1 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3303.1 as follows:

§ 38.2-3408. Policy providing for reimbursement for services that may be performed by certain practitioners other than physicians.

A. If an accident and sickness insurance policy provides reimbursement for any service that may be legally performed by a person licensed in this Commonwealth as a chiropractor, optometrist, optician, professional counselor, psychologist, clinical social worker, podiatrist, physical therapist, chiropodist, clinical nurse specialist who renders mental health services, audiologist, speech pathologist, certified nurse midwife or other nurse practitioner, marriage and family therapist, or licensed acupuncturist, reimbursement under the policy shall not be denied because the service is rendered by the licensed practitioner.

B. If an accident and sickness insurance policy provides reimbursement for a service that may be legally performed by a licensed pharmacist, reimbursement under the policy shall not be denied because the service is rendered by the licensed pharmacist, provided that (i) the service is performed for an insured for a condition under the terms of a collaborative agreement, as defined in § 54.1-3300, ~~between a pharmacist and the physician with whom the insured is undergoing a course of treatment or~~ (ii) the service is for the administration of vaccines for immunization~~. Notwithstanding the provisions of § 38.2-3407, the insurer may require the pharmacist, any pharmacy or provider that may employ such pharmacist, or the collaborating physician to enter into a written agreement with the insurer as a condition for reimbursement for such services. In addition, reimbursement to pharmacists acting under the terms of a collaborative agreement under this subsection shall not be subject to the provisions of § 38.2-3407.7~~, *or (iii) the service is provided in accordance with § 54.1-3303.1.*

C. This section shall not apply to Medicaid, or any state fund.

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

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

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include *(i)* the proper and safe storage and distribution of drugs; *(ii)* the maintenance of proper records; *(iii)* the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; ~~and~~ *(iv)* the management of patient care under the terms of a collaborative agreement as defined in this section*; and (v) the initiating of treatment with or dispensing or administering of certain drugs in accordance with the provisions of § 54.1-3303.1.*

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) unless the context requires a different meaning.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative ~~practice~~ agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes *for patients who meet the criteria set forth in the collaborative agreement*. However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

~~No patient shall be required to participate in a collaborative procedure without such patient's consent.~~

B. A patient who *meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who* chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

C. Collaborative agreements may include the implementation, modification, continuation, or discontinuation of drug therapy pursuant to written or electronic protocols, provided implementation of drug therapy occurs following diagnosis by the prescriber; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

D. Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

§ 54.1-3303.1. Initiating of treatment with and dispensing and administering of controlled substances by pharmacists.

A. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older in accordance with a statewide protocol developed by the Board in collaboration with the Board of Medicine and the Department of Health and set forth in regulations of the Board:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and

6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

B. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

2. That the Board of Pharmacy, in collaboration with the Board of Medicine and the Department of Health, shall establish protocols for the initiating of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as created by this act, by November 1, 2020, and shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the Health Insurance Portability and Accountability Act, 42 U.S.C. § 1320d et seq.

3. That the Board of Pharmacy (the Board) shall establish a work group consisting of representatives of the Board of Medicine, the Department of Health, schools of medicine and pharmacy located in the Commonwealth, and such other stakeholders as the Board may deem appropriate to provide recommendations regarding the development of protocols for the initiating of treatment with and dispensing and administering by pharmacists to persons 18 years of age or older of drugs and devices, including (i) vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention; (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy; (iii) tuberculin purified protein derivative for tuberculosis testing; (iv) controlled substances or devices for the treatment of diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, Helicobacter pylori bacteria, urinary tract infection, and group A Streptococcus bacteria; (v) controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention; and (vi) drugs other than controlled substances, including drugs sold over the counter, for which the patient's health insurance provider requires a prescription. The work group shall report its findings and recommendations to the Governor and the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2020.

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SENATE BILL NO. 270

AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on January 30, 2020)
(Patron Prior to Substitute—Senator Bell)

A BILL to amend and reenact §§ 53.1-234 and 54.1-3307 of the Code of Virginia, relating to practice of pharmacy; compounding; regulation by Board of Pharmacy.

Be it enacted by the General Assembly of Virginia:

1. That §§ 53.1-234 and 54.1-3307 of the Code of Virginia are amended and reenacted as follows:

§ 53.1-234. Transfer of prisoner; how death sentence executed; who to be present.

The clerk of the circuit court in which is pronounced the sentence of death against any person shall, after such judgment becomes final in the circuit court, deliver a certified copy thereof to the Director. Such person so sentenced to death shall be confined prior to the execution of the sentence in a state correctional facility designated by the Director. Prior to the time fixed in the judgment of the court for the execution of the sentence, the Director shall cause the condemned prisoner to be conveyed to the state correctional facility housing the death chamber.

The Director, or the assistants appointed by him, shall at the time named in the sentence, unless a suspension of execution is ordered, cause the prisoner under sentence of death to be electrocuted or injected with a lethal substance, until he is dead. The method of execution shall be chosen by the prisoner. In the event the prisoner refuses to make a choice at least 15 days prior to the scheduled execution, the method of execution shall be by lethal injection. Execution by lethal injection shall be permitted in accordance with procedures developed by the Department. At the execution, there shall be present the Director or an assistant, a physician employed by the Department or his assistant, such other employees of the Department as may be required by the Director, and, in addition thereto, at least six citizens who shall not be employees of the Department. In addition, the counsel for the prisoner and a clergyman may be present.

The Director may make and enter into contracts with a ~~pharmacy, as defined in § 54.1-3300, or~~ *an* outsourcing facility, as defined in § 54.1-3401, for the compounding of drugs necessary to carry out an execution by lethal injection. Any such drugs provided to the Department pursuant to the terms of such a contract shall be used only for the purpose of carrying out an execution by lethal injection. ~~The compounding of such drugs pursuant to the terms of such a contract (i) shall not constitute the practice of pharmacy as defined in § 54.1-3300; (ii) is not subject to the jurisdiction of the Board of Pharmacy, the Board of Medicine, or the Department of Health Professions; and (iii) is exempt from the provisions of Chapter 33 (§ 54.1-3300 et seq.) of Title 54.1 and the Drug Control Act (§ 54.1-3400 et seq.).~~ The contract shall label each such drug with the drug name, its quantity, a projected expiration date for the drug, and a statement that the drug shall be used only by the Department for the purpose of carrying out an execution by lethal injection.

The ~~identities~~ *identity* of any ~~pharmacy or~~ outsourcing facility that enters into a contract with the Department for the compounding of drugs necessary to carry out an execution by lethal injection, any officer or employee of such ~~pharmacy or~~ outsourcing facility, and any person or entity used by such ~~pharmacy or~~ outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs ~~and any information reasonably calculated to lead to the identities of such persons or entities, including their names,~~ *shall not be confidential, shall be subject to the Virginia Freedom of Information Act (§ 2.2-3700 et seq.), and may be subject to discovery or introduction as evidence in any civil proceeding. However, the* residential and office addresses, residential and office telephone numbers, social security numbers, and tax identification numbers~~;~~ *of officers and employees of the outsourcing facility and any person or entity used by the outsourcing facility to obtain equipment or substances to facilitate the compounding of such drugs* shall be confidential~~; shall be~~ *and* exempt from the *Virginia* Freedom of Information Act (§ 2.2-3700 et seq.)~~; and shall not be subject to discovery or introduction as evidence in any civil proceeding unless good cause is shown~~.

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

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

The Board's regulations shall include criteria for:

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

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

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

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

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

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

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

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

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

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

C. The Board shall report annually by December 1 to the Chairmen of the Senate Committee on Education and Health and the House Committee on Health, Welfare and Institutions on (i) the number ~~of pharmacies and~~ outsourcing facilities permitted or registered by the Board that ~~compounding in Virginia or ship sterile compounded drugs into Virginia~~ and ~~perform sterile pharmacies or~~ (ii) the name of any such outsourcing facilities that received disciplinary action for a violation of law or regulation related to compounding.

have a contract with DOC

Chart of Regulatory Action

Board of Pharmacy

May 11, 2020

Board	Board of Pharmacy	
Chapter		**Action / Stage Information**
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] NOIRA - *At Secretary's Office for 80 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Proposed - *Register Date: 11/11/19* *Board to adopt final regs, May 18, 2020*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] Proposed - *Register Date: 2/3/20* *Board to adopt final regs, May 11, 2020*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 719 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Final - *At Secretary's Office for 201 days*
[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Proposed - *Register Date: 10/14/19* *Board to adopt final regs, May 11, 2020*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Emergency/NOIRA - *Register Date: 1/6/20* *Board to adopt final regs, May 11, 2020*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452] Emergency/NOIRA - *At Secretary's Office for 122 days*

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 in Schedule I

Amendments 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 in sections 322

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 24, 2020** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to March 13, 2020 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified eleven (11) compounds for recommended inclusion into the Code of Virginia. I have provided a brief description, chemical name, and common name for each compound.

The following compounds are classified as 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-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl)**, 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. **1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237)**, its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

3. **N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-3.4-DMA)**, 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-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-3.4-DMA)**, 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. **2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone)**, 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. **1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone)**, 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. **2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone)**, 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 classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

8. **Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201)**, 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.

9. **Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA)**, 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.

10. **Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA)**, 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.

11. **1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA)**, 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.

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. Synthetic opioid: N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-benzamide (other names: Phenyl fentanyl, Benzoyl 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. Research chemicals:

a. 4-acetyloxy-N,N-diallyltryptamine (other name: 4-AcO-DALT), 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. 4-chloro-N,N-dimethylcathinone, 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-hydroxy-N,N-methylisopropyltryptamine (other name: 4-hydroxy-MiPT), its optical, position, and geometric isomers, salts, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

d. 3,4-Methylenedioxy-alpha-pyrrolidinohexanophenone (other name: MDPHP), 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. Cannabimimetic agent: Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3,3-dimethylbutanoate (other name: 5-Fluoro-MDMB-PICA), 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 October 2, 2020, 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. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-isopropyl-benzamide (other name: Isopropyl U-47700), 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. Alpha-pyrrolidinoisohexiophenone (other name: alpha-PiHP), 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. 1-[1-(3-hydroxyphenyl)cyclohexyl]piperidine (other name: 3-hydroxy PCP), 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 placement of drugs listed in this subsection shall remain in effect until December 25, 2020, 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. Synthetic opioids.

a. N-[2-(dimethylamino)cyclohexyl]-N-phenylfuran-2-carboxamide (other name: Furanyl UF-17), 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-(dimethylamino)cyclohexyl]-N-phenylpropionamide (other name: UF-17), 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. Research chemicals.

a. 5-methoxy-N,N-dibutyltryptamine (other name: 5-methoxy-DBT), 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. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-butanone (other name: Eutylone, bk-EBDB), 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. 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone (other name: N-butylpentylone), 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. N-benzyl-3,4-dimethoxyamphetamine (other name: N-benzyl-3,4-DMA), 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.

e. 3,4-methylenedioxy-N-benzylcathinone (other name: BMDP), 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. Cannabimimetic agents.

a. Ethyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other name: EMB-FUBINACA), 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.

b. Methyl 2-[1-4-fluorobutyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: 4-fluoro-MDMB-BUTINACA), 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 10, 2021, 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. Synthetic opioids.

a. N-phenyl-N-[1-(2-phenylmethyl)-4-piperidinyl]-2-furancarboxamide (other name: N-benzyl Furanyl norfentanyl), 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. 1-[2-methyl-4-(3-phenyl-2-propen-1-yl)-1-piperazinyl]-1-butanone (other name: 2-methyl AP-237), 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. Research chemicals.

a. N-hexyl-3,4-dimethoxyamphetamine (other names: N-hexyl-3.4-DMA), 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. N-heptyl-3,4-dimethoxyamphetamine (other names: N-heptyl-3.4-DMA), 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. 2-(isobutylamino)-1-phenylhexan-1-one (other names: N-Isobutyl Hexedrone, α-isobutylaminohexanphenone), 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. 1-(benzo[d][1,3]dioxol-5-yl)-2-(sec-butylamino)pentan-1-one (other name: N-sec-butyl Pentylone), 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.

e. 2-fluoro-Deschloroketamine (other name: 2-(2-fluorophenyl)-2-(methylamino)-cyclohexanone), 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. Cannabimimetic agents.

a. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-methylbutanoate (other name: MMB 2201), 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.

b. Methyl 2-[1-(4-penten-1-yl)-1H-indole-3-carboxamido]-3-methylbutanoate (other names: MMB022, MMB-4en-PICA), 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.

c. Methyl 2-[1-(5-fluoropentyl)-1H-indole-3-carboxamido]-3-phenylpropanoate (other name: 5-fluoro-MPP-PICA), 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.

d. 1-(5-fluoropentyl)-N-(1-methyl-1-phenylethyl)-1H-indole-3-carboxamide (other name: 5-fluoro CUMYL-PICA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

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

Statutory Authority

§§ 54.1-2400 and 54.1-3443 of the Code of Virginia.

Historical Notes

Derived from Virginia Register Volume 31, Issue 10, eff. February 11, 2015; amended, Virginia Register Volume 31, Issue 23, eff. August 12, 2015; Volume 32, Issue 5, eff. December 2, 2015; Volume 32, Issue 19, eff. June 15, 2016; Volume 32, Issue 25, eff. September 7, 2016; Volume 33, Issue 4, eff. November 16, 2016; Volume 33, Issue 11, eff. February 22, 2017; Volume 33, Issue 19, eff. June 14, 2017; Volume 34, Issue 1, eff. October 4, 2017; Volume 34, Issue 6, eff. December 13, 2017; Volume 34, Issue 11, eff. February 21, 2018; Volume 34, Issue 19, eff. June 13, 2018; Volume 34, Issue 25, eff. September 5, 2018; Volume 35, Issue 5, eff. November 28, 2018; Errata, 35:7, VA.R. 1060 November 26, 2018; Errata, 35:11, VA.R. 1394-1395 January 21, 2019; amended, Virginia Register Volume 35, Issue 14, eff. April 3, 2019; Volume 35, Issue 20, eff. June 26, 2019; Volume 36, Issue 6, eff. December 11, 2019.

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

Scheduling changes for consistency with DEA - Exempt action

Included in agenda package:

Copy of Notice of Public Hearing on rescheduling

Amendments to regulation: 18VAC110-20-323

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 A 13.

Board action:

Adoption of final regulation in sections 323

Notice of Public Hearing
Scheduling to Conform to Federal Actions

Pursuant to subsection E of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider amendments regulations for consistency with recent scheduling actions by the Drug Enforcement Administration. The public hearing will be conducted at **9:10 a.m. on March 24, 2020** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233.

Changes to be considered for inclusion in the Drug Control Act are:

- Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I;
- Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV;
- Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II;
- Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V;
- Adds brexanolone (3α-hydroxy-5α-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV;
- Deletes naloxegol and 6β-naltrexol from Schedule II;
- Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);
- Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I; and
- Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I.

Subsection E of § 54.1-3443 of the Code of Virginia:

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 30 days from publication in the Federal Register of a final or interim final order or rule designating a substance as a controlled substance or rescheduling or descheduling a substance by amending its regulations in

accordance with the requirements of Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. The Board shall include a list of all substances it intends to schedule by regulation in such notice.

Excerpts from Federal Register

[Federal Register Volume 85, Number 21 (Friday, January 31, 2020)]
[Rules and Regulations]
[Pages 5557-5562]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2020-01957]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-558]

Schedules of Controlled Substances: Placement of Lasmiditan in Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Interim final rule with request for comments.

SUMMARY: On October 11, 2019, the U.S. Food and Drug Administration approved a new drug application for Reyvow (lasmiditan) tablets for oral use. Lasmiditan is chemically known as [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide]. Thereafter, the Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place lasmiditan in schedule V of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing lasmiditan, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule V of the CSA.

DATES: The effective date of this rulemaking is January 31, 2020. Interested persons may file written comments on this rulemaking in accordance with **21 U.S.C. 811**(j)(3) and **21 CFR 1308.43**(g). Electronic comments must be submitted, and written comments must be postmarked, on or before March 2, 2020. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period.

Background and Legal Authority

Lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4- carbonyl)pyridine-2-yl-benzamide] is a new molecular entity with central nervous system (CNS) depressant properties. Lasmiditan is a 5-hydroxytryptamine (5-HT, serotonin) 1F receptor agonist. One of its metabolites has low GABAA channel positive allosteric activity. On October 11, 2018, Eli Lilly and Company (Sponsor) submitted an NDA to FDA for Reyvow (lasmiditan) 50 and 100 mg oral tablets. On November 4, 2019, DEA received notification that FDA, on October 11, 2019, approved the NDA for Reyvow (lasmiditan), under section 505(c) of the FDCA, for the acute treatment of migraine with or without aura in adults.\2\

[Federal Register Volume 85, Number 16 (Friday, January 24, 2020)]
[Rules and Regulations]
[Pages 4211-4215]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2020-00665]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-446]

Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA.

DATES: Effective: January 24, 2020.

[Federal Register Volume 85, Number 16 (Friday, January 24, 2020)]
[Rules and Regulations]
[Pages 4215-4217]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2020-00664]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-492]

Schedules of Controlled Substances: Removal of 6β-Naltrexol From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Acting Administrator of the Drug Enforcement Administration removes (5α,6β)-17-(cyclopropylmethyl)-4,5-epoxymorphinan-3,6,14-triol (6β-naltrexol) and its salts from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, 6β-naltrexol was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle 6β-naltrexol.

DATES: Effective Date: January 24, 2020.

Background

6β-Naltrexol is the major metabolite of naltrexone. Naltrexone and 6β-naltrexol are reversible opioid receptor antagonists. Opioid receptor antagonists are commonly used in the treatment of opioid addiction and overdose. On December 24, 1974, naloxone, an opioid receptor antagonist that works similarly to naltrexone, was removed from all schedules for control under the CSA. Effective on March 6, 1975, title 21 of the Code of Federal Regulations was amended to remove naltrexone from all schedules for control under the CSA. The Administrator of the DEA found that both naltrexone and naloxone and their salts have an accepted medical use for treatment in the United States and that they do not have a potential for abuse to justify continued control in any schedule under the CSA. In June 2003 and April 2008, the DEA received two separate citizen petitions to initiate proceedings to amend **21 CFR 1308.12**(b)(1) to decontrol 6β-naltrexol from schedule II of the CSA. These petitions complied with the requirements of **21 CFR 1308.44**(b) and were accepted for filing. Both petitioners argue that 6β-naltrexol has been characterized as an opioid receptor antagonist, a class of drugs with no abuse potential.

[Federal Register Volume 80, Number 15 (Friday, January 23, 2015)]
[Rules and Regulations]
[Pages 3468-3470]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2015-01172]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-400]

Schedules of Controlled Substances: Removal of Naloxegol From Control

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Administrator of the Drug Enforcement Administration removes naloxegol ((5[alpha],6[alpha])- 17-allyl-6-((20 hydroxy-3,6,9,12,15,18-hexaoxaicos-1-yl)oxy) 4,5- epoxymorphinon-3,14-diol) and its salts from the schedules of the Controlled Substances Act (CSA). This scheduling action is pursuant to the CSA which requires that such actions be made on the record after opportunity for a hearing through formal rulemaking. Prior to the effective date of this rule, naloxegol was a schedule II controlled substance because it can be derived from opium alkaloids. This action removes the regulatory controls and administrative, civil, and criminal sanctions applicable to controlled substances, including those specific to schedule II controlled substances, on persons who handle (manufacture, distribute, reverse distribute, dispense, conduct research, import, export, or conduct chemical analysis) or propose to handle naloxegol.

DATES: Effective Date: January 23, 2015.

Background

Naloxegol, or PEG-naloxol, is a new molecular entity and is a polyethylene glycolyated (PEGylated) derivative of naloxone. Its chemical names are (5[alpha],6[alpha])-17-allyl-6-((20-hydroxy- 3,6,9,12,15,18-hexaoxaicos-1-yl)oxy)-4,5-epoxymorphinon-3,14-diol or alpha-6mPEG7-O-naloxol. Naloxegol is an antagonist predominantly of peripheral mu opioid receptors. The Food and Drug Administration (FDA) approved naloxegol for marketing on September 16, 2014, under the brand name MovantikTM.\2\ It is indicated for the treatment of opioid-induced constipation (OIC) in adults with chronic non-cancer pain. Gastrointestinal adverse events (AEs) effects are commonly experienced by chronic users of opioid analgesics. Opioids delay gastric emptying and intestinal transport, which over time leads to debilitating constipation. OIC is caused by activation of the mu opioid receptor in the GI tract.

[Federal Register Volume 85, Number 16 (Friday, January 24, 2020)]
[Rules and Regulations]
[Pages 4217-4219]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2020-00669]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-503]

Schedules of Controlled Substances: Placement of Brexanolone in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts without change an interim final rule with request for comments published in the Federal Register on June 17, 2019. That interim final rule placed the substance brexanolone (3[alpha]-hydroxy-5[alpha]-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains brexanolone in schedule IV of the Controlled Substances Act.

DATES: Effective January 24, 2020.

[Federal Register Volume 85, Number 4 (Tuesday, January 7, 2020)]
[Rules and Regulations]
[Pages 643-645]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2019-27955]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-504]

Schedules of Controlled Substances: Placement of Solriamfetol in Schedule IV

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: This final rule adopts, without change, an interim final rule with request for comments published in the Federal Register on June 17, 2019, placing solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the Controlled Substances Act. With the issuance of this final rule, the Drug Enforcement Administration maintains solriamfetol, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV of the CSA.

DATES: The effective date of this final rulemaking is January 7, 2020.

FOR FURTHER INFORMATION CONTACT: Scott A. Brinks, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598-6812.

SUPPLEMENTARY INFORMATION:

Background and Legal Authority

Solriamfetol (2-amino-3-phenylpropyl carbamate) is a new molecular entity with central nervous system (CNS) stimulant properties. Solriamfetol primarily acts as a dopamine and norepinephrine reuptake inhibitor and does not bind to any other receptors that are typically associated with abuse, such as opioid or cannabinoid receptors, GABAergic, and other ion channels. On December 20, 2017, Jazz Pharmaceuticals, Inc. (Sponsor) submitted a new drug application (NDA) to the Food and Drug Administration (FDA) for SUNOSI (solriamfetol) 75 and 150 mg oral tablets. On March 19, 2019, DEA received from HHS a scientific and medical evaluation document (dated March 8, 2019) prepared by the FDA related to solriamfetol. Pursuant to **21 U.S.C. 811**(b), this document contained an eight-factor analysis of the abuse potential of solriamfetol, along with HHS' recommendation to control solriamfetol under schedule IV of the CSA. Subsequently, on March 20, 2019, the DEA received notification that the FDA, on that same date, approved the NDA for SUNOSI (solriamfetol), under section 505(c) of the FDCA, to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea (OSA).

[Federal Register Volume 84, Number 159 (Friday, August 16, 2019)]
[Rules and Regulations]
[Pages 41913-41914]

From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2019-17623]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-332]

Listing of Noroxymorphone in the Code of Federal Regulations and Assignment of a Controlled Substances Code Number

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: Noroxymorphone is a derivative of opium and opiates and, as such, is a schedule II controlled substance. The Drug Enforcement Administration (DEA) has established the use of the Drug Enforcement Administration Code Number 9668 for tracking noroxymorphone and for establishing aggregate production quotas. This rule amends the Code of Federal Regulations (CFR) to reflect the current practice of using the Code Number 9668 for noroxymorphone. This rulemaking will list the schedule II controlled substance noroxymorphone as a basic class with the Code Number 9668. This rule does not affect the control of noroxymorphone as a schedule II controlled substance.

DATES: Effective: August 16, 2019.

SUPPLEMENTARY INFORMATION: Noroxymorphone is a schedule II controlled substance defined in the Controlled Substances Act (CSA) by **21 U.S.C. 812**(c), Schedule II (a)(1) and **21 CFR 1308.12**(b)(1), which control "opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate." It meets the statutory definition of a "narcotic drug" as stated in **21 U.S.C. 802**(17) as it can be obtained from the chemical modification of substances extracted from vegetable origin, specifically from the plant species Papaver somniferum L. that is lawfully defined as "opium poppy" by 21 U.S.C. 802(19). It is not an isoquinoline alkaloid, which is categorically excluded from the statutory definition of a "narcotic drug." 21 U.S.C. 802(17)(A). Rather, noroxymorphone is a phenanthrene alkaloid with a similar chemical structure to other opium and opiate phenanthrene alkaloids listed in 21 CFR 1308.12(b)(1), such as hydrocodone, hydromorphone, dihydroetorphine, ethylmorphine, etorphine hydrochloride, metopon, thebaine, morphine, codeine, oxycodone, and oxymorphone. Noroxymorphone meets the statutory definition of "opiate" as it can be readily converted to other morphine-like substances including oxymorphone, which has an addiction-forming or addiction-sustaining abuse liability similar to morphine. Based on the similarity of the chemical structure of noroxymorphone to opium alkaloids listed in 21 CFR 1308.12(b)(1), and the fact that it is obtained by the chemical modification of these listed opium alkaloids, noroxymorphone is a derivative of opium and opiates and a schedule II controlled substance as defined by 21 U.S.C. 812(a)(1) Schedule II and 21 CFR 1308.12(b)(1).

As provided in **21 CFR 1308.03**, each controlled substance or basic class thereof is assigned a four digit Drug Enforcement Administration Controlled Substances Code Number that is used to track quantities of the controlled substance imported and exported to and from the United States. Additionally, DEA uses these Code Numbers in establishing aggregate production quotas for basic classes of controlled substances listed in schedules I and II as required by **21 U.S.C. 826**.

Since 1996, DEA has established an aggregate production quota for noroxymorphone using the DEA Controlled Substances Code Number 9668. In this final rule, DEA is amending the CFR to reflect the current practice of using the DEA Controlled Substances Code Number 9668 for noroxymorphone. Listing noroxymorphone and its DEA Controlled Substances Code Number in **21 CFR 1308.12**(b)(1) does not alter

the status of noroxymorphone as a Schedule II controlled substance. Noroxymorphone already is included as a Schedule II controlled substance because 21 CFR 1308.12(b)(1) controls any salt, compound, derivative, or preparation of the listed substances. Accordingly, noroxymorphone has been controlled as a derivative of the listed substances and this rule will not result in adding any new substances into the schedules. Listing noroxymorphone also will not affect the aggregate production quota currently established. DEA-registered manufacturers of noroxymorphone previously granted individual quotas for such purposes may continue to apply for quota after this rule is finalized.

[Federal Register Volume 84, Number 73 (Tuesday, April 16, 2019)]
[Rules and Regulations]
[Pages 15505-15511]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2019-07460]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-491]

Schedules of Controlled Substances: Temporary Placement of 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA, and FUB-144 into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Temporary amendment; temporary scheduling order.

SUMMARY: The Acting Administrator of the Drug Enforcement Administration is issuing this temporary scheduling order to schedule the synthetic cannabinoids (SC), ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-EDMB-PINACA); methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (trivial name: 5F-MDMB-PICA); N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (trivial names: FUB-AKB48; FUB-APINACA; AKB48 N-(4-FLUOROBENZYL)); 1-(5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (trivial names: 5F-CUMYL-PINACA; SGT-25); and (1-(4-fluorobenzyl)-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone (trivial name: FUB-144), and their optical, positional, and geometric isomers, salts, and salts of isomers in

[[Page 15506]]

schedule I. This action is based on a finding by the Acting Administrator that the placement of these SCs in schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, 5F-EDMB-PINACA, 5F-MDMB-PICA, FUB-AKB48, 5F-CUMYL-PINACA or FUB-144.

DATES: This temporary scheduling order is effective April 16, 2019, until April 16, 2021. If this order is extended or made permanent, the DEA will publish a document in the Federal Register.

[Federal Register Volume 85, Number 16 (Friday, January 24, 2020)]
[Rules and Regulations]
[Pages 4211-4215]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2020-00665]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-446]

Schedules of Controlled Substances: Placement of 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA and MDMB-FUBINACA in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration places methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [5F-ADB; 5F-MDMB-PINACA]; methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate [5F-AMB]; N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide [5F-APINACA, 5F-AKB48]; N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide [ADB-FUBINACA]; methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-CHMICA, MMB-CHMINACA]; and methyl 2-(1-(4-fluorobenzyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate [MDMB-FUBINACA], including their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule I of the Controlled Substances Act. This action continues the imposition of the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle 5F-ADB, 5F-AMB, 5F-APINACA, ADB-FUBINACA, MDMB-CHMICA, and MDMB-FUBINACA.

DATES: Effective: January 24, 2020.

BOARD OF PHARMACY

DEA scheduling

18VAC110-20-323. Scheduling for conformity with federal law or rule.

Pursuant to subsection E of § 54.1-3443 of the Code of Virginia and in order to conform the Drug Control Act to recent scheduling changes enacted in federal law or rule, the board:

1. Adds MT-45 (1-cyclohexyl-4-(1,2-diphenylethyl)piperazine) to Schedule I;

2. Adds 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;

3. Deletes naldemedine from Schedule II; ~~and~~

4. Adds a drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1% (w/w) residual tetrahydrocannabinols to Schedule V;

5. Adds methyl 2-(1-(cyclohexylmethyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: MDMB-CHMICA, MMB-CHMINACA), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in Schedule I;

6. Adds solriamfetol (2-amino-3-phenylpropyl carbamate), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule IV;

7. Adds noroxymorphone, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule II;

8. Adds lasmiditan [2,4,6-trifluoro-N-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide], including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, to Schedule V;

9. Adds brexanolone (3α-hydroxy-5α-pregnan-20-one), including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, in schedule IV;

10. Deletes naloxegol and 6β-naltrexol from Schedule II;

11. Replaces 4-anilino-N-phenethyl-4-piperidine (CASRN 21409-26-7) in Schedule II with 4-anilino-N-phenethylpiperidine (ANPP);

12. Adds ethyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-EDMB-PINACA), methyl 2-(1-(5-fluoropentyl)-1H-indole-3-carboxamido)-3,3-dimethylbutanoate (other name: 5F-MDMB-PICA), and 1-5-fluoropentyl)-N-(2-phenylpropan-2-yl)-1H-indazole-3-carboxamide (other name: 5F-CUMYL-PINACA), and their optical, positional, and geometric isomers, salts, and salts of isomers to Schedule I; and

13. Adds other name 5F-APINACA to N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48) which is currently placed in Schedule I.

Agenda Item: Proposed action on Delivery of Dispensed Prescription Devices – replacement of emergency regulations

Included in your package are copies of:

Copy of the posting on the Virginia Regulatory Townhall

(No comment was received on proposed regulations)

Proposed regulations – identical to emergency regulations currently in effect

Action:

Motion to adopt the final regulations as proposed or as amended by the Board

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter

Regulations Governing Wholesale Distributors, Manufacturers and Warehousers [18 VAC 110 - 50]

Action: Delivery of Schedule VI prescription devices

Proposed Stage

Action 5084 / Stage 8584

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	9/27/2019 8:52 am	Sync Text with RIS
Agency Background Document	4/1/2019	Upload / Replace
Attorney General Certification	5/1/2019	
DPB Economic Impact Analysis	6/10/2019	
Agency Response to EIA	9/18/2019	Upload / Replace
Governor's Review Memo	9/18/2019	
Registrar Transmittal	9/18/2019	

Status	
Changes to Text	The proposed text for this stage is identical to the emergency regulation.
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 4/1/2019 Review Completed: 5/1/2019 Result: Certified
DPB Review	Submitted on 5/2/2019 Economist: Oscar Ozfidan Policy Analyst: Jeannine Rose Review Completed: 6/12/2019 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 9/10/2019
Governor's Review	Review Completed: 9/18/2019 Result: Approved
Virginia Registrar	Submitted on 9/18/2019 **The Virginia Register of Regulations** Publication Date: 10/14/2019 **Volume: 36 Issue: 4**

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Public Hearings	**12/09/2019 9:05 AM**
Comment Period	Ended 12/13/2019 0 comments

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

This person is the primary contact for this chapter.
This stage was created by Elaine J. Yeatts on 04/01/2019
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Project 5526 - Proposed

BOARD OF PHARMACY

Delivery of Schedule VI prescription devices

18VAC110-50-55. Delivery of Schedule VI devices.

A. In accordance with the provisions of subsection A of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user or consumer on behalf of a medical equipment supplier.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity named in this subsection and a medical equipment supplier in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and an individual medical equipment supplier or multiple medical equipment suppliers under shared ownership. The agreement shall be applicable to all ultimate users or consumers receiving services from the medical equipment supplier who require delivery of Schedule VI prescription devices.

3. The medical equipment supplier shall represent to the delivering entity that it has complied with the provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a valid order from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of orders of prescribers shall be the responsibility of the medical equipment supplier upon request of the board or delivering entity.

B. In accordance with the provisions of subsection B of § 54.1-3415.1 of the Code of Virginia, a manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesaler distributor, third-party logistics provider, nonresident third-party logistics provider, warehouser, or nonresident warehouser licensed, permitted, or registered in Virginia may deliver Schedule VI prescription devices directly to an ultimate user's or consumer's residence to be administered by persons

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authorized to administer such devices, provided that (i) such delivery is made on behalf of 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 and directs the delivery of such device to the ultimate user's or consumer's residence and (ii) the medical director on whose behalf such Schedule VI prescription device is being delivered has entered into an agreement with the manufacturer, nonresident manufacturer, wholesale distributor, nonresident wholesale distributor, warehouser, nonresident warehouser, third-party logistics provider, or nonresident third-party logistics provider for such delivery.

1. Such delivery shall only occur in accordance with an agreement between a delivering entity authorized in this subsection and a medical director of a home health agency, nursing home, assisted living facility, or hospice and in compliance with law and regulation.

2. The agreement shall be between an individual delivering entity or multiple delivering entities under shared ownership and the medical director of an individual home health agency, nursing home, assisted living facility, or hospice, or multiple such entities under shared ownership. The agreement shall be applicable to all ultimate users or consumers of the home health agency, nursing home, assisted living facility, or hospice who require delivery of Schedule VI prescription devices.

3. The home health agency, nursing home, assisted living facility, or hospice shall represent to the delivering entity that it has complied with provisions of § 54.1-3415.1 of the Code of Virginia regarding the existence of a request from a prescriber for the delivery of a Schedule VI prescription device to an ultimate user or consumer. Validation of the request from a prescriber shall be the responsibility of the home health agency, nursing home, assisted living facility, or hospice upon request of the board or delivering entity.

C. The agreement, as required by subdivisions A 1 and B 1 of this section, shall be in written or electronic format and shall be retained in a format available upon request to the board at all times the agreement is in effect and for two years after the date the agreement is terminated or concluded.

D. An agreement shall not contain any patient specific or patient health information that would be subject to the provisions of the Health Insurance Portability and Accountability Act of 1996, P.L. No. 104-191.

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Agenda Item: Adoption of Final Regulations for Delivery of Dispensed Prescriptions, Labeling

Included in agenda package:

- Copy of proposed regulations
- Copy of comment submitted by 4/3/2020 (one comment received)

Board Action:

Motion to adopt the final regulations as proposed or amended by the Board.

PROPOSED

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient ~~pickup~~ pick-up or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist ~~or pharmacists~~ responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

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

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. ~~The procedure~~ Procedure for assuring confidentiality of patient information; and

e. ~~The procedure~~ Procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

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VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Public Comment Forum

On this Action:
Delivery of dispensed prescriptions; labeling

Proposed Stage - View the regulatory documents

CLOSED Opened on 2/3/2020 and Ended on 4/3/2020

More about public comment forums and policies

View all comments

Comment Title	Commenter	Date
CVS Health's comments on proposed amendments 18VAC110-20-275. Delivery of dispensed prescriptions	Lauren Paul, CVS Health	3/24/20 2:39 pm

1 comments

Trouble posting comments? These pages have been tested with multiple versions of all the major browsers. If you have trouble: (1) try another computer if you have access to one, (2) try another browser if your computer has one installed (3) contact Town Hall support staff for assistance.

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VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action	Delivery of dispensed prescriptions; labeling
Stage	Proposed
Comment Period	Ends 4/3/2020

Back to List of Comments

Commenter: Lauren Paul, CVS Health

3/24/20 2:39 pm

CVS Health's comments on proposed amendments 18VAC110-20-275. Delivery of dispensed prescriptions

Dear Ms. Yeatts:

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

CVS Health appreciates the Board's acceptance of our Petition for Rule-making and proposed language to amend 18VAC 110-20-275, which changes the policy and procedure requirements for delivery to another pharmacy, allowing for a unique identifier to be used in identifying all pharmacies utilized in filling and dispensing the prescription. Amendments also include the allowance for the unique identifier to not be placed on the label if the pharmacy solely holds the prescription for further pickup and delivery without being involved in the filling and dispensing. As we have mentioned previously, the Institute for Safe Medication Practices published industry guidelines for medication labels for community and mail order pharmacies in which they suggest maximizing the use of white space on a label to improve medication adherence and reduce inadvertent medication errors.[1] The proposed language would assist in achieving maximum white space, while still providing an audit trail for the tracking of the prescription, as required, and providing the patient with one contact pharmacy (the dispensing pharmacy) to answer any questions or provide additional counseling.

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

Sincerely,

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Agenda Item: Regulations for Pharmaceutical Processors – Replacement of emergency regulations; adoption of proposed regulations

Enclosed:

Copy of emergency regulations for registered agents and wholesale distribution

Copy of notice on Townhall

Staff note:

Emergency regulations became effective 12/30/19 and must be replaced within 18 months.
There were no comments on the Notice of Intended Regulatory Action to replace the emergency regulations.
The proposed regulations are identical to the emergency regulations

Board action:

Adoption of proposed amendments to replace emergency regulations for registered agents and wholesale distribution by pharmaceutical processors

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing Pharmaceutical Processors [18 VAC 110 - 60]

Action: Registered agents and wholesale distribution

Emergency/NOIRA Stage

Action 5398 / Stage 8778

Edit Stage | Go to RIS Project | Request Emergency Extension

Documents		
Emergency Text	1/3/2020 8:23 am	Sync Text with RIS
Agency Background Document	10/2/2019 (modified 11/25/2019)	Upload / Replace
Attorney General Certification	11/13/2019	
Governor's Review Memo	12/20/2019	
Registrar Transmittal	12/20/2019	

Status	
Public Hearing	Will be held at the **proposed** stage
Emergency Authority	2.2-4011
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 10/2/2019 Review Completed: 11/13/2019 Result: Certified
DPB Review	Submitted on 11/13/2019 Policy Analyst: Melanie West Review Completed: 11/25/2019 *DPB's policy memo is "Governor's Confidential Working Papers"*
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Project 6129 - Emergency/NOIRA

BOARD OF PHARMACY

Registered agents and wholesale distribution

Part I

General Provisions

18VAC110-60-10. Definitions.

In addition to words and terms defined in §§ 54.1-3408.3 and 54.1-3442.5 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"90-day supply" means the amount of cannabidiol oil or THC-A oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

"Batch" means a quantity of cannabidiol oil or THC-A oil from a production lot that is identified by a batch number or other unique identifier.

"Board" means the Board of Pharmacy.

"Certification" means a written statement, consistent with requirements of § 54.1-3408.3 of the Code of Virginia, issued by a practitioner for the use of cannabidiol oil or THC-A oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease determined by the practitioner to benefit from such use.

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

1. Variation from the intended oil to be dispensed, including:

a. Incorrect oil;

b. Incorrect oil strength;

c. Incorrect dosage form;

d. Incorrect patient; or

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

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

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

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

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

3. Delivery of an oil to the incorrect patient.

4. An act or omission relating to the dispensing of cannabidiol oil or THC-A oil that results in, or may reasonably be expected to result in, injury to or death of a registered patient or results in any detrimental change to the medical treatment for the patient.

"Electronic tracking system" means an electronic radio-frequency identification (RFID) seed-to-sale tracking system that tracks the Cannabis from either the seed or immature plant stage until the cannabidiol oil and THC-A oil are sold to a registered patient, parent, ~~or~~ legal guardian, or registered agent or until the Cannabis, including the seeds, parts of plants, and extracts, are destroyed. The electronic tracking system shall include, at a minimum, a central inventory management system and standard and ad hoc reporting functions as required by the board and shall be capable of otherwise satisfying required recordkeeping.

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

"PIC" means the pharmacist-in-charge.

"Production" or "produce" means the manufacture, planting, preparation, cultivation, growing, harvesting, propagation, conversion, or processing of marijuana, (i) directly or indirectly by extraction from substances of natural origin, (ii) independently by means of chemical synthesis, or (iii) by a

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combination of extraction and chemical synthesis. "Production" or "produce" includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Qualifying patient" means a Virginia resident who has received from a practitioner, as defined in § 54.1-3408.3 of the Code of Virginia, a written certification for the use of cannabidiol oil or THC-A oil for treatment of or to alleviate the symptoms of any diagnosed condition or disease.

"Registered patient" means a qualifying patient who has been issued a registration by the board for the dispensing of cannabidiol oil or THC-A oil to such patient.

"Registration" means an identification card or other document issued by the board that identifies a person as a practitioner or a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

"Resident" means a person whose principal place of residence is within the Commonwealth as evidenced by a federal or state income tax return or a current Virginia driver's license. If a person is a minor, residency may be established by evidence of Virginia residency by a parent or legal guardian.

"Temperature and humidity" means temperature and humidity maintained in the following ranges:

Room or Phase	Temperature	Humidity
Mother room	65 - 75°	50% - 60%
Nursery phase	71 - 85° F	65% - 75%
Vegetation phase	71 - 85° F	55% - 65%
Flower/harvest phase	71 - 85° F	55% - 60%
Drying/extraction rooms	< 75° F	55% - 60%

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

1. Initial registration.	$50
2. Annual renewal of registration.	$50
3. Replacement of registration for a qualifying practitioner whose information has changed or whose original registration certificate has been lost, stolen, or destroyed.	$50

C. Registration by a qualifying patient, parent, ~~or~~ legal guardian, or registered agent.

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1. Initial registration of a patient.	$50
2. Annual renewal of registration of a patient.	$50
3. Initial registration of a parent or legal guardian.	$25
4. Annual renewal of registration of a parent or guardian.	$25
5. Initial registration or annual renewal of a registered agent.	$25
6. Replacement of registration for a qualifying patient, parent, ~~or~~ legal guardian, or registered agent whose original registration certificate has been lost, stolen, or destroyed.	$25

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000
4. Change of name of processor.	$100
5. Change of PIC or any other information provided on the permit application.	$100
6. Change of ownership not requiring a criminal background check.	$100
7. Change of ownership requiring a criminal background check.	$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
9. Reinspection fee.	$1,000
10. Registration of each cannabidiol oil or THC-A oil product.	$25

18VAC110-60-40. Prohibited practices for practitioners.

A. A practitioner who issues certifications shall not:

1. Directly or indirectly accept, solicit, or receive anything of value from any person associated with a pharmaceutical processor or provider of paraphernalia, excluding information on products or educational materials on the benefits and risks of cannabidiol oil or THC-A oil;

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2. Offer a discount or any other thing of value to a qualifying patient, parent, ~~or~~ guardian, or registered agent based on the patient's agreement or decision to use a particular pharmaceutical processor or cannabidiol oil or THC-A oil product;

3. Examine a qualifying patient for purposes of diagnosing the condition or disease at a location where cannabidiol oil or THC-A oil is dispensed or produced; or

4. Directly or indirectly benefit from a patient obtaining a certification. Such prohibition shall not prohibit a practitioner from charging an appropriate fee for the patient visit.

B. A practitioner who issues certifications, and such practitioner's coworker, employee, spouse, parent, or child, shall not have a direct or indirect financial interest in a pharmaceutical processor or any other entity that may benefit from a qualifying patient's acquisition, purchase, or use of cannabidiol oil or THC-A oil, including any formal or informal agreement whereby a pharmaceutical processor or other person provides compensation if the practitioner issues a certification for a qualifying patient or steers a qualifying patient to a specific pharmaceutical processor or cannabidiol oil or THC-A oil product.

C. A practitioner shall not issue a certification for himself or for family members, employees, or coworkers.

D. A practitioner shall not provide product samples containing cannabidiol oil or THC-A oil other than those approved by the U.S. Food and Drug Administration.

18VAC110-60-50. Registration of a patient, parent, ~~or~~ legal guardian, or registered agent.

A. A qualifying patient for whom a practitioner has issued a certification shall register with the board in accordance with this section. If the qualifying patient is a minor or an incapacitated adult, the qualifying patient's parent or legal guardian shall register with the board in accordance with this section. For a registration application to be considered complete, the following items shall be submitted:

1. A copy of the certification issued by a registered practitioner;

2. Proof of residency of the qualifying patient and proof of residency of a parent or legal guardian, if applicable, such as a government-issued identification card or tax receipt;

3. Proof of identity of the qualifying patient and, if the patient is a minor, proof of identity of the parent or legal guardian in the form of a government-issued identification card;

4. Proof of the qualifying patient's age in the form of a birth certificate or other government-issued identification;

5. Payment of the appropriate fees; and

6. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

B. A patient, or the patient's parent or legal guardian, may choose a registered agent to receive cannabidiol oil or THC-A oil on behalf of the patient. An individual may serve as a registered agent for no more than two registered patients. For a registration application to be approved, the following shall be submitted:

1. The name, address, birthdate, and registration number of each registered patient for whom the individual intends to act as a registered agent;

2. Proof of identity in the form of a copy of a government-issued identification card;

3. Payment of the applicable fee; and

4. Such other information as the board may require to determine the applicant's suitability for registration or to protect public health and safety.

C. A qualifying patient shall not be issued a written certification by more than one practitioner during a given time period.

~~C.~~ D. Patients, parents, ~~and~~ legal guardians, and registered agents issued a registration shall carry their registrations with them whenever they are in possession of cannabidiol oil or THC-A oil.

18VAC110-60-60. Denial of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent registration application.

A. The board may deny an application or renewal of the registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent if the applicant:

1. Does not meet the requirements set forth in law or regulation or fails to provide complete information on the application form;

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2. Does not provide acceptable proof of identity, residency, or age of the patient to the board;

3. Provides false, misleading, or incorrect information to the board;

4. Has had a qualifying registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent denied, suspended, or revoked by the board in the previous six months;

5. Has a certification issued by a practitioner who is not authorized to certify patients for cannabidiol oil or THC-A oil; or

6. Has a prior conviction of a violation of any law pertaining to controlled substances.

B. If the board denies an application or renewal of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent applicant, the board shall provide the applicant with notice of the grounds for the denial and shall inform the applicant of the right to request a hearing pursuant to § 2.2-4019 of the Code of Virginia.

18VAC110-60-70. Reporting requirements for practitioners, patients, parents, ~~or~~ legal guardians, or registered agents.

A. A practitioner shall report to the board, on a form prescribed by the board, the death of a registered patient or a change in status involving a registered patient for whom the practitioner has issued a certification if such change affects the patient's continued eligibility to use cannabidiol oil or THC-A oil or the practitioner's inability to continue treating the patient. A practitioner shall report such death, change of status, or inability to continue treatment not more than 15 days after the practitioner becomes aware of such fact.

B. A patient, parent, or legal guardian who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change. The patient, parent, or legal guardian shall report changes that include a change in name, address, contact information, medical status of the patient, or change of the certifying practitioner. The patient, parent, or legal guardian shall report such changes on a form prescribed by the board.

C. A registered agent who has been issued a registration shall notify the board of any change in the information provided to the board not later than 15 days after such change, to include a change in the identifying information of the patient for whom he is serving as a registered agent.

D. If a patient, parent, ~~or~~ legal guardian, or registered agent notifies the board of any change that results in information on the registration of the patient, parent, ~~or~~ legal ~~guardian's registration~~ guardian, or registered agent being inaccurate, the board shall issue a replacement registration. Upon receipt of a new registration, the qualifying patient, parent, ~~or~~ legal guardian, or registered agent shall destroy in a nonrecoverable manner the registration that was replaced.

~~D.~~ E. If a patient, parent, ~~or~~ legal guardian, or registered agent becomes aware of the loss, theft, or destruction of the registration of such patient, parent, ~~or~~ legal guardian, or registered agent, the ~~patient, parent, or legal guardian~~ registrant shall notify the board not later than five business days after becoming aware of the loss, theft, or destruction, and submit the fee for a replacement registration. The board shall inactivate the initial registration upon receiving such notice and issue a replacement registration upon receiving the applicable fee, provided the applicant continues to satisfy the requirements of law and regulation.

18VAC110-60-80. Proper storage and disposal of cannabidiol oil or THC-A oil by patients, parents, ~~or~~ legal guardians, or registered agents.

A. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall exercise reasonable caution to transport and store cannabidiol oil or THC-A oil in a manner to prevent theft, loss, or access by unauthorized persons.

B. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall dispose of all usable cannabidiol oil or THC-A oil in possession of the registered patient, parent, ~~or~~ legal ~~guardian's possession~~ guardian, or registered agent no later than 10 calendar days after the expiration of the patient's registration if such registration is not renewed, or sooner should the patient no longer wish to possess cannabidiol oil or THC-A oil. A registered patient, parent, ~~or~~ legal guardian, or registered agent shall complete such disposal by one of the following methods:

1. By removing the oil from the original container and mixing it with an undesirable substance such as used coffee grounds, dirt, or kitty litter. The mixture shall be placed in a sealable bag, empty can, or other container to prevent the drug from leaking or breaking out of a garbage bag.

2. By transferring it to law enforcement via a medication drop-box or drug take-back event if permissible under state and federal law.

18VAC110-60-90. Revocation or suspension of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent registration.

The board may revoke or suspend the registration of a registrant (i.e., a patient, parent, ~~or~~ legal guardian, or registered agent) under the following circumstances:

1. The patient's practitioner notifies the board that the practitioner is withdrawing the written certification submitted on behalf of the patient, and 30 days after the practitioner's withdrawal of the written certification, the patient has not obtained a valid written certification from a different practitioner;

2. The ~~patient, parent, or legal guardian~~ registrant provided false, misleading, or incorrect information to the board;

3. The ~~patient, parent, or legal guardian~~ registrant is no longer a resident of Virginia;

4. The ~~patient, parent, or legal guardian~~ registrant obtained more than a 90-day supply of cannabidiol oil or THC-A oil in a 90-day period;

5. The ~~patient, parent, or legal guardian~~ registrant provided or sold cannabidiol oil or THC-A oil to any person, including another ~~registered patient, parent, or legal guardian~~ registrant;

6. The ~~patient, parent, or legal guardian~~ registrant permitted another person to use the registration of the ~~patient, parent, or legal guardian~~ registrant, except as required for a registered agent to act on behalf of a patient;

7. The ~~patient, parent, or legal guardian~~ registrant tampered, falsified, altered, modified, or allowed another person to tamper, falsify, alter, or modify the registration of the ~~patient, parent, or legal guardian~~ registrant;

8. The registration of the ~~patient, parent, or legal guardian~~ registrant was lost, stolen, or destroyed, and the ~~patient, parent, or legal guardian~~ registrant failed to notify the board or notified the board of such incident more than five business days after becoming aware that the registration was lost, stolen, or destroyed;

9. The ~~patient, parent, or legal guardian~~ registrant failed to notify the board of a change in registration information or notified the board of such change more than ~~14~~ 15 days after the change; or

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10. The ~~patient, parent, or legal guardian~~ registrant violated any federal or state law or regulation.

18VAC110-60-130. Granting of a pharmaceutical processor permit.

A. The board may issue a pharmaceutical processor permit when all requirements of the board have been met, to include:

1. Designation of a PIC;

2. Evidence of criminal background checks for all employees and delivery agents of the processor to ensure compliance with § 54.1-3442.6 of the Code of Virginia;

3. Evidence of utilization of an electronic tracking system; and

4. A satisfactory inspection of the facility conducted by the board or ~~its~~ the board's agents.

B. The permit shall not be awarded until any deficiency identified by inspectors has been corrected and the facility has been satisfactorily reinspected if warranted.

C. Before any permit is issued, the applicant shall attest to compliance with all state and local laws and ordinances. A pharmaceutical processor permit shall not be issued to any person to operate from a private dwelling or residence.

D. If an applicant has been awarded a pharmaceutical processor permit and has not commenced operation of such facility within 180 days of being notified of the issuance of a pharmaceutical processor permit, the board may rescind such permit, unless such delay was caused by circumstances beyond the control of the permit holder.

E. A pharmaceutical processor shall be deemed to have commenced operation if Cannabis plants are under cultivation by the processor in accordance with the approved application.

F. In the event a permit is rescinded pursuant to this section, the board may award a pharmaceutical processor permit by selecting among the qualified applicants who applied for the pharmaceutical processor permit subject to rescission. If no other qualified applicant who applied for such pharmaceutical processor permit satisfied the criteria for awarding a permit, the board shall publish in accordance with this section a notice of open applications for a pharmaceutical processor permit.

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G. Once the permit is issued, ~~Cannabis may not be grown or held in the pharmaceutical processor earlier than two weeks prior to the opening date designated on the application~~ a processor may begin cultivation of Cannabis. Once Cannabis has been placed in the pharmaceutical processor, a pharmacist shall be present during hours of operation to ensure the safety, security, and integrity of the Cannabis. If there is a change in the designated opening date, the pharmaceutical processor shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

18VAC110-60-160. Grounds for action against a pharmaceutical processor permit.

In addition to the bases enumerated in § 54.1-3316 of the Code of Virginia, the board may suspend, revoke, or refuse to grant or renew a permit issued; place such permit on probation; place conditions on such permit; or take other actions permitted by statute or regulation on the following grounds:

1. Any criminal conviction under federal or state statutes or regulations or local ordinances, unless the conviction was based on a federal statute or regulation related to the possession, purchase, or sale of cannabidiol oil or THC-A oil that is authorized under state law and regulations;

2. Any civil action under any federal or state statute or regulation or local ordinance (i) relating to the applicant's, licensee's, permit holder's, or registrant's profession or (ii) involving drugs, medical devices, or fraudulent practices, including fraudulent billing practices;

3. Failure to maintain effective controls against diversion, theft, or loss of Cannabis, cannabidiol oil or THC-A oil, or other controlled substances;

4. Intentionally or through negligence obscuring, damaging, or defacing a permit or registration card;

5. Permitting another person to use the permit of a permit holder or registration of a qualifying patient, parent, ~~or~~ legal guardian, or registered agent, except as required for a registered agent to act on behalf of a patient;

6. Failure to cooperate or give information to the board on any matter arising out of conduct at a pharmaceutical processor; or

7. Discontinuance of business for more than 60 days, unless the board approves an extension of such period for good cause shown upon a written request from a pharmaceutical processor. Good cause includes exigent circumstances that necessitate the closing of the facility. Good cause shall not include a voluntary closing of the pharmaceutical processor or production facility.

Part IV

Requirements for Pharmaceutical Processor Personnel

18VAC110-60-170. Pharmaceutical processor employee licenses and registrations.

A. A pharmacist with a current, unrestricted license issued by the board practicing at the location of the address on the pharmaceutical processor application shall be in full and actual charge of a pharmaceutical processor and serve as the pharmacist-in-charge.

B. A pharmacist with a current, unrestricted license issued by the board shall provide personal supervision on the premises of the pharmaceutical processor at all times during hours of operation or whenever the processor is being accessed.

C. A person who holds a current, unrestricted registration as a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia and who has had at least two years of experience practicing as a pharmacy technician may perform the following duties under supervision of a pharmacist:

1. The entry of drug dispensing information and drug history into a data system or other recordkeeping system;

2. The preparation of labels for dispensing the oils or patient information;

3. The removal of the oil to be dispensed from inventory;

4. The measuring of the oil to be dispensed;

5. The packaging and labeling of the oil to be dispensed and the repackaging thereof;

6. The stocking or loading of devices used in the dispensing process;

7. The selling of the oil to the registered patient, parent, ~~or~~ legal guardian, or registered agent; and

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8. The performance of any other task restricted to pharmacy technicians by the board's regulations.

D. A pharmacist with a current, unrestricted license; a registered pharmacy intern who has completed the first professional year of pharmacy school; or a pharmacy technician with a current, unrestricted registration issued by the board may perform duties associated with the cultivation, extraction, and dispensing of the oils as authorized by the PIC or as otherwise authorized in law.

E. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in horticulture or has at least two years of experience cultivating plants may perform duties associated with the cultivation of Cannabis as authorized by the PIC.

F. A person who does not maintain licensure as a pharmacist or registration as a pharmacy technician but has received a degree in chemistry or pharmacology or has at least two years of experience extracting chemicals from plants may perform duties associated with the extraction of cannabidiol oil and THC-A oil as authorized by the PIC.

G. A pharmaceutical processor may employ individuals who may have less than two years of experience to perform (i) cultivation-related duties under the supervision of an individual who has received a degree in horticulture or a certification recognized by the board or who has at least two years of experience cultivating plants and (ii) extraction-related duties under the supervision of an individual who has a degree in chemistry or pharmacology or at least two years of experience extracting chemicals from plants.

H. A pharmacist on duty shall directly supervise the activities in all areas designated for cultivation, extraction, and dispensing or have a process in place, approved by the board, that provides adequate supervision to protect the security of the Cannabis, seeds, extracts, cannabidiol oil, and THC-A oil and ensure quality of the dispensed oils.

~~H.~~ I. At no time shall a pharmaceutical processor operate or be accessed without a pharmacist on duty.

~~I.~~ J. No person shall be employed by or serve as an agent of a pharmaceutical processor without being at least 18 years of age.

~~J.~~ K. No person who has had a license or registration suspended or revoked or been denied issuance of such license or registration shall serve as an employee or agent of the pharmaceutical processor unless such license or registration has been reinstated and is current and unrestricted.

18VAC110-60-190. Pharmacy technicians; ratio; supervision and responsibility.

A. The ratio of pharmacy technicians to pharmacists on duty in the areas of a pharmaceutical processor designated for production or dispensing shall not exceed four pharmacy technicians to one pharmacist.

B. The pharmacist providing direct supervision of pharmacy technicians may be held responsible for the pharmacy technicians' actions. Any violations relating to the dispensing of cannabidiol oil or THC-A oil resulting from the actions of a pharmacy technician shall constitute grounds for action against the license of the pharmacist and the registration of the pharmacy technician. As used in this subsection, "direct supervision" means a supervising pharmacist who:

1. Is on duty where the pharmacy technician is performing routine cannabidiol oil or THC-A oil production or dispensing functions; and

2. Conducts in-process and final checks on the pharmacy technician's performance.

C. Pharmacy technicians shall not:

1. Counsel a registered patient or the patient's parent ~~or~~, legal guardian, or registered agent regarding (i) cannabidiol oil, THC-A oil, or other drugs either before or after cannabidiol oil or THC-A oil has been dispensed or (ii) any medical information contained in a patient medication record;

2. Consult with the practitioner who certified the qualifying patient, or the practitioner's agent, regarding a patient or any medical information pertaining to the patient's cannabidiol oil or THC-A oil or any other drug the patient may be taking;

3. Interpret the patient's clinical data or provide medical advice;

4. Determine whether a different formulation of cannabidiol oil or THC-A oil should be substituted for the cannabidiol oil or THC-A oil product or formulation recommended by the practitioner or requested by the registered patient or parent or legal guardian; or

5. Communicate with a practitioner who certified a registered patient, or the practitioner's agent, to obtain a clarification on a qualifying patient's written certification or instructions.

18VAC110-60-200. Responsibilities of the PIC.

A. No person shall be PIC for more than one pharmaceutical processor or for one processor and a pharmacy at any one time. A processor shall employ the PIC at the pharmaceutical processor for at least 35 hours per week, except as otherwise authorized by the board.

B. The PIC or the pharmacist on duty shall control all aspects of the practice of the pharmaceutical processor. Any decision overriding such control of the PIC or other pharmacist on duty may be grounds for disciplinary action against the pharmaceutical processor permit.

C. The pharmaceutical processor PIC shall be responsible for ensuring that:

1. Pharmacy technicians are registered and all employees are properly trained;

2. All record retention requirements are met;

3. All requirements for the physical security of the Cannabis, to include the seeds, any parts or extracts of the Cannabis plants, the cannabidiol oil, and the THC-A oil are met;

4. The pharmaceutical processor has appropriate pharmaceutical reference materials to ensure that cannabidiol oil or THC-A oil can be properly dispensed;

5. The following items are conspicuously posted in the pharmaceutical processor in a location and in a manner so as to be clearly and readily identifiable to registered patients, parents, ~~or~~ legal guardians, or registered agents:

a. Pharmaceutical processor permit;

b. Licenses for all pharmacists practicing at the pharmaceutical processor; and

c. The price of all cannabidiol oil or THC-A oil products offered by the pharmaceutical processor; and

6. Any other required filings or notifications are made on behalf of the processor as set forth in regulation.

D. When the PIC ceases practice at a pharmaceutical processor or no longer wishes to be designated as PIC, he shall immediately return the pharmaceutical processor permit to the board indicating the effective date on which he ceased to be the PIC.

E. An outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Cannabis, to include plants, extracts, cannabidiol oil, or THC-A oil on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

F. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. If the PIC knows of an upcoming absence of longer than 30 days, he shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC that exceed 15 days with no known return date within the next 15 days, the permit holder shall immediately notify the board and shall obtain a new PIC.

G. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmaceutical processor to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

Part V

Operation of a Pharmaceutical Processor

18VAC110-60-210. General provisions.

A. A pharmaceutical processor shall only sell cannabidiol oil or THC-A oil ~~only~~ in a child-resistant, secure, and light-resistant container. Upon a written request from the registered patient, parent, ~~or~~ legal guardian, or registered agent, the oil may be dispensed in a non-child-resistant container so long as all labeling is maintained with the product.

B. Only a pharmacist may dispense cannabidiol oil or THC-A oil to registered patients or parents or legal guardians of patients who are minors or incapacitated adults and who are registered with the board, or to a patient's registered agent. A pharmacy technician who meets the requirements of

18VAC110-60-170 C may assist, under the direct supervision of a pharmacist, in the dispensing and selling of cannabidiol oil or THC-A oil.

C. The PIC or pharmacist on duty shall restrict access to the pharmaceutical processor to:

1. A person whose responsibilities necessitate access to the pharmaceutical processor and then for only as long as necessary to perform the person's job duties; or

2. A person who is a registered patient, parent, ~~or~~ legal guardian, or registered agent, in which case such person shall not be permitted behind the service counter or in other areas where Cannabis plants, extracts, cannabidiol oil, or THC-A oil ~~is~~ are stored.

D. All pharmacists and pharmacy technicians shall at all times while at the pharmaceutical processor have their current license or registration available for inspection by the board or the board's agent.

E. While inside the pharmaceutical processor, all pharmaceutical processor employees shall wear name tags or similar forms of identification that clearly identify them, including their position at the pharmaceutical processor.

F. A pharmaceutical processor shall be open for registered patients, parents, ~~or~~ legal guardians, or registered agents to purchase cannabidiol oil or THC-A oil products for a minimum of 35 hours a week, except as otherwise authorized by the board.

G. A pharmaceutical processor that closes during its normal hours of operation shall implement procedures to notify registered patients, parents, ~~and~~ legal guardians, and registered agents of when the pharmaceutical processor will resume normal hours of operation. Such procedures may include telephone system messages and conspicuously posted signs. If the pharmaceutical processor is or will be closed during its normal hours of operation for longer than two business days, the pharmaceutical processor shall immediately notify the board.

H. A pharmacist shall counsel registered patients, parents, ~~and~~ legal guardians, and registered agents, if applicable, regarding the use of cannabidiol oil or THC-A oil. Such counseling shall include information related to safe techniques for proper use and storage of cannabidiol oil or THC-A oil and for disposal of the oils in a manner that renders them nonrecoverable.

I. The pharmaceutical processor shall establish, implement, and adhere to a written alcohol-free, drug-free, and smoke-free work place policy that shall be available to the board or the board's agent upon request.

18VAC110-60-220. Pharmaceutical processor prohibitions.

A. No pharmaceutical processor shall:

1. Cultivate Cannabis plants or produce or dispense cannabidiol oil or THC-A oil in any place except the approved facility at the address of record on the application for the pharmaceutical processor permit;

2. Sell, deliver, transport, or distribute Cannabis, including cannabidiol oil or THC-A oil, to any other facility, except for the wholesale distribution of cannabidiol oil or THC-A oil products between pharmaceutical processors;

3. Produce or manufacture cannabidiol oil or THC-A oil for use outside of Virginia; or

4. Provide cannabidiol oil or THC-A oil samples.

B. No pharmaceutical processor shall be open or in operation, and no person shall be in the pharmaceutical processor, unless a pharmacist is on the premises and directly supervising the activity within the pharmaceutical processor. At all other times, the pharmaceutical processor shall be closed and properly secured.

C. No pharmaceutical processor shall sell anything other than cannabidiol oil or THC-A oil products from the pharmaceutical processor.

D. A pharmaceutical processor shall not advertise cannabidiol oil or THC-A oil products, except it may post the following information on websites:

1. Name and location of the processor;

2. Contact information for the processor;

3. Hours and days the pharmaceutical processor is open for dispensing cannabidiol oil or THC-A oil products;

4. Laboratory results;

5. Product information and pricing; and

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6. Directions to the processor facility.

E. No cannabidiol oil or THC-A oil shall be consumed on the premises of a pharmaceutical processor, except for emergency administration to a registered patient.

F. No person except a pharmaceutical processor employee ~~or~~, a registered patient, parent, or legal guardian; or a registered agent shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis, cannabidiol oil, or THC-A oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee prior to entering the pharmaceutical processor.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.

3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

H. No cannabidiol oil or THC-A oil shall be sold, dispensed, or distributed via a delivery service or any other manner outside of a pharmaceutical processor, except that a registered parent, ~~or~~ legal

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guardian, or registered agent or an agent of the processor may deliver cannabidiol oil or THC-A oil to the registered patient or in accordance with 18VAC110-60-310 A. Products may also be wholesale distributed between pharmaceutical processors.

I. Notwithstanding the requirements of subsection F of this section, an agent of the board or local law enforcement or other federal, state, or local government officials may enter any area of a pharmaceutical processor if necessary to perform their governmental duties.

18VAC110-60-230. Inventory requirements.

A. Each pharmaceutical processor prior to commencing business shall:

1. Conduct an initial comprehensive inventory of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, at the facility. The inventory shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. If a facility commences business with no Cannabis on hand, the pharmacist shall record this fact as the initial inventory; and

2. Establish ongoing inventory controls and procedures for the conduct of inventory reviews and comprehensive inventories of all Cannabis plants, including the seeds, parts of plants, extracts, cannabidiol oil, and THC-A oil, that shall enable the facility to detect any diversion, theft, or loss in a timely manner.

B. Upon commencing business, each pharmaceutical processor and production facility shall conduct a weekly inventory of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil in stock, that shall include, at a minimum, the date of the inventory, a summary of the inventory findings, and the name, signature, and title of the pharmacist or pharmacy technician who conducted the inventory. ~~The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale; the name of the pharmaceutical processor; the registered patient, parent, or legal guardian to whom the cannabidiol oil or THC-A oil was sold; the address of such person; and the kind and quantity of cannabidiol oil or THC-A oil sold.~~

C. The record of all cannabidiol oil and THC-A oil sold, dispensed, or otherwise disposed of shall show the date of sale or disposition; the name of the pharmaceutical processor; the name and

address of the registered patient, parent, ~~or~~ legal guardian, or registered agent to whom the cannabidiol oil or THC-A oil was sold; the kind and quantity of cannabidiol oil or THC-A oil sold or disposed of; and the method of disposal.

D. A complete and accurate record of all Cannabis plants, including the seeds, parts of plants, cannabidiol oil, and THC-A oil on hand shall be prepared annually on the anniversary of the initial inventory or such other date that the PIC may choose, so long as it is not more than one year following the prior year's inventory.

E. All inventories, procedures, and other documents required by this section shall be maintained on the premises and made available to the board or its agent.

F. Inventory records shall be maintained for three years from the date the inventory was taken.

G. Whenever any sample or record is removed by a person authorized to enforce state or federal law for the purpose of investigation or as evidence, such person shall tender a receipt in lieu thereof and the receipt shall be kept for a period of at least three years.

18VAC110-60-251. Wholesale distribution of cannabidiol oil and THC-A oil products.

A. Cannabidiol oil and THC-A oil products from a batch that passed the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test and are packaged and labeled for sale with an appropriate expiration date in accordance with 18VAC110-60-300 may be wholesale distributed between pharmaceutical processors.

B. A pharmaceutical processor wholesale distributing the oil products shall create a record of the transaction that shows the date of distribution, the names and addresses of the processor distributing the product and receiving the product, and the kind and quantity of product being distributed. The record of the transaction shall be maintained by the distributing pharmaceutical processor with its records of distribution, and a copy of the record shall be provided to and maintained by the processor receiving the product in its records of receipt. Such records shall be maintained by each pharmaceutical processor for three years in compliance with 18VAC110-60-260.

C. A pharmaceutical processor wholesale distributing cannabidiol oil or THC-A oil products shall store and handle products and maintain policies and procedures, to include a process for executing or responding to mandatory and voluntary recalls, in a manner that complies with 18VAC110-60-250.

D. If a pharmaceutical processor wholesale distributing cannabidiol oil or THC-A oil products uses an electronic system for the storage and retrieval of records related to distributing cannabidiol oil or THC-A oil, the pharmaceutical processor shall use a system that is compliant with 18VAC110-60-260.

18VAC110-60-300. Laboratory requirements; testing.

A. No pharmaceutical processor shall utilize a laboratory to handle, test, or analyze cannabidiol oil or THC-A oil unless such laboratory:

1. Is independent from all other persons involved in the cannabidiol oil or THC-A oil industry in Virginia, which shall mean that no person with a direct or indirect interest in the laboratory shall have a direct or indirect financial interest in a pharmacist, pharmaceutical processor, certifying practitioner, or any other entity that may benefit from the production, manufacture, dispensing, sale, purchase, or use of cannabidiol oil or THC-A oil; and

2. Has employed at least one person to oversee and be responsible for the laboratory testing who has earned from a college or university accredited by a national or regional certifying authority at least (i) a master's level degree in chemical or biological sciences and a minimum of two years of post-degree laboratory experience or (ii) a bachelor's degree in chemical or biological sciences and a minimum of four years of post-degree laboratory experience.

B. After processing and before dispensing the cannabidiol oil or THC-A oil product, a pharmaceutical processor shall make a sample available from each batch of product for a laboratory to (i) test for microbiological contaminants, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue and (ii) conduct an active ingredient analysis and terpenes profile. The sample size shall be a statistically valid sample as determined by the board.

C. From the time that a batch of cannabidiol oil or THC-A oil product has been homogenized for sample testing until the laboratory provides the results from its tests and analysis, the pharmaceutical processor shall segregate and withhold from use the entire batch, except the samples that have been removed by the laboratory for testing. During this period of segregation, the pharmaceutical processor shall maintain the batch in a secure, cool, and dry location so as to prevent the batch from becoming contaminated or losing its efficacy.

D. Under no circumstances shall a pharmaceutical processor sell a cannabidiol oil or THC-A oil product prior to the time that the laboratory has completed its testing and analysis and provided a certificate of analysis to the pharmaceutical processor or other designated facility employee.

E. The processor shall require the laboratory to immediately return or properly dispose of any cannabidiol oil or THC-A oil products and materials upon the completion of any testing, use, or research.

F. If a sample of cannabidiol oil or THC-A oil product does not pass the microbiological, mycotoxin, heavy metal, or pesticide chemical residue test based on the standards set forth in this subsection, the pharmaceutical processor shall dispose of the entire batch from which the sample was taken.

1. For purposes of the microbiological test, a cannabidiol oil or THC-A oil sample shall be deemed to have passed if it satisfies the standards set forth in Section 1111 of the United States Pharmacopeia.

2. For purposes of the mycotoxin test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Test Specification	
Aflatoxin B1	<20 ug/kg of Substance
Aflatoxin B2	<20 ug/kg of Substance
Aflatoxin G1	<20 ug/kg of Substance
Aflatoxin G2	<20 ug/kg of Substance
Ochratoxin A	<20 ug/kg of Substance

3. For purposes of the heavy metal test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the following standards:

Metal	Limits - parts per million (ppm)
Arsenic	<10 ppm
Cadmium	<4.1 ppm
Lead	<10 ppm
Mercury	<2 ppm

4. For purposes of the pesticide chemical residue test, a sample of cannabidiol oil or THC-A oil product shall be deemed to have passed if it satisfies the most stringent acceptable

standard for a pesticide chemical residue in any food item as set forth in Subpart C of the federal Environmental Protection Agency's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food, 40 CFR Part 180.

5. For purposes of the active ingredient analysis, a sample of the cannabidiol oil or THC-A oil product shall be tested for:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiols (CBD); and

d. Cannabidiolic acid (CBDA).

6. For the purposes of the residual solvent test, a sample of the cannabidiol oil or THC-A oil product shall be deemed to have passed if it meets the standards and limits recommended by the American Herbal Pharmacopia for Cannabis Inflorescence. If a sample does not pass the residual solvents test, the batch can be remediated with further processing. After further processing, the batch must be retested for microbiological, mycotoxin, heavy metal, residual solvents, and pesticide chemical residue, and an active ingredient analysis and terpenes profile must be conducted.

G. If a sample of cannabidiol oil or THC-A oil product passes the microbiological, mycotoxin, heavy metal, residual solvent, and pesticide chemical residue test, the entire batch may be utilized by the processor for immediate packaging and labeling for sale. An expiration date shall be assigned to the product that is based upon validated stability testing that addresses product stability when opened and the shelf-life for unopened products.

H. The processor shall require the laboratory to file with the board an electronic copy of each laboratory test result for any batch that does not pass the microbiological, mycotoxin, heavy metal, residual solvents, or pesticide chemical residue test at the same time that it transmits those results to the pharmaceutical processor. In addition, the laboratory shall maintain the laboratory test results and make them available to the board or an agent of the board.

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I. Each pharmaceutical processor shall have such laboratory results available upon request to registered patients, parents, ~~or~~ legal guardians, or registered agents and registered practitioners who have certified qualifying patients.

18VAC110-60-310. Dispensing of cannabidiol oil or THC-A oil.

A. A pharmacist in good faith may dispense cannabidiol oil or THC-A oil to any registered patient, parent, or legal guardian as indicated on the written certification or to a registered agent for a specific patient.

1. Prior to the initial dispensing of oil pursuant to each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall view a current photo identification of the patient, parent, ~~or~~ legal guardian, or registered agent. The pharmacist or pharmacy technician shall verify in the Virginia Prescription Monitoring Program of the Department of Health Professions or other program recognized by the board that the registrations are current, the written certification has not expired, and the date and quantity of the last dispensing of cannabidiol oil or THC-A oil to the registered patient.

2. The pharmacist or pharmacy technician shall make and maintain for three years a paper or electronic copy of the current written certification that provides an exact image of the document that is clearly legible.

3. Prior to any subsequent dispensing, the pharmacist, pharmacy technician, or delivery agent shall view the current written certification and a current photo identification and current registration of the patient, parent, ~~or~~ legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the processor.

B. A pharmacist may dispense a portion of a registered patient's 90-day supply of cannabidiol oil or THC-A oil. The pharmacist may dispense the remaining portion of the 90-day supply of cannabidiol oil or THC-A oil at any time except that no registered patient, parent, ~~or~~ legal guardian, or registered agent shall receive more than a 90-day supply of cannabidiol oil or THC-A oil for a patient in a 90-day period from any pharmaceutical processor.

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C. A dispensing record shall be maintained for three years from the date of dispensing, and the pharmacist or pharmacy technician under the direct supervision of the pharmacist shall affix a label to the container of oil that contains:

1. A serial number assigned to the dispensing of the oil;

2. The brand name of cannabidiol oil or THC-A oil that was registered with the board pursuant to 18VAC110-60-285 and its strength;

3. The serial number assigned to the oil during production;

4. The date of dispensing the cannabidiol oil or THC-A oil;

5. The quantity of cannabidiol oil or THC-A oil dispensed;

6. A terpenes profile and a list of all active ingredients, including:

a. Tetrahydrocannabinol (THC);

b. Tetrahydrocannabinol acid (THC-A);

c. Cannabidiol (CBD); and

d. Cannabidiolic acid (CBDA);

7. A pass rating based on the laboratory's microbiological, mycotoxins, heavy metals, residual solvents, and pesticide chemical residue analysis;

8. The name and registration number of the registered patient;

9. The name and registration number of the certifying practitioner;

10. Directions for use as may be included in the practitioner's written certification or otherwise provided by the practitioner;

11. The name or initials of the dispensing pharmacist;

12. Name, address, and telephone number of the pharmacist processor;

13. Any necessary cautionary statement; and

14. A prominently printed expiration date based on stability testing and the pharmaceutical processor's recommended conditions of use and storage that can be read and understood by the ordinary individual.

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D. A pharmaceutical processor shall not label cannabidiol oil or THC-A oil products as "organic" unless the Cannabis plants have been organically grown and the cannabidiol oil or THC-A oil products have been produced, processed, manufactured, and certified to be consistent with organic standards in compliance with 7 CFR Part 205.

E. The cannabidiol oil or THC-A oil shall be dispensed in child-resistant packaging, except as provided in 18VAC110-60-210 A. A package shall be deemed child-resistant if it satisfies the standard for "special packaging" as set forth in the Poison Prevention Packaging Act of 1970 Regulations, 16 CFR 1700.1(b)(4).

F. No person except a pharmacist or a pharmacy technician operating under the direct supervision of a pharmacist shall alter, deface, or remove any label so affixed.

G. A pharmacist shall be responsible for verifying the accuracy of the dispensed oil in all respects prior to dispensing and shall document that each verification has been performed.

H. A pharmacist shall document a registered patient's self-assessment of the effects of cannabidiol oil or THC-A oil in treating the registered patient's diagnosed condition or disease or the symptoms thereof. A pharmaceutical processor shall maintain such documentation in writing or electronically for three years from the date of dispensing and such documentation shall be made available in accordance with regulation.

I. A pharmacist shall exercise professional judgment to determine whether to dispense cannabidiol oil or THC-A oil to a registered patient, parent, ~~or~~ legal guardian, or registered agent if the pharmacist suspects that dispensing cannabidiol oil or THC-A oil to the registered patient, parent, ~~or~~ legal guardian, or registered agent may have negative health or safety consequences for the registered patient or the public.

18VAC110-60-320. Dispensing error review and reporting; quality assurance program.

A. A pharmaceutical processor shall implement and comply with a quality assurance program that describes, in writing, policies and procedures to detect, identify, and prevent dispensing errors. A pharmaceutical processor shall distribute the written policies and procedures to all pharmaceutical processor employees and shall make the written policies and procedures readily available on the premises of the pharmaceutical processor. The policies and procedures shall include:

1. Directions for communicating the details of a dispensing error to the practitioner who certified a qualifying patient and to the qualifying patient, the patient's parent or legal guardian, the patient's registered agent, or appropriate family member if the patient is deceased or is unable to fully comprehend the communication. The communication shall describe methods of correcting the dispensing error or reducing the negative impact of the error on the qualifying patient; and

2. A process to document and assess dispensing errors to determine the cause of the error and an appropriate response.

B. A pharmaceutical processor shall use the findings of its quality assurance program to develop systems and workflow processes designed to prevent dispensing errors. A pharmaceutical processor PIC shall:

1. Inform pharmaceutical processor employees of changes to policy, procedure, systems, or processes made as a result of recommendations generated by the quality assurance program;

2. Notify all processor employees that the discovery or reporting of a dispensing error shall be relayed immediately to a pharmacist on duty;

3. Ensure that a pharmacist performs a quality assurance review for each dispensing error. A pharmacist shall commence such review as soon as is reasonably possible, but no later than two business days from the date the dispensing error is discovered; and

4. Create a record of every quality assurance review. This record shall contain at least the following:

a. The date of the quality assurance review and the names and titles of the persons performing the review;

b. The pertinent data and other information relating to the dispensing error reviewed;

c. Documentation of contact with the registered patient, parent, ~~or~~ legal guardian, or registered agent, where applicable, and the practitioner who certified the patient;

d. The findings and determinations generated by the quality assurance review; and

e. Recommended changes to pharmaceutical processor policy, procedure, systems, or processes if any.

C. A pharmaceutical processor shall maintain for three years a copy of the pharmaceutical processor's quality assurance program and records of all reported dispensing errors and quality assurance reviews in an orderly manner and filed by date.

Agenda Item: Adoption of Final Regulations – White bagging and brown bagging

Included in your agenda package are:

Notice from the Va. Regulatory Townhall

Copy of comments on proposed regulations

A copy of the proposed regulations with one change requested by commenter

Board action:

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

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Action: Brown bagging and white bagging

Proposed Stage

Action 4968 / Stage 8585

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	11/5/2019 11:05 am	Sync Text with RIS
Agency Background Document	4/1/2019 (modified 6/11/2019)	Upload / Replace
Attorney General Certification	5/1/2019	
DPB Economic Impact Analysis	6/14/2019	
Agency Response to EIA	10/23/2019	Upload / Replace
Governor's Review Memo	10/23/2019	
Registrar Transmittal	10/23/2019	

Status	
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
Attorney General Review	Submitted to OAG: 4/1/2019 Review Completed: 5/1/2019 Result: Certified
DPB Review	Submitted on 5/1/2019 Economist: Larry Getzler Policy Analyst: Cari Corr Review Completed: 6/14/2019 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 9/15/2019
Governor's Review	Review Completed: 10/23/2019 Result: Approved
Virginia Registrar	Submitted on 10/23/2019 The Virginia Register of Regulations Publication Date: 11/11/2019 Volume: 36 Issue: 6
Public Hearings	12/09/2019 9:10 AM

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Comment Period	**Ended 1/10/2020** **3 comments**

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
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This person is the primary contact for this chapter.
This stage was created by Elaine J. Yeatts on 04/01/2019
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Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action	**Brown bagging and white bagging**
Stage	**Proposed**
Comment Period	Ends 1/10/2020

3 comments

All good comments for this forum **Show Only Flagged**

Back to List of Comments

Commenter: Janice Kuhn 1/8/20 7:55 am

Brown bagging and inherited bleeding disorders

Brown bagging and inherited bleeding disorders

On behalf of the federally funded Virginia comprehensive hemophilia treatment centers (HTCs) at the University of Virginia, Virginia Commonwealth University, Children's Hospital of the Kings Daughters and the Children's National Hospital, we are requesting an modification to the exception for 18VAC110-20-275, section G to read:

"An exception to this requirement may be made for patients with **inherited bleeding disorders**[1] who may require **therapy**[2] to **prevent or treat bleeding episodes**[3]."

Our rationale for the request is the following:

1) The term "hemophilia" is sometimes restricted to just Factor VIII and Factor IX Deficiencies whereas "inherited bleeding disorders" captures other inherited factor deficiencies.

2) Most factor concentrates are not blood products. Some newer hemophilia treatments are not factor concentrates.

3) Hemophilia medications are given in non-emergent outpatient settings, as a part of best practice. Most hospitals do not carry factor concentrates; HTCs do not carry all of the products used by patients to meet their specialized needs. Pharmacokinetic studies in clinic are completed in clinic to monitor home therapy and prevent bleeding episodes. Outpatient reimbursement often requires prior authorization which can delay treatment. Teaching home therapy to patients and families in the outpatient setting ensures that policies and procedures are followed for patient safety.

Thank you for the opportunity to share our concerns

CommentID: 78764

Commenter: Natalie Nguyen, Virginia Society of Health-System Pharmacists 1/10/20 12:59 pm

Requesting Exemption for Prohibition Language on White Bagging

The Virginia Society of Health-System Pharmacists (VSHP) supports the Board's actions to improve the integrity of the supply chain regarding drugs delivered through the white bagging process. The lack of notification and logistical information of receipt of drugs through this process has been a longstanding point of frustration for our members who have to allocate additional resources to track down shipments and follow the trail of information to connect these drugs with the intended patient.

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Summary of Public Comment on Proposed Regulations
Board of Pharmacy

Proposed regulations were published on November 11, 2019 with comment received until January 10, 2020. The following comments were received.

Commenter	Comment
Janice Kuhn Virginia hemophilia treatment centers	Requested amendment to subsection G of section 275 to allow an exception for patients with inherited bleeding disorders, rather than the proposed term "hemophilia" because the more expansive terms captures other inherited factor deficiencies. Also requested deletion of the phrase who may require "emergent blood factor treatment" and inclusion of the phrase " therapy to prevent or treat bleeding episodes" to include newer hemophilia treatments that are not factor concentrates.
Natalie Nguyen Va. Society of Health-System Pharmacists	Supports Board's action to improve integrity of the supply chain. Asks for exception to subsection F 4 for certain types of administration.
Cynthia Williams Riverside Health Systems	Agree with proposed language but asked for allowance for health systems to practice "clear bagging" Also requested some type of phase in period. *Asked for clarification about "clear bagging," the commenter sent a subsequent email noted that an exemption for health system-owned pharmacies would be inconsistent. Commenter did reiterate request for reasonable timeline to allow dissemination of requirements and registration of physician practices as alternative delivery locations.*

The Board will consider the comment and decide whether to amend its proposed regulations at its meeting on March 24, 2020. No additional comment can be received at that meeting.

VSHP would like to ask the Board to consider exemptions to the 4th proposed regulation prohibiting delivery of drugs that are delivered to the patient's residence for self-administration that require special storage, reconstitution, or compounding prior to administration. There are some drugs, such as factors for the treatment of hemophilia which requires the patient to bring their drugs to the clinic or the emergency department for assessment of self-administration and/or drawing of labs prior to observation of administration. This process is critical to ensuring positive outcomes for patients as the observation of administration technique or demonstration of administration technique is part of ensuring that the drug is received by the body in the indicated manner. This is very similar to asking a patient to bring their inhaler to a physician's office to demonstrate their inhalation technique as part of evaluation for efficacy. The way the proposed regulation is written does not account for this unique population.

We recommend the following: "Prohibiting delivery to a patient's residence of any drug that requires special storage, reconstitution, or compounding prior to administration is intended and that will be subsequently transported by the patient for administration. Drugs that may require compounding or reconstitution, but either are self-administered or that the patient must possess because the drugs are for emergent use for rare conditions and are not stocked in the facilities who would treat the patient, are exempted from this prohibition."

Thank you for your time and consideration.

CommentID: **78813**

Commenter: Cynthia Williams, BS Pharm, FASHP, Riverside Health System 1/10/20 3:41 pm

Comments on 18 VAC 110-20-275

Thank you for the opportunity to comment on proposed regulation related to the practice of white bagging/brown bagging. Many insurance providers/pharmacy benefit managers are disrupting the traditional patient-provider relationship, adding increased burden to the provider and patient, and potentially jeopardizing the integrity of medication and provision of timely patient care through the mandate to have medications supplied through a "white bag" or "brown bag" process. Overall, I agree with the regulation language, and specifically with the changes that allow for exemptions for certain circumstances.

Within many health systems, the pharmacy department routinely provides purchasing oversight for hospital owned clinics. For health systems, such as ours, where there is a specialty pharmacy presence, we attempt to practice "clear bagging" where the medication is filled through an organization owned pharmacy and delivered to the provider location using organization resources and tracking. Based on the language under (F) related to "the alternate delivery site does not routinely receive delivery form the pharmacy, I wanted to make sure that this practice of "clear bagging" would not be at risk nor would require that we register every physician clinic with a BOP CSR or practitioner of the healing arts license to sell controlled substance registration.

Additionally, I would suggest some type of phase in period for the regulation to allow adequate time for notification to providers, patients and payers in order to not disrupt care.

Thank you

CommentID: **78824**

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Virginia Board of Pharmacy

9960 Mayland Drive, Suite 300

Richmond, VA 23233

Attn: Caroline Juran, RPh, DPh

Executive Director

February 25, 2020

Ms. Juran,

I am writing to amend my public comment on the proposed Virginia Board of Pharmacy White/Brown bagging regulation. Upon further review, the suggestion I made related to potential exemption of health system owned pharmacies from the requirements of alternate delivery location would be inconsistent with current legislation. I do still ask for a reasonable implementation timeline to allow for discrimination of requirements to pharmacy providers and physician practices, as well as time for physician practices to obtain the required registration to operate as alternate delivery locations.

Sincerely,

Cynthia Williams, BS Pharm

VP/Chief Pharmacy Officer

Riverside Health System

Project 5376 - Proposed

BOARD OF PHARMACY

Brown bagging and white bagging

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping

for identifying the pharmacist ~~or pharmacists~~ responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.

1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is a written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.

2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:

a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;

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b. Procedure for providing counseling;

c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;

d. The procedure for assuring confidentiality of patient information; and

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.

F. The pharmacy and alternate delivery site shall be exempt from compliance with subsections B through E of this section if (i) the alternate delivery site is a pharmacy, a practitioner of healing arts licensed by the board to practice pharmacy or sell controlled substances, or other entity holding a controlled substances registration for the purpose of delivering controlled substances; (ii) the alternate delivery site does not routinely receive deliveries from the pharmacy; and (iii) compliance with subsections B through E of this section would create a delay in delivery that may result in potential patient harm. However, the pharmacy and alternate delivery site shall comply with following requirements:

1. To ensure appropriate coordination of patient care, the pharmacy shall notify the alternate delivery site of the anticipated arrival date of the shipment, the exact address to where the

drug was shipped, the name of the patient for whom the drug was dispensed, and any special storage requirements.

2. The pharmacy shall provide counseling or ensure a process is in place for the patient to receive counseling.

3. Prescriptions delivered to the alternate delivery site shall be stored in a lockable room or lockable cabinet, cart, or other device that cannot be easily moved and that shall be locked at all times when not in use. Access shall be restricted to the licensed prescriber, pharmacist, or either person's designee.

4. The pharmacy shall provide a procedure for the return of any prescription drugs not delivered or subsequently administered to the patient.

G. A pharmacy shall not deliver dispensed drugs to a patient's residence that are intended to be subsequently transported by the patient or patient's agent to a hospital, medical clinic, prescriber's office, or pharmacy for administration and that require special storage, reconstitution or compounding prior to administration. An exception to this requirement may be made for patients with [~~hemophilia~~ inherited bleeding disorders] who may require [~~emergent blood factor treatment~~ therapy to prevent or treat bleeding episodes] .

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Board action: Amendment to fee for returned checks

Included in agenda package:

Applicable sections of the Code of Virginia

Revised Fee section

Staff note:

Auditors from the Office of the Comptroller have advised DHP that we should be charging $50 for a returned check, rather than the current $35. That amount was based on language in § 2.2-614.1. However, § 2.2-4805 (from the Va. Debt Collection Act) requires the fee for a returned check to be $50.

Board counsel for DHP boards has advised that the handling fee of $50 in Virginia Code 2.2-4805 governs. Section 2.2-614.1 states that a "penalty of $35 or the amount of any costs, **whichever is greater**," shall be imposed. By amending § 2.2-4805 in 2009, the General Assembly determined that the costs, in the form of a "handling fee," is $50, and thus greater than the $35 penalty imposed under 2.2-614.1.

Therefore, all board regulations will need to be amended to reflect the higher "handling" fee.

Code of Virginia
Title 2.2. Administration of Government
Chapter 6. General Provisions

§ 2.2-614.1. Authority to accept revenue by commercially acceptable means; service charge; bad check charge.

A. Subject to § 19.2-353.3, any public body that is responsible for revenue collection, including, but not limited to, taxes, interest, penalties, fees, fines or other charges, may accept payment of any amount due by any commercially acceptable means, including, but not limited to, checks, credit cards, debit cards, and electronic funds transfers.

B. The public body may add to any amount due a sum, not to exceed the amount charged to that public body for acceptance of any payment by a means that incurs a charge to that public body or the amount negotiated and agreed to in a contract with that public body, whichever is less. Any state agency imposing such additional charges shall waive them when the use of these means of payment reduces processing costs and losses due to bad checks or other receivable costs by an amount equal to or greater than the amount of such additional charges.

C. If any check or other means of payment tendered to a public body in the course of its duties is not paid by the financial institution on which it is drawn, because of insufficient funds in the account of the drawer, no account is in the name of the drawer, or the account of the drawer is closed, and the check or other means of payment is returned to the public body unpaid, the amount thereof shall be charged to the person on whose account it was received, and his liability and that of his sureties, shall be as if he had never offered any such payment. A penalty of $35 or the amount of any costs, whichever is greater, shall be added to such amount. This penalty shall be in addition to any other penalty provided by law, except the penalty imposed by § 58.1-12 shall not apply.

2002, c. 719; 2004, c. 565.

Code of Virginia
Title 2.2. Administration of Government
Chapter 48. Virginia Debt Collection Act

§ 2.2-4805. Interest, administrative charges and penalty fees

A. Each state agency and institution may charge interest on all past due accounts receivable in accordance with guidelines adopted by the Department of Accounts. Each past due accounts receivable may also be charged an additional amount that shall approximate the administrative costs arising under § 2.2-4806. Agencies and institutions may also assess late penalty fees, not in excess of ten percent of the past-due account on past-due accounts receivable. The Department of Accounts shall adopt regulations concerning the imposition of administrative charges and late penalty fees.

B. Failure to pay in full at the time goods, services, or treatment are rendered by the Commonwealth or when billed for a debt owed to any agency of the Commonwealth shall result in the imposition of interest at the judgment rate as provided in § 6.2-302 on the unpaid balance unless a higher interest rate is authorized by contract with the debtor or provided otherwise by statute. Interest shall begin to accrue on the 60th day after the date of the initial written demand for payment. A public institution of higher education in the Commonwealth may elect to impose a late fee in addition to, or in lieu of, interest for such time as the institution retains the claim pursuant to subsection D of § 2.2-4806. Returned checks or dishonored credit card or debit card payments shall incur a handling fee of $50 unless a higher amount is authorized by statute to be added to the principal account balance.

C. If the matter is referred for collection to the Division, the debtor shall be liable for reasonable attorney fees unless higher attorney fees are authorized by contract with the debtor.

D. A request for or acceptance of goods or services from the Commonwealth, including medical treatment, shall be deemed to be acceptance of the terms specified in this section.

1988, c. 544, § 2.1-732; 2001, c. 844;2009, c. 797.

The chapters of the acts of assembly referenced in the historical citation at the end of this section may not constitute a comprehensive list of such chapters and may exclude chapters whose provisions have expired.

BOARD OF PHARMACY

Handling fee

18VAC110-20-20. Fees.

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

B. Initial application fees.

1. Pharmacy permit	$270
2. Permitted physician licensed to dispense drugs	$270
3. Medical equipment supplier permit	$180
4. Outsourcing facility permit	$270
5. Nonresident pharmacy registration	$270
6. Nonresident outsourcing facility registration	$270
7. Controlled substances registrations	$90
8. Innovative program approval. If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.	$250
9. Approval of a repackaging training program	$50

C. Annual renewal fees.

1. Pharmacy permit – due no later than April 30	$270
2. Physician permit to practice pharmacy – due no later than February 28	$270
3. Medical equipment supplier permit – due no later than February 28	$180
4. Outsourcing facility permit – due no later than April 30	$270
5. Nonresident pharmacy registration – due no later than the date of initial registration	$270
6. Nonresident outsourcing facility registration – due no later than the date of initial registration	$270

7. Controlled substances registrations – due no later than February 28	$90
8. Innovative program continued approval based on board order not to exceed $200 per approval period.	
9. Repackaging training program	$30 every two years

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

1. Pharmacy permit	$90
2. Physician permit to practice pharmacy	$90
3. Medical equipment supplier permit	$60
4. Outsourcing facility permit	$90
5. Nonresident pharmacy registration	$90
6. Nonresident outsourcing facility registration	$90
7. Controlled substances registrations	$30
8. Repackaging training program	$10

E. Reinstatement fees.

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

2. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

a. Pharmacy permit	$240
b. Physician permit to practice pharmacy	$240
c. Medical equipment supplier permit	$210
d. Outsourcing facility permit	$240
e. Nonresident pharmacy registration	$115
f. Nonresident outsourcing facility registration	$240
g. Controlled substances registration	$180
h. Repackaging training program	$50

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

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

G. Miscellaneous fees.

1. ~~Returned check~~ Handling fee for returned check or a dishonored credit card or debit card	~~$35~~ $50
2. Duplicate permit or registration	$10
3. Verification of permit or registration	$25

18VAC110-21-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	$180
2. Pharmacy intern registration	$15
3. Pharmacy technician registration	$25
4. Approval of a pharmacy technician training program	$150
5. Approval of a continuing education program	$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$90
2. Pharmacist inactive license – due no later than December 31	$45
3. Pharmacy technician registration – due no later than December 31	$25
4. Pharmacy technician training program	$75 every two years

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

1. Pharmacist license	$30
2. Pharmacist inactive license	$15
3. Pharmacy technician registration	$10
4. Pharmacy technician training program	$15

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

1. Pharmacist license	$210

2. Pharmacist license after revocation or suspension	$500
3. Pharmacy technician registration	$35
4. Pharmacy technician registration after revocation or suspension	$125
5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.	

G. Miscellaneous fees.

1. Duplicate wall certificate	$25
2. ~~Returned check~~ Handling fee for returned check or a dishonored credit card or debit card	~~$35~~ $50
3. Duplicate license or registration	$10
4. Verification of licensure or registration	$25

18VAC110-30-15. Fees.

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

B. Initial application fees.

1. License for practitioner of the healing arts to sell controlled substances: $180.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

C. Annual renewal fees.

1. License for practitioner of the healing arts to sell controlled substances: $90.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

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

1. License for practitioner of the healing arts to sell controlled substances: $30.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $40.

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

1. License for practitioner of the healing arts to sell controlled substances: $150.

2. Permit for facility in which practitioners of the healing arts sell controlled substances: $240.

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely: $500.

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit. Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.

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

H. The handling fee for a returned check or dishonored credit card or debit card shall be ~~$35~~ $50.

18VAC110-50-20. Fees.

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

B. Initial application fees.

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

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

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

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

1. Nonrestricted manufacturer permit	$90
2. Restricted manufacturer permit	$60
3. Wholesale distributor license	$90
4. Warehouser permit	$90

5. Nonresident wholesale distributor registration	$90
6. Controlled substances registration	$30
7. Third-party logistics provider permit	$90
8. Nonresident manufacturer registration	$90
9. Nonresident warehouser registration	$90
10. Nonresident third-party logistics provider registration	$90

E. Reinstatement fees.

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

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

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

i. Nonresident warehouser registration	$240
j. Nonresident third-party logistics provider registration	$240

F. Application for change or inspection fees.

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

G. The handling fee for a returned check or a dishonored credit card or debit card shall be ~~$35~~ $50.

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

18VAC110-60-20. Fees.

A. Fees are required by the board as specified in this section. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Registration of practitioner.

1. Initial registration.	$50
2. Annual renewal of registration.	$50
3. Replacement of registration for a qualifying practitioner whose information has changed or whose original registration certificate has been lost, stolen, or destroyed.	$50

C. Registration by a qualifying patient, parent, or legal guardian.

1. Initial registration of a patient.	$50
2. Annual renewal of registration of a patient.	$50
3. Initial registration of a parent or legal guardian.	$25
4. Annual renewal of registration of a parent or guardian.	$25
5. Replacement of registration for a qualifying patient, parent, or legal guardian whose original	$25

registration certificate has been lost, stolen, or destroyed.

D. Pharmaceutical processor permit.

1. Application.	$10,000
2. Initial permit.	$60,000
3. Annual renewal of permit.	$10,000
4. Change of name of processor.	$100
5. Change of PIC or any other information provided on the permit application.	$100
6. Change of ownership not requiring a criminal background check.	$100
7. Change of ownership requiring a criminal background check.	$250
8. Any acquisition, expansion, remodel, or change of location requiring an inspection.	$1,000
9. Reinspection fee.	$1,000
10. Registration of each cannabidiol oil or THC-A oil product.	$25

E. The handling fee for returned check or dishonored credit card or debit card shall be $50.

Agenda Topic: Consideration of certification from a substantially similar program approved by the Board for nonresident pharmacies (§ 54.1-3434.1(A)(4))

Included in your agenda package:

- Relevant statute - § 54.1-3434.1
- Letter from Covetrus
- Letter from Virginia Veterinary Medical Association
- Letter from Jason A. Flanary, DVM

Staff Note:
The Verified Internet Pharmacy Practice Site (VIPPS) certification is no longer issued by the National Association of Boards of Pharmacy (NABP). This NABP site-specific certification was incorporated into a company-specific dotPharmacy accreditation issued by NABP approximately 1-2 years ago. Since then the dotPharmacy accreditation has been accepted in lieu of the VIPPS certification.

Possible Board Action:

Motion to approve LegitScript's certification as a substantially similar program to the Verified Internet Pharmacy Practice Site certification formerly issued by the National Association of Boards of Pharmacy;

from *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2019

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

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

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

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

3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than six months prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

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

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

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

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

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

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

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

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

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

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

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

covetrus

May 11, 2020

Cynthia Warriner
Chair

Caroline Juran
Executive Director

Virginia Board of Pharmacy
Perimeter Center
9960 Maryland Dr., Suite 300
Henrico, VA 23233-1463

RE: Approval of LegitScript for Certification of Non-Resident Pharmacies –
VFC Pharmacy #101, LLC dba Covetrus Maine ("Covetrus Maine")

Dear Ms. Warriner and Ms. Juran:

Covetrus Maine is one of the subsidiary pharmacies operated by Covetrus, Inc. that serves the veterinary market in Virginia. Covetrus Maine has submitted an application to renew its Non-Resident Pharmacy License with the Virginia Board. That license expires on May 31, 2020. Covetrus Maine is just one of the pharmacies operated by Covetrus, Inc. providing pharmacy services to over 1,900 veterinarian clients in Virginia. The ability for veterinary practices to allow its pet patients to obtain their prescription drugs via the internet and mail delivery has proven to be of tremendous value to pet owners, especially in these times of social distancing.

Covetrus Maine respectfully requests that the Virginia Board approve LegitScript as an approved certification and as an alternative to the NABP .Pharmacy certification. Covetrus Maine is not eligible to renew its .Pharmacy certification with NABP at this time due to the current NABP rules which do not allow affiliate pharmacies to apply for certification if there is an entity under common ownership which is subject to an open Warning Letter from the FDA. Unfortunately, Covetrus Maine's affiliate, Atlas Pharmaceuticals, has an open FDA Warning Letter. Atlas is working with FDA to resolve all outstanding issues; however, the Covid-19 pandemic has delayed follow-up inspections and impeded FDA's ability to close-out outstanding matters in a timely fashion. Atlas Pharmaceuticals is a registered 503B Outsourcing Facility and its license with Virginia was recently renewed. Atlas Pharmaceuticals is not a pharmacy and it does not provide its products to its affiliate pharmacies, including Covetrus Maine.

Although Covetrus Maine does not have .Pharmacy certification, it does have LegitScript certification. LegitScript is a nationally recognized certification organization. It was founded in 2007 to provide an independent means for consumers to be confident that the internet sites they

are accessing and shopping from are safe and maintain strong standards to combat misuse by cybercriminals. LegitScript offers monitoring, investigation and certification services to merchants and platforms using the internet. Their certification services are specifically designed to help pharmacies, telemedicine providers, addiction treatment facilities and health product merchants demonstrate the highest level of credibility to consumers. LegitScript certification is recognized and accepted by Google, Amazon and Visa as a trusted resource in evaluating pharmacies that may choose to use their services. In addition, LegitScript is accepted by other state Boards of Pharmacy including, but not limited to, Indiana, as an approved certification body for non-resident or internet based pharmacies.

LegitScript's certification process is detailed and robust. LegitScript evaluates not only the payment environment but also looks at areas of the pharmacy operation to ensure compliance with regulatory requirements. Among other things, pharmacies must demonstrate competency in the following areas:

- Licensing and registrations;
- Compliance with controlled substance standards;
- Involvement in regulatory action and prior disciplines;
- Compliance with privacy standards; and
- Prescription processing and quality of service.

This evaluation process examines the pharmacy and its operations on par [or more robust] with the NABP .Pharmacy certification review process.

If Covetrus Maine is not permitted to renew its license in Virginia, thousands of animal patients will either lose their access to medications, or will suffer needless interruption in treatment. Pet parents will also be forced to leave their homes and risk exposure to Covid-19 in order to properly medicate their pets. As such, we request that you accept LegitScript, a nationally recognized certification, as an alternative certification to NABP's .Pharmacy, so that the license of Covetrus Maine may be renewed in a timely manner.

Sincerely,

Greg O'Grady RPh

Greg O'Grady, R.Ph
Pharmacist in Charge

cc: Jennifer O'Grady, VP Pharmacy, Covetrus
A. Randall, Covetrus Legal
R. Pontikes, ReedSmith
Ben Dendy, Vectre Corporation

VIRGINIA VETERINARY MEDICAL ASSOCIATION

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May 11, 2020

Caroline Juran
Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Maryland Dr., Suite 300
Henrico, VA 23233-1463

Dear Ms. Juran:

I am writing on behalf of the Virginia Veterinary Medicine Association (VVMA) in support of the renewal of the non-resident pharmacy license for Vets First Choice and the acceptance of LegitScript certification as an alternative to the required National Association of Boards of Pharmacy (NABP) ".pharmacy" certification. It is our understanding that a variance to NABP certification is necessary in order to address inspection delays at the FDA brought on by the COVID-19 national response. LegitScript is another nationally recognized certification that ensures that companies selling medicines, pharmaceuticals, telemedicine services, and other healthcare products are in compliance with all applicable laws and regulations.

Without action by the Board, our clinics that are served by Vets First Choice will be left without the ability to provide prescription products safely online and through mail fulfillment. In response to COVID-19, Veterinary practices are using various strategies to increase social distancing and limiting person-to-person contact when offering care for animals. It is critical to our practices that on-line pharmacy choices continue in order to meet our client's needs and safety. Vets First Choice is a leading provider of technology-enabled pharmacy services for companion and equine veterinary practitioners in the Commonwealth.

Many of the world's leading companies and state pharmacy boards require or recognize LegitScript certification and the VVMA urges the Board to accept this additional Verified Internet Pharmacy Practice Site certification for non-resident pharmacies.

Sincerely,

Jay Margolis, DVM
President, Virginia Veterinary Medical Association

May 11, 2020

Ms. Cynthia Warriner
Chairman
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

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

Dear Ms. Warriner and Ms. Juran:

I am a licensed and practicing veterinarian at Pender Veterinary Centre in Fairfax, Virginia. I am writing today because it is my understanding that the Board of Pharmacy will be considering whether or not to accept alternative certification from Legitscript for Vets First Choice. Legitscript is another nationally recognized certification available to pharmacies and their websites. The State of Indiana which has a rule similar to Virginia has accepted Legitscript certification as have other states.

Vets First Choice has been used by veterinarians across the Commonwealth. There have been no complaints about their services. Vets First Choice has had no issues with the FDA. An affiliated company, Atlas, whose license was recently renewed by the Board of Pharmacy does have a FDA Warning Letter that cannot be addressed because the FDA is not doing inspections on cases like this for the next two years.

It is critically important to veterinarians across Virginia that the alternative certification be approved. This pharmacy needs to remain in operation and continue to provide prescription products to pet owners safely and effectively through the internet and mail fulfillment. This is especially important during the current pandemic. The veterinary clinics that are served by Vets First Choice have found their program to be a tremendous asset to be able to provide quality and timely fulfillment of prescriptions during this time of social distancing.

I urge the Board of Pharmacy to approve the certification from Legitscript.

With best wishes, I am

Sincerely,

Jason A. Flanary, DVM
Pender Veterinary Centre

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Virginia Board of Pharmacy
Inspection Report
March 24, 2020
Licenses Issued

	9/1/18-11/30/18	12/1/18-2/28/19	3/1/19-4/20/19	5/1/19-7/31/19	8/1/19-10/31/19	11/1/19-1/31/20	License Count 2/5/2020
Business CSR	59	41	19	36	32	23	1,448
CE Courses	2	0	0	0	0	0	9
Limited Use Pharmacy Technician	1	0	0	0	0	0	11
Medical Equipment Supplier	1	2	1	3	7	1	234
Nonresident Manufacturer	7	24	8	11	11	10	191
Nonresident Medical Equipment Supplier	9	10	5	30	12	14	358
Non-resident Outsourcing Facility	2	0	0	1	0	1	28
Non-resident Pharmacy	27	24	22	27	18	21	786
Non-resident Third Party Logistics Provider			8	58	42	17	122
Non-resident Warehouser			6	10	16	6	37
Non-resident Wholesale Distributor	12	13	3	22	13	8	670
Non-restricted Manufacturer	1	1	1	2	0	0	31
Outsourcing Facility	0	0	0	0	0	0	0
Permitted Physician	0	0	0	0	0	0	0
Pharmaceutical Processor						1	1
Pharmacist	250	157	134	316	328	187	15,219
Pharmacist Volunteer Registration	0	0	0	2	1	0	0
Pharmacy	21	13	7	13	10	11	1,787
Pharmacy Intern	189	122	74	65	225	43	1,466
Pharmacy Technician	378	388	249	426	433	485	12,456
Pharmacy Technician Training Program	4	3	2	3	3	1	134
Physician Selling Controlled Substances	42	44	7	25	18	23	590
Physician Selling Drugs Location	4	8	3	7	4	3	162
Pilot Programs	0	0	2	1	0	1	23
Registered Practitioner For CBD/THC-A Oil	83	40	25	52	59	39	273
Repackaging Training Program	0	0	1	0	0	0	2
Restricted Manufacturer	0	1	0	1	0	0	48
Third Party Logistics Provider	1	0	0	1	0	0	5
Warehouser	7	9	0	0	1	3	112
Wholesale Distributor	0	0	0	1	3	0	70
Total	**1,100**	**900**	**577**	**1,113**	**1,236**	**898**	**36,273**

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Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Inspections Completed

	9/1/18-11/30/18		12/1/18-2/28/19		3/1/19-4/30/19		5/1/19-7/31/19		8/1/19-10/31/19		11/1/19-1/31/20	
License Type												
Controlled Substances Registration	174		164		83		145		177		111	
Medical Equipment Supplier	19		10		11		21		19		36	
Non-restricted Manufacturer	3		3		1		3		0		0	
Permitted Physician	0		0		0		0		0		1	
Physician Selling Drugs Location	38		30		11		39		30		39	
Restricted Manufacturer	0		1		0		1		0		0	
Third Party Logistics Provider	2		1		0		1		2		0	
Warehouse	12		10		7		10		7		11	
Wholesale Distributor	7		9		2		11		7		5	
Pharmacy	306		227		207		348		284		274	
Pilot	1		0		1		0		0		0	
Pharmaceutical Processor											6	
Total	**562**		**455**		**323**		**579**		**526**		**483**	

Pharmacy (0201) Inspections												
Change of Location	7		0		0		7		5		5	
New	18		12		6		13		10		10	
Reinspection	13		14		4		9		15		10	
Remodel	42		40		38		53		49		39	
Routine	222		159		159		253		193		207	
Focus	4		0		0		2		3		2	
Federal Agency	0		0		0		11		9		0	
Compliance	0		2		0		0		0		1	
Pilot	0		0		0		0		0		0	
Total	**306**		**227**		**207**		**348**		**284**		**274**	

Pharmacy Routine Inspections												
No Deficiency	109	49%	57	36%	53	33%	98	39%	64	33%	73	35%
Deficiency	64	29%	55	34%	47	34%	76	34%	66	34%	70	34%
Deficiency & IPHCO	49	22%	47	30%	59	37%	79	31%	63	33%	64	31%
Total	**222**		**159**		**159**		**253**		**193**		**207**	

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Virginia Board of Pharmacy
December 9, 2019
Frequently Cited Deficiencies
September 2018 - January 2020

Deficiencies Numbered Less 1-100 (Formerly Major Deficiency)	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	122
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	66
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)	47
7. Change of location or remodel of pharmacy without submitting application or Board approval	28
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	27
20. Pharmacist not checking and documenting repackaging or bulk packaging	27
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	24
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounding of sterile preparations.	23
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	22
12. Storage of prescription drugs not in the prescription department	22
Deficiencies Numbered Greater Than 100 (Formerly Minor Deficiency)	**Cumulative Total**
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)	179
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.	112
127. Repackaging records and labeling not kept as required or in compliance	102
123. Engaging in remote processing not in compliance	85
130a. Compounded products not properly labeled	70
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	70
108. Emergency access alarm code/key not maintained in compliance	66
124. Labels do not include all required information	60
119. Not properly documenting partial filling of prescriptions	46
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	43

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
Routine Inspections Completed	**222**	**159**	**159**	**253**	**193**	**207**	**1193**	**Repeat**	**Repeat**
Total Deficiencies	**83**	**60**	**101**	**123**	**119**	**111**	**597**	**15**	**260**
Average Deficiencies per Inspection	**0.4**	**0.4**	**0.6**	**0.5**	**0.6**	**0.5**	**0.5**		
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	0	1	2	0	0	4	7		
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	12	6	12	14	7	15	66	1	3
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	7	2	5	1	4	4	23		
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	0	0	1	1	0	0	2		
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	1	0	0	2	6	5	14		1
6. Exceeds pharmacist to pharmacy technician ratio (12/12/13 New Minor 43 for first offense)	1	0	0	1	0	1	3		1
7. Change of location or remodel of pharmacy without submitting application or Board approval	3	2	5	11	4	2	27		1
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.	1	1	1	0	0	3	6		1
9. Alarm not operational or not being set	0	0	1	0	0	1	2		
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)	1	0	3	2	11	5	22		1

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
10. Unauthorized access to alarm or locking device to the prescription department	1	0	4	2	7	3	17		1
11. Insufficient enclosures or locking devices (12/12/13 New Minor 45 if no drug loss)	1	1	2	3	1	3	11		
12. Storage of prescription drugs not in the prescription department	1	1	3	5	5	3	18	1	11
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	3	2	4	13		4
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)	0	2	3	8	5	4	22		4
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)	9	8	9	6	7	8	47		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	20	16	19	31	19	17	122	3	115
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	2	3	4	4	5	3	21		4
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	2	1	0	3	0	6		
18. Records of dispensing not maintained as required	2	3	2	1	4	1	13		1

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	0	1	0	2	3	2	8	2	3
20. Pharmacist not checking and documenting repackaging or bulk packaging	4	0	3	10	5	5	27	1	18
20a. Pharmacist not documenting final verification of non-sterile compounding	3	1	5	5	1	2	17		4
20b. Pharmacist not documenting final verification of sterile compounding	3	1	3	1	3	4	15	2	16
21. No clean room	0	0	0	0	0	0	0		
21a. Performing sterile compounding outside of a clean room (Added 12/12/13)	0	0	0	0	0	0	0		
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	0	0	0	0	1	0	1		
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.	0	2	0	0	0	0	2		1
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	0	0	0	0	0	0	0		
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	0	0	0		2
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	1	0	1		1

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies 1 - 100
(Formerly Major Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	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.	4	2	3	4	5	6	24	2	33
26a. Documentation that a person who failed a media-fill test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test	0	0	1	0	0	1	2		1
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	0	4		1
29. Unlawful compounding for further distribution by other entities	0	1	0	1	1	0	3		
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	6	4	4	4	6	4	28	3	21
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	0	0	0	0	1	0	1		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	0	0	0	0	1	2		1

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
Routine Inspections Completed	**222**	**159**	**159**	**253**	**193**	**207**	**1193**	**Repeat**	**Repeat**
Total Deficiencies	**160**	**160**	**150**	**238**	**239**	**208**	**947**	**35**	**370**
Average Deficiencies per Inspection	**0.7**	**1.0**	**0.9**	**0.9**	**1.2**	**1.0**	**0.8**		
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	0	0	1	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.	1	7	1	3	1	3	16		7
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	1	1	0	1	0	4	7		7
106. Prescription department substantially not clean and sanitary and in good repair	1	2	0	2	0	0	5		2
107. Current dispensing reference not maintained	1	6	4	2	2	2	17	1	11
108. Emergency access alarm code/key not maintained in compliance	8	8	9	20	10	11	66		18
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	26	23	31	38	37	179	8	53
110. Storage of paraphernalia/Rx devices not in compliance	1	0	0	0	0	0	1		
111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	0	1	2	0	0	0	3		2
112. Biennial taken late but within 30 days	3	2	2	2	0	1	10		
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.	26	20	14	21	16	15	112	4	63

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
114. Records of receipt (e.g. invoices) not on site or retrievable	2	0	0	1	2	0	5		
115. Other records of distributions not maintained as required	0	0	2	0	0	1	3		
116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	2	4	7	12	11	7	43	1	2
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	1	0	2		
119. Not properly documenting partial filling of prescriptions	4	5	3	13	10	11	46	2	27
120. Offer to counsel not made as required	0	0	0	0	0	0	0		
121. Prospective drug review not performed as required	1	2	0	0	0	0	3		
122. Engaging in alternate delivery not in compliance	9	6	5	3	13	6	42		10
123. Engaging in remote processing not in compliance	4	8	11	25	23	14	85	2	9
124. Labels do not include all required information	10	7	5	12	14	12	60	1	15
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	0	8	4	8	10	7	37	1	10
126. Special packaging not used or no documentation of request for non-special packaging	0	0	0	2	1	0	3		5
Repackaging, specialty dispensing, compounding:									
127. Repackaging records and labeling not kept as required or in compliance	17	9	17	20	20	19	102	5	37
128. Unit dose procedures or records not in compliance	2	0	0	0	0	0	2		
129. Robotic pharmacy systems not in compliance	0	0	1	0	0	0	1		
130. Required compounding/dispensing/distribution records not complete and properly maintained	6	4	6	9	8	9	42	2	16
130a. Compounded products not properly labeled	9	9	9	14	14	15	70	2	17

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	Cumulative
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	3	3	1	1	7	7	22		
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	4	3	8	7	8	6	36	2	7
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	0	0	0	0	1	0	1		
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	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	1	1		
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	1	0	0	0	1	0	2		2
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	4	1	3	2	3	0	13		1
139. Emergency medical services procedures or records not in compliance	2	0	0	1	2	2	7		5
140. Emergency kit or stat-drug box procedures or records not in compliance	1	0	1	0	3	2	7		7
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	10	10	10	14	14	12	70	4	19
143. Exceeds pharmacist to pharmacy technician ratio (Added 12/12/13)	0	0	0	0	0	0	0		

Virginia Board of Pharmacy
Inspection Report
March 24, 2020

Deficiencies Above 100
(Formerly Minor Deficiency)

	9/18-11/18	12/18-2/19	3/19-4/19	5/19-7/19	8/19-10/19	11/19-1/20	Total	11/19-1/20	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)	0	0	0	0	0	0	0		6
145. Insufficient enclosures or locking devices (Added 12/12/13)	0	0	0	0	0	0	0		4
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	0	0	0	0	0	0		2
147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. (Added 12/12/13)	0	1	0	0	1	0	2		3
148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy (Added 6/21/18)	3	7	2	11	4	4	31		3

Inspection Deficiencies
September 2012 through January 2020
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCC
Inspections Completed
Percent Of Total Deficiencies
Virginia Board of Pharmacy
March 24, 2020

Pharmaceutical Processors Report-March 24, 2020

- Permit inspections were completed for all 5 conditionally permitted pharmaceutical processors by December 21, 2019
- Dharma Pharmaceuticals, LLC (Bristol) was awarded their pharmaceutical processor permit on January 14, 2020
- Remaining processors have submitted a plan of correction for cited deficiencies to include an intended reinspection date
- Ongoing work to establish the CBD/THC-A product registration process through the Prescription Monitoring Program and patient verification through Virginia Interactive.
- The admin specialist position for the Pharmaceutical Processors program has been filled effective 2/25/2020
- Presentations provided to the Board of Long-Term Care Administrators, LeadingAge VA, UVA 2020 Advance Practice Provider conference and the Board of Audiology and Speech-Language Pathology

Pharmaceutical Processors Program-By the Numbers
As of 2/28/2020

Registered Practitioners	430
Registered Patients	1930
Registered Parents/Guardians	36
Pending applications for Patients	388
Pending applications for Parents/Guardians	20
Registered Agents	0
Pending applications for Registered Agents	0

Discipline Program Report

Open Cases as of 2-28-2020:

	PC	APD	Investigation	FH	IFC	Entry	Pending Closure	TOTALS
Patient Care Cases	31	21	77	1	10	4	0	144
Non-Patient Care Cases	43	7	51	0	10	0	14	125
						TOTAL:		**269**

Notes:

1) Patient care cases:
   - We have thirty-one (31) patient care cases at Probable Cause compared to fifty-three (53) that were reported in December 2019. Eleven (11) of these cases are pending an IFC or FH.
   - We have twenty percent (10%) fewer cases compared to December 2019.
2) Non-patient care cases (inspection cases or compliance related cases)
   - The number of cases is approximately 20% fewer than last reported.
3) Cases greater than 250 work days: We have twenty (28) cases exceeding 250 work days. Of this number, six (6) cases are in CAP status and 21 (21) cases are at a status of formal/informal hearing.

Upcoming Disciplinary Proceedings:

March 24, 2020	Formal Hearing	
April 1, 2020	IFCs	Kris Ratliff/Melvin Boone
April 22, 2020	Formal Hearings	
April 28, 2020	Pilot Committee	Cindy Warriner/Ryan Logan
May 12, 2020	IFCs	Patricia Richards-Spruill/Glenn Bolyard
May 13, 2020	Regulation Committee/Formal Hearings	
May 19, 2020	Pilot Committee	Cindy Warriner/Ryan Logan

Virginia Department of
Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 2 – Fiscal Year 2020

The "Received, Open, Closed" table below shows the number of received and closed cases during the quarters specified and a "snapshot" of the cases still open at the end of the quarter.

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

		Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	C Q
Pharmacy	Number of Cases Received	119	179	146	143	160	171	213	148	126	133	223	211	
	Number of Cases Open	386	355	309	302	271	287	319	303	306	262	259	310	
	Number of Cases Closed	164	204	192	148	185	162	199	161	123	177	237	158	
sical Therapy	Number of Cases Received	9	7	21	6	15	9	4	13	10	9	7	26	
	Number of Cases Open	24	28	39	36	44	48	50	46	44	37	32	46	
	Number of Cases Closed	9	5	9	10	7	2	4	15	11	17	12	13	
sychology	Number of Cases Received	26	13	22	23	23	28	26	20	31	38	27	55	
	Number of Cases Open	87	49	34	46	44	52	57	64	83	75	75	97	
	Number of Cases Closed	17	52	38	16	24	19	24	13	11	46	29	34	

Virginia Department of Health Professions

Average Age of Cases Closed

Quarterly Summary

Quarter 2 - Fiscal Year 2020

e age of cases closed is a measurement of how long it takes, on average, for a case to be processed from entry to closure. These calculations include only cases closed within the quarter speci

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

RD	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q
Audiology	n/a	135.3	259.8	255.7	192	179	463.3	97.4	190.3	149	208	241	
Counseling	292.8	247.9	106.1	251.5	128.2	153.7	185	164.2	161.3	251	279	173	
Dentistry	289.5	271.2	228.7	337.8	182.9	239.7	165	141.5	83.6	192	394	316	
Funeral Directing	166.5	295	223.7	229.3	169.1	383.3	211.8	225.7	298.8	116	259	287	
g Term Care Administrator	260.5	282.8	395	171.2	350.6	424.1	395.5	253	396.8	400	433	291	
Medicine	147.1	135.5	136.9	146.5	135	153.5	133.3	142.1	147.3	240	170	172	
Nurse aide	198.6	191.4	223.8	297.4	273.3	200.7	235.3	150.1	201.7	204	147	164	
Nursing	179.5	207.4	202.1	203.6	204.5	215.8	280.3	192.3	198.3	276	202	300	
Optometry	216.2	95.3	106.3	557.6	268.1	240	190.7	194.2	506.5	379	129	275	
Pharmacy	303.6	343.2	192.9	215.4	172.2	173.7	114.1	160.2	152.3	255	116	275	
Physical therapy	273.7	102.4	291.3	239.4	112	152.5	412.8	389.3	366.5	467	322	280	
Psychology	291.7	357.7	252.7	119.5	183.3	118.8	175.2	170.4	228.6	225	153	72	
Social Work	407.6	366.2	228.8	292.7	123.6	277.5	237.2	113.8	200.7	263	211	271	
Veterinary Medicine	301.2	283.5	295.6	223	357.7	278.7	376.7	321.9	261.9	293	423	285	
Agency total	207.7	222.8	194.1	255.7	186.5	196.4	201.1	173.8	169.2	258	204	214	

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Virginia Department of

Health Professions

Cases Closed in Less than One Year

Fiscal Year Summary

Fiscal Year 2019

t of cases closed in fewer than 365 days shows, from the total of all cases closed during the specified period, from entry to closure. These calculations include only cases closed within the qu

Quarter Date Ranges	
Quarter 1	July 1 - September 30
Quarter 2	October 1- December 31
Quarter 3	January 1 - March 31
Quarter 4	April 1 - June 30

	FY 2014	Change Between FY 15 & FY 14	FY 2015	Change Between FY 16 & FY 15	FY 2016	Change Between FY 17 & FY 16	FY 2017	Change Between FY 18 & FY 17	FY 2018	Change Between FY 19 & FY 18
Audiology	100.0%	-3.2%	96.8%	3.3%	100.0%	-10.5%	89.5%	-10.6%	80.0%	9.3%
Counseling	87.6%	-12.6%	76.6%	-25.8%	56.8%	35.0%	76.8%	13.8%	87.4%	-11.3%
Dentistry	65.1%	11.1%	72.4%	0.0%	72.4%	3.4%	74.8%	13.9%	85.2%	-6.1%
neral Directing	90.8%	5.4%	95.7%	-6.0%	90.0%	-14.4%	77.1%	0.5%	77.4%	8.6%
m Care Administrator	88.6%	1.6%	90.0%	-6.4%	84.2%	-19.0%	68.3%	-38.9%	41.7%	-16.5%
Medicine	91.7%	-1.0%	90.8%	-1.7%	89.3%	5.0%	93.7%	0.1%	93.8%	-9.6%
Nurse Aide	96.1%	-0.1%	96.0%	-2.2%	94.0%	-9.4%	85.1%	-3.0%	82.5%	-0.4%
Nursing	92.3%	-2.2%	90.3%	-4.7%	86.1%	0.7%	86.7%	-9.7%	78.3%	-0.9%
Optometry	83.3%	4.0%	86.7%	4.9%	90.9%	-1.4%	89.7%	-29.4%	63.3%	1.1%
Pharmacy	92.0%	-4.3%	88.0%	4.4%	91.9%	-15.6%	77.6%	14.6%	89.0%	4.3%
ıysical Therapy	95.4%	-5.6%	90.0%	3.4%	93.0%	-33.3%	62.1%	25.3%	77.8%	-130.2%
Psychology	93.7%	0.1%	93.8%	-49.5%	47.3%	21.8%	57.6%	60.0%	92.2%	-8.2%
Social Work	92.7%	-8.3%	85.0%	-28.4%	60.9%	-15.3%	51.5%	57.1%	81.0%	-16.4%
ɪrinary Medicine	95.2%	5.1%	100.0%	-37.6%	62.4%	16.7%	72.8%	-9.2%	66.2%	-4.7%
AGENCY	91.3%	-0.4%	90.9%	-1.6%	89.5%	-6.2%	83.9%	0.7%	84.5%	-5.6%

Closed Within One Year

Fiscal Year 2019

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days Removed): Quarterly Performance Measurement, Q2 2016 - Q2 2020

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. Beginning this quarter. the agency also tracks the Age of Pending Caseload and Time to Disposition based upon a 415 day model(These results are displayed by the green square).

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.

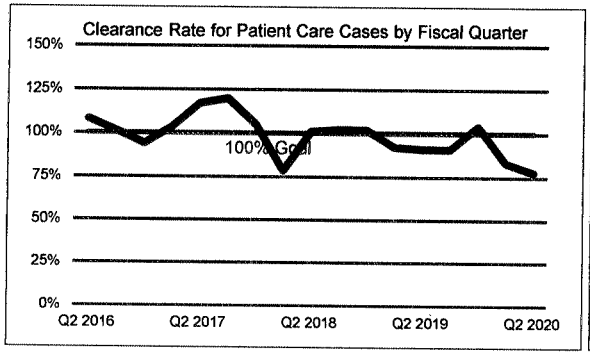
The current quarter's clearance rate is 78%, with 1209 patient care cases received and 940 closed.

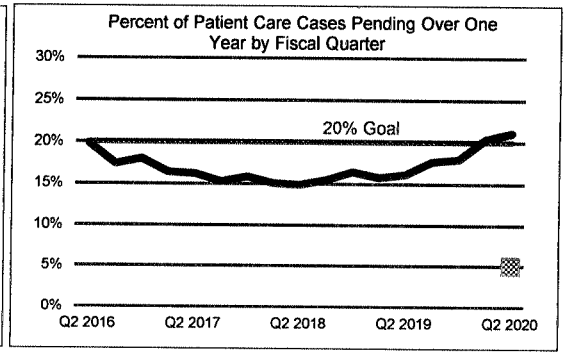
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

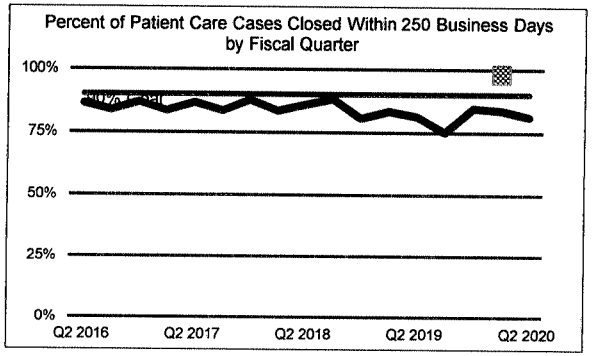
The current quarter shows 21% patient care cases pending over 250 business days with 3590 patient care cases pending and 757 pending over 250 business days. 192 Cases are pending over 415 business days for a percentage of 5%

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 81% of patient care cases being resolved within 250 business days with 893 cases closed and 725 closed within 250 business days. 877 Cases are pending over 415 business days for a percentage of 98%







Submitted: 1/29/2020

Prepared by: Department of Health Professions

Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days Removed), by Board

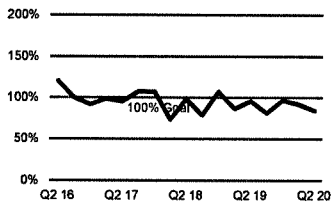
Medicine

Clearance Rate: 91%
399 Cases Received
365 Cases Closed

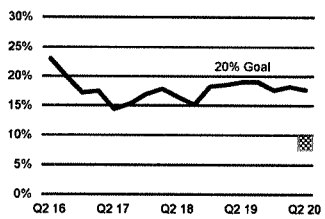
Pending Caseload: 18%
158 Cases Pending over 250 Days
Pending Caseload Over 415: 9%
78 Cases Pending over 415 Days

Time to Disposition: 93%
303 Cases Closed within 250 Days
Time to Disposition within 415: 99%
321 Cases Closed within 415 Days

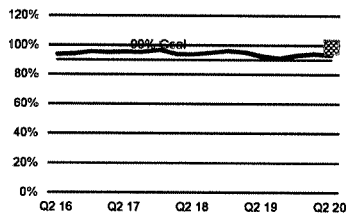
Clearance Rate



Age of Pending Caseload
(percent of cases pending over one year)



Time to Disposition

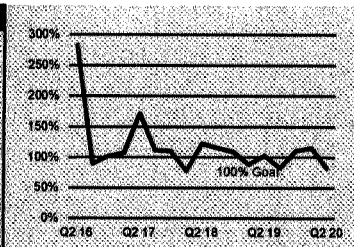


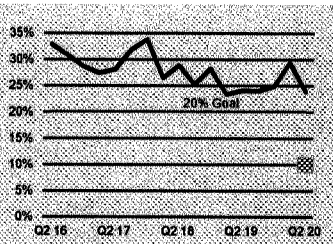
Dentistry

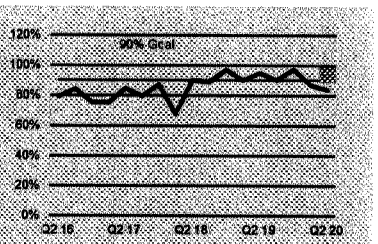
Clearance Rate: 81%
69 Cases Received
56 Cases Closed

Pending Caseload: 24%
51 Cases Pending over 250 Days
Pending Caseload Over 415: 10%
21 Cases Pending over 250 Days

Time to Disposition: 83%
40 Cases Closed within 250 Days
Time to Disposition within 415: 94%
45 Cases Closed within 415 Days





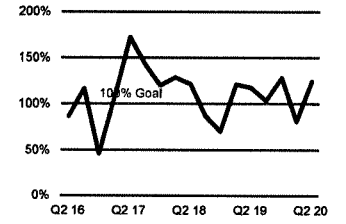


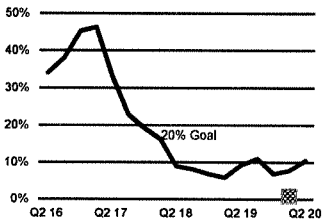
Pharmacy

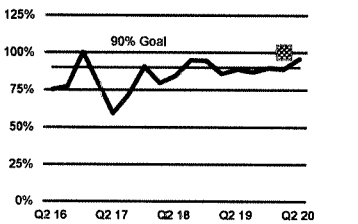
Clearance Rate: 124%
37 Cases Received
46 Cases Closed

Pending Caseload: 11%
14 Cases Pending over 250 Days
Pending Caseload Over 415: 1%
1 Cases Pending over 415 Days

Time to Disposition: 96%
43 Cases Closed within 250 Days
Time to Disposition within 415: 100%
45 Cases Closed within 415 Days







Executive Director's Report – May 18, 2020

Recent Presentations/Meetings:

- February 18-21, 2020, NABP Executive Committee Meeting
- March 5-6, 2020, VSHP Spring Seminar Presentation
- March 11-13, 2020, NABP Item Writing (O'Halloran, Shinaberry, Johnson)
- March 24, 2020, Full Board Meeting – *cancelled due to pandemic*
- March 26, 2020, VCU School of Pharmacy
- April 3, 2020, VCU Researcher Presentation – *cancelled due to pandemic*
- April 7, 2020, PMP InterConnect Steering Committee Meeting
- April 15, 2020, Food and Drug Law Institute (FDLI) Updates in Compounding Conference Presentation – *cancelled due to pandemic*
- April 21, 2020, NABP Districts 1 & 2 Planning Committee Conference Call
- April 22, 2020, Formal Hearing – *cancelled due to pandemic*
- April 27, 2020, Howard University (O'Halloran)
- May 11, 2020, Regulation Committee Meeting/Formal Hearing – *cancelled due to pandemic*
- May 14, NABP Annual Meeting – *virtual meeting*
- COVID-19 Pharmacy Services Subcommittee of the Healthcare Coordination Committee – *ongoing*
- VDH/VHHA Healthcare Coordination Committee Call – *ongoing*
- COVID Partner Call - *ongoing*

Upcoming Meetings:

- June 16, 2020, Full Board Meeting

Staffing:

- Inspector Don Jackson retiring; New inspector, Amy Branson, hired by Enforcement
- Sean Nealon hired as Program Specialist for Pharmaceutical Processor Program
- Licensing administrative assistant vacancy