# COMMONWEALTH OF VIRGINIA
# Meeting of the Board of Pharmacy

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


## Tentative Agenda of Public Hearings and Full Board Meeting
***March 24, 2020***
**9:00AM**

| **TOPIC** | **PAGES** |
|---|---|
| **Call to Order of Public Hearings:** Cindy Warriner, Chairman | |
| • Welcome & Introductions | |
| • Reading of Emergency Evacuation Script | |
| **Public Hearings:** | |
| • Placement of Chemicals into Schedule I | **57-65** |
| • Conforming Drug Schedules to Actions Taken by DEA | **67-78** |
| • Delivery of Dispensed Prescription Devices | **80-83** |
| **Adjournment of Public Hearings** | |
| **Call to Order of Full Board Meeting:** Cindy Warriner, Chairman | |
| • Approval of Agenda | |
| • Approval of Previous Board Meeting Minutes: | |
| o December 4, 2019, Special Conference Committee | **1-6** |
| o December 9, 2019, Full Board Meeting | **7-14** |
| o December 9, 2019, Public Hearing | **15-16** |
| o December 9, 2019, Formal Hearing | **17-18** |
| o December 9, 2019, Formal Hearing | **19-20** |
| o December 10, 2019, Formal Hearing | **21-22** |
| o February 14, 2020, Telephone Conference Call | **23-24** |
| o February 18, 2020, Special Conference Committee | **25-28** |
| o March 10, 2020, Special Conference Committee | **Handout** |

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

**DHP Director's Report:** David Brown, DC

**Legislative/Regulatory/Guidance:** Elaine Yeatts/Caroline Juran

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| • Update on Legislative/ Policy Actions | **29-54** |
| • Update on Regulatory Actions | **55** |
| • Adoption of Exempt Regulation to Schedule Certain Chemicals into Schedule I | **56-65** |
| • Adoption of Exempt Regulation to Conform Drug Schedules to Actions Taken by DEA | **66-78** |
| • Adoption of Final Regulations for Delivery of Dispensed Prescription Devices | **79-83** |
| • Adoption of Proposed Regulations for Pharmaceutical Processors | **84-115** |

- Adoption of Final Regulations for White Bagging and Brown Bagging **116-126**
- Adoption of Regulatory Amendments for Handling Fee for Returned Check **127-139**
- Consider Adoption of Fast-track Regulation to Allow Volunteer CE to Satisfy Live CE Requirement **140**
- Amend Guidance Documents 110-4, 110-8, 110-9, 110-14, 110-27, 110-35, and 110-48 **141-206**
    - Guidance Documents 110-16, 110-19, 110-20, 110-22, 110-32, 110-40 included for informational purposes
- Request to Amend Guidance Document 110-39, Guidance for Continuous Hours Worked by Pharmacists and Breaks **207**
- Request for Guidance Regarding PIC Eligibility Exceptions **208**
- Request to Amend Regulation to Extend Change of PIC Timeframe from 14 to 30 Days **209-210**

**Old Business:**

- Consideration for Requiring CE on a Specific Topic in 2021 **211**
- Verbal Update on Action Item from December 2019 Board Meeting regarding Virginia Immunization Information System

**New Business:**

- Review of the inspection report for PharmaCann's pharmaceutical processor location, PharmaCann's submitted corrective action plan, and PharmaCann's application for a pharmaceutical processor permit **Confidential Handout**

**Reports:**

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – Beth O'Halloran **212**
- Report on Inspection Program – Sammy Johnson **213-223**
- Report on Pharmaceutical Processors – Annette Kelley **224**
- Report on Disciplinary Program – Ellen B. Shinaberry **225-231**
- Executive Director's Report – Caroline D. Juran **232**

**Consideration of consent orders, summary suspensions, or summary restrictions, if any.**

**Adjourn**

****The Board will have a working lunch at approximately 12pm and will honor former board member Rafael Saenz.****

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

(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

| | |
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| 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<br>Mykl Egan, Discipline Case Manager<br>Ileita Redd, Discipline Program Specialist<br>Jess Kelley, DHP Adjudication Specialist |
| Brenda L. Epps<br>0202-005189<br>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. |

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| 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<br>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<br>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.

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| 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<br>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. |

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| 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<br>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 |

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|---|---|
| Patricia Richards-Spruill, Chair | Ellen B. Shinaberry<br>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

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| | Mortier, and Pascale M. El Hayek, pharmacist-in-charge, testified on behalf of Lansdowne Pharmacy.<br><br>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. |

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| 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.

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| | Rose Dematteo, DHP Compliance Case Manager, testified in person on behalf of the Commonwealth.<br><br>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. |

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| 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.

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| 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. |

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| Cynthia Warriner, Chair | Ellen Shinaberry,<br>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

**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., 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 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.**

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.*

**§ 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.**

2/12/20 10:31

INTRODUCED

HB1654

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 ~~pharmacy or~~ outsourcing facility providing such drugs to the Department pursuant to the terms of such a 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 ~~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.*

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# Board of Pharmacy
# Chart of Regulatory Actions as of February 28, 2020

| | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Use of medication carousels and RFID technology [Action 5480]<br>NOIRA - *At DPB* [Stage 8892] |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Brown bagging and white bagging [Action 4968]<br>Proposed - *Register Date: 11/11/19*<br>*Board to adopt final regulations: 3/24/20* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Delivery of dispensed prescriptions; labeling [Action 5093]<br>Proposed - *Register Date: 2/3/20*<br>*Public hearing: 3/24/20*<br>*Comment closes: 4/3/20* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Prohibition against incentives to transfer prescriptions [Action 4186]<br>Final - *At Governor's Office for 646 days* |
| [18 VAC 110 - 20] | Regulations Governing the Practice of Pharmacy | Increase in fees [Action 4938]<br>Final - *At Secretary's Office for 128 days* |
| [18 VAC 110 - 50] | Regulations Governing Wholesale Distributors, Manufacturers and Warehousers | Delivery of Schedule VI prescription devices [Action 5084]<br>Proposed - *Register Date: 10/14/19*<br>*Board to adopt final regulations: 3/24/20* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Registered agents and wholesale distribution [Action 5398]<br>Emergency/NOIRA - *Register Date: 1/6/20*<br>*Comment on NOIRA closed: 2/5/20*<br>*Board to adopt proposed regulations: 3/24/20* |
| [18 VAC 110 - 60] | Regulations Governing Pharmaceutical Processors | Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452]<br>Emergency/NOIRA - *At Secretary's Office for 49 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]

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**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.

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**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.

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**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]

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**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.

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**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]

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**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.

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**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 (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 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]

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**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.

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**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]

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**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.

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**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]

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**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]

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**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.

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**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<br>Review Completed: 5/1/2019<br>Result: Certified |
| **DPB Review** | Submitted on 5/2/2019<br>Economist: Oscar Ozfidan Policy Analyst: Jeannine Rose<br>Review Completed: 6/12/2019<br>*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<br>Result: Approved |
| **Virginia Registrar** | Submitted on 9/18/2019<br>The Virginia Register of Regulations<br>Publication Date: 10/14/2019 Volume: 36 Issue: 4 |

| | |
|---|---|
| **Public Hearings** | **12/09/2019 9:05 AM** |
| **Comment Period** | Ended 12/13/2019<br>0 comments |

| Contact Information | |
|---|---|
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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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go back | open in word

**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

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.

**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<br>Review Completed: 11/13/2019<br>Result: Certified |
| **DPB Review** | Submitted on 11/13/2019<br>Policy Analyst: Melanie West<br>Review Completed: 11/25/2019<br>*DPB's policy memo is "Governor's Confidential Working Papers"* |
| **Secretary Review** | Secretary of Health and Human Resources Review Completed: 12/17/2019 |
| **Governor's Review** | Review Completed: 12/20/2019<br>Result: Approved |
| **Virginia Registrar** | Submitted on 12/20/2019<br>The Virginia Register of Regulations<br>Publication Date: 1/6/2020 Volume: 36 Issue: 10 |
| **Comment Period** | Ended 2/5/2020<br>0 comments |
| **Effective Date** | 12/30/2019 |

| | |
|---|---|
| **Expiration Date** | 6/29/2021 |

| Contact Information | |
|---|---|
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*This person is the primary contact for this board.*
*This stage was created by Elaine J. Yeatts on 10/02/2019*
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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

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

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.

| | |
|---|---|
| 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;

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;

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

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.

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

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

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

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.

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.

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 pharmaceutical 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.

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<br>Review Completed: 5/1/2019<br>Result: Certified |
| **DPB Review** | Submitted on 5/1/2019<br>Economist: Larry Getzler Policy Analyst: Cari Corr<br>Review Completed: 6/14/2019<br>*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<br>Result: Approved |
| **Virginia Registrar** | Submitted on 10/23/2019<br>The Virginia Register of Regulations<br>Publication Date: 11/11/2019 Volume: 36 Issue: 6 |
| **Public Hearings** | 12/09/2019 9:10 AM |

| | |
|---|---|
| **Comment Period** | **Ended 1/10/2020**<br>**3 comments** |

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

*This person is the primary contact for this chapter.*
*This stage was created by Elaine J. Yeatts on 04/01/2019*
16

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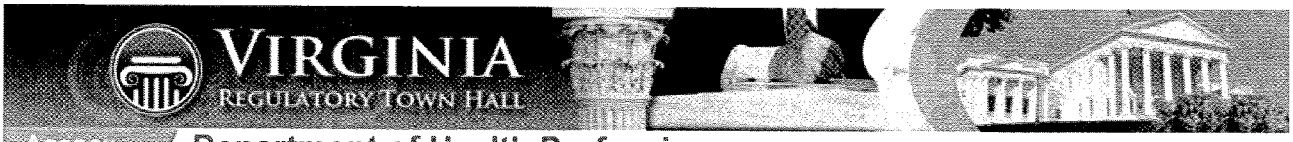



Agency **Department of Health Professions**

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.

## 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<br>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<br>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<br>Riverside Health Systems | Agree with proposed language but asked for allowance for health systems to practice "clear bagging"<br>Also requested some type of phase in period.<br>*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

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;

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 ] .

**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.

**18VAC110-21-120. Requirements for continuing education.**

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the ACPE;

2. One that is approved as a Category I continuing medical education course, the primary focus of which is pharmacy, pharmacology, or drug therapy; or

3. One that is approved by the board in accordance with the provisions of 18VAC110-21-130.

C. Of the 15 contact hours required for annual renewal, at least three hours shall be obtained in courses or programs that are live or real-time interactive. Included in the three hours, the following may be credited:

1. A maximum of one hour for attendance at a board meeting or formal hearing; or

2. A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

D. Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacist, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. The board may grant an extension pursuant to § 54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

F. Pharmacists are required to attest to compliance with the CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years CE documents to verify compliance with the requirements. Pharmacists are required to maintain for two years following renewal the original certificates documenting successful completion of CE, showing the date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

# Virginia Board of Pharmacy

# Guide to Continuing Pharmacy Education Requirements

~~Since 1993,~~ To maintain an active license in Virginia, pharmacists ~~who are licensed in Virginia have been~~ are required to obtain a minimum of 15 contact hours of continuing pharmacy education (CE) per calendar year, at least three of which must be from courses or programs that are live or real-time interactive ~~in order to maintain an active license~~. Pharmacy technicians are required to obtain a minimum of 5 contact hours of CE per calendar year. The requirement for obtaining CE from a live or real-time interactive program does not apply to pharmacy technicians. This brochure is intended to help pharmacists and pharmacy technicians better understand the CE requirements. The Board of Pharmacy prepared this document as a guide in order to promote compliance with the statutes and regulations concerning CE.

**Q. What is the minimum number of CE hours required? When do I have to take them?**
A. The law requires a minimum of 15 contact hours for pharmacists and 5 contact hours for pharmacy technicians per calendar year. For pharmacists, at least three of the required 15 hours must be from courses or programs that are live or real-time interactive. Pharmacists and pharmacy technicians ~~You~~ should ~~receive all your certificates~~ obtain all required CE prior to ~~sending in the license renewal~~ renewing their license or registration in order to properly attest that ~~you~~ they have met the CE requirements. The certificates or transcript of awarded CE should be dated between January 1 and December 31, inclusive, of the calendar year they are used.

**Q: What types of courses or programs may a pharmacist successfully complete to meet the requirement for obtaining at least 3 hours annually of "live or real-time interactive" CE?**
A. The following options will satisfy the requirement for live or real-time interactive CE:

- Programs accredited by the Accreditation Council for Pharmacy Education (ACPE) designated with the letter "L" in the second to last section of the program number;
- Category 1 continuing medical education courses accredited by the American Medical Association (AMA), the primary focus of which is pharmacy, pharmacology, or drug therapy designated with the term "live" in the statement of credit provided to the attendee;
- Board-approved CE designated in the certificate of completion as having been approved by the board as "live or real-time interactive" CE; and
- Credit obtained from the board for:
  - A maximum of one hour for attendance at a board meeting or formal hearing; or
  - A maximum of one hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program or for a foreign-trained student obtaining hours of practical experience.

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

Form for Volunteer Practice" found at www.dhp.virginia.gov/pharmacy under "Forms and Applications". Credit

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

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

**Q. What is the NABP CPE Monitor and must I sign up for this?**
A. NABP CPE Monitor is a collaborative service from NABP and ACPE that provides an electronic system for pharmacists and pharmacy technicians to track their completed CE credits. All ACPE-approved continuing education credits are now required to report to CPE Monitor within 60 days of completion of a course. In order to receive credit for an ACPE-approved continuing education course, you must have an e-profile ID number obtained from CPE Monitor through www.nabp.pharmacy and provide this number to receive credit for these ACPE-approved CE courses.

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

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

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

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

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

**Q. I received my pharmacist license from Virginia in October. When will I need to renew my license for the first time and how do I comply with the CE requirement?**
A. Regulation 18VAC110-21-~~1100-80~~ states that a pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year. Regulation 18VAC110-21-~~1300-90~~ states a pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure, at least three of which must be from courses or programs that are live or real-time interactive. Therefore, unless exempted from obtaining CE as indicated in §54.1-3314.1 C and discussed above, the pharmacist must obtain 1.5 CEUs or 15 contact hours of CE between the date of issuance of the Virginia pharmacist license and December 31 of the following year.

**Q. I received my pharmacy technician registration from Virginia in July. When will I need to renew my registration for the first time and how do I comply with the CE requirement?**
A. Regulation 18VAC110-~~20-105~~ 21-170 states that a pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Regulation 18VAC110-~~20-106~~ 21-180 states a pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved CE for each annual renewal of registration. Therefore, the pharmacy technician must obtain 0.5 CEUs or 5 contact hours of CE between the date of issuance of the Virginia pharmacy technician registration and December 31 of the following year.

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

**Q. Do I have to obtain credits from any particular providers?**
A. Yes. In order to meet the CE requirements, courses must be ACPE-approved, Board-approved, or ~~certain~~ Category 1 CME, the primary focus of which is pharmacy, pharmacology, or drug therapy. Any credits taken that do not meet these requirements cannot be used to satisfy CE hours. For pharmacists, at least three of the required 15 hours must be from courses or programs that are live or real-time interactive.

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

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

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

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

**Q. What should I do if the Board audits me?**
A. Whenever the Board contacts you, you should respond promptly. Failure to respond may cause the Board to pursue disciplinary action. If the Board audits your continuing pharmacy education credits, find your original certificates and make a copy for yourself or download a copy of your transcript from NABP CPE Monitor and provide the Board with this transcript. Send the original certificates or printed transcript to the Board office by the deadline in the letter. Although not required, you may want to send your response by certified mail so that you have proof of mailing. If you have lost some or all of your certificates, you should immediately contact the respective providers for a replacement certificate and inform the Board of your actions. The Board has approved standard sanctions for CE non-compliance which can be found in guidance document 110-42.

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

- 15 contact hours for pharmacists, at least 3 hours of which must be from live or real-time interactive courses or programs, or 5 contact hours for pharmacy technicians (some courses may carry a different number of credits for other professions)
- ACPE approved for either pharmacists, pharmacy technicians, or both (look for the ACPE logo), or Category 1 CME courses focused on pharmacy, pharmacology or drug therapy
- each of your CE certificates or the CE transcript shows a "date issued" on or prior to December 31 for the year in question.

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

Guidance document: 110-8

Revised: March 24, 2020
Effective: May 13, 2020

# Virginia Board of Pharmacy
## Prescriptive Authority in Virginia

Reference: § 54.1-3400 *et seq.* of the Code of Virginia commonly known as the Drug Control Act and § 54.1-3303 of the Code of Virginia, and respective Board regulations.

In Virginia all prescription drugs are categorized into schedules. Schedules I through V, for the most part, mirror the federal schedules. All prescription or legend drugs not included in Schedules II through V are placed in Schedule VI in Virginia and are also referred to as "controlled" drugs or substances within the Drug Control Act. This is sometimes confusing as the term "controlled" is usually applied only to drugs in Schedules II through V.

Before prescribing any drug in Schedules II-V, a practitioner must obtain a registration from the U.S Drug Enforcement Administration (DEA). The DEA registration must also be on any prescription written for a Schedule II-V drug.

Nurse practitioners who meet certain criteria may be ~~issued a license~~ authorized to prescribe Schedule II-VI drugs by the Boards of Nursing and Medicine. Unless a nurse practitioner has been authorized for autonomous practice, the authorization to prescribe schedules or categories of drugs will be set out in a practice agreement with a collaborating physician. Nurse practitioners with prescriptive authority may dispense samples of those drugs they are authorized to prescribe and may also sign for the receipt of those samples.

Physician assistants (PA's) who meet criteria and have been approved by the Board of Medicine for prescriptive authority may prescribe Schedule II-VI drugs that have been approved by the ~~supervising~~ collaborating ~~medical practitioner~~ physician or podiatrist. A prescription written by a physician assistant for a Schedule II-V drug must include the name of the ~~supervising~~ collaborating physician or podiatrist. Physician assistants may dispense samples of those drugs they are authorized to prescribe and may sign for receipt of samples.

Nurse practitioners or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For nurse practitioners, there is a 10-digit license number beginning with ~~0017~~0024, which should be on the prescription. To verify the license ~~and~~ click on "License Lookup" at ~~can be verified through the web site~~ www.dhp.virginia.gov ~~under "License Lookup" and~~ using "Licensed Nurse Practitioner" for ~~checking~~ the occupation. On the screen displaying the results of the individual's licensure information, the phrase "Rx Authority" will appear under "Specialization" if the nurse practitioner is authorized to prescribe drugs. ~~"Authorization to Prescribe"~~ For physician assistants, there is a 10-digit license number beginning with 011, which can be verified through the web site www.dhp.virginia.gov under "License Lookup" and checking the occupation "Physician Assistant."

Practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine have independent prescriptive authority and may prescribe drugs in Schedules II through VI.

Optometrists who have been certified to use therapeutic pharmaceutical agents have independent authority to prescribe and administer certain controlled substances and devices to treat diseases and abnormal conditions of the human eye and its adnexa in these categories:

1. Oral analgesics - Schedule II controlled substances consisting of hydrocodone in combination with acetaminophen and Schedule III, IV and VI narcotic and non-narcotic agents. They may also prescribe gabapentin in Schedule V.

2. Topically administered Schedule VI agents:
    a. Alpha-adrenergic blocking agents;
    b. Anesthetic (including esters and amides);
    c. Anti-allergy (including antihistamines and mast cell stabilizers);
    d. Anti-fungal;
    e. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
    f. Anti-infective (including antibiotics and antivirals);
    g. Anti-inflammatory;
    h. Cycloplegics and mydriatics;
    i. Decongestants; and
    j. Immunosuppressive agents.
3. Orally administered Schedule VI agents:
    a. Aminocaproic acids (including antifibrinolytic agents);
    b. Anti-allergy (including antihistamines and leukotriene inhibitors);
    c. Anti-fungal;
    d. Anti-glaucoma (including carbonic anhydrase inhibitors and hyperosmotics);
    e. Anti-infective (including antibiotics and antivirals);
    f. Anti-inflammatory (including steroidal and non-steroidal);
    g. Decongestants; and
    h. Immunosuppressive agents.

Inquiries as to the certification of an optometrist to prescribe therapeutic pharmaceutical agents or requests for regulations may be made by checking the web site www.dhp.virginia.gov under "on-line license lookup" and checking for the occupation "TPA certified optometrist." After June 30, 2004, every person who is initially licensed to practice optometry in Virginia must meet the qualifications for a TPA-certified optometrist.

In order to be valid, prescriptions must meet the criteria set forth in § 54.1-3303 of the Code of Virginia (attached). A prescription must be written in the context of a bona fide practitioner-patient relationship, for a medicinal or therapeutic purpose, and within the course of the professional practice of the prescriber. The elements that constitute a bona fide practitioner patient relationship are set forth in this statute.

***from the Code of Virginia:***

***§ 54.1-3303. (Effective July 1, 2020) Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.***

*A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32. The prescription shall be issued for a medicinal or therapeutic purpose and may be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship.*

*For purposes of this section, a bona fide practitioner-patient-pharmacist relationship is one in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to his patient for a medicinal or therapeutic purpose within the course of his professional practice. In addition, a bona fide practitioner-patient relationship means that the practitioner shall (i) ensure that a medical or drug history is obtained; (ii) provide information to the patient about the benefits and risks of the drug being prescribed; (iii) perform or have performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; except for medical emergencies, the examination of the patient shall have been performed by the practitioner himself, within the group in which he practices, or by a consulting practitioner prior to issuing a prescription; and (iv) initiate additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. A practitioner who performs or has performed an appropriate examination of the patient required pursuant to clause (iii), either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, for the purpose of establishing a bona fide practitioner-patient relationship, may prescribe Schedule II through VI controlled substances to the patient, provided that the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.*

*For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.*

*For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural*

*animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.*

*Any practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than medicinally or for therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.*

*B. In order to determine whether a prescription that appears questionable to the pharmacist results from a bona fide practitioner-patient relationship, the pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed. The person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.*

*No prescription shall be filled unless there is a bona fide practitioner-patient-pharmacist relationship. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription.*

*C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona-fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.*

*D. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, a nurse practitioner, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).*

*E. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*F. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*G. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers' professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.*

*H. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.*

*I. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.*

***§ 54.1-3303. (Effective until July 1, 2020) Prescriptions to be issued and drugs to be dispensed for medical or therapeutic purposes only.***

*A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, or by a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32.*

*B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship.*

*A bona fide practitioner-patient relationship shall exist if the practitioner has (i) obtained or caused to be obtained a medical or drug history of the patient; (ii) provided information to the patient about the benefits and risks of the drug being prescribed; (iii) performed or caused to be performed an appropriate examination of the patient, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically; and (iv) initiated additional interventions and follow-up care, if necessary, especially if a prescribed drug may have serious side effects. Except in cases involving a medical emergency, the examination required pursuant to clause (iii) shall be performed by the practitioner prescribing the controlled substance, a practitioner who practices in the same group as the practitioner prescribing the controlled substance, or a consulting practitioner. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health*

*department and is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, the examination required by clause (iii) shall not be required.*

*A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient, provided that, in cases in which the practitioner has performed the examination required pursuant to clause (iii) by use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically, the prescribing of such Schedule II through V controlled substance is in compliance with federal requirements for the practice of telemedicine.*

*For the purpose of prescribing a Schedule VI controlled substance to a patient via telemedicine services as defined in § 38.2-3418.16, a prescriber may establish a bona fide practitioner-patient relationship by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; and (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations. Nothing in this paragraph shall permit a prescriber to establish a bona fide practitioner-patient relationship for the purpose of prescribing a Schedule VI controlled substance when the standard of care dictates that an in-person physical examination is necessary for diagnosis. Nothing in this paragraph shall apply to: (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.*

*For purposes of this section, a bona fide veterinarian-client-patient relationship is one in which a veterinarian, another veterinarian within the group in which he practices, or a veterinarian with whom he is consulting has assumed the responsibility for making medical judgments regarding the health of and providing medical treatment to an animal as defined in § 3.2-6500, other than an equine as defined in § 3.2-6200, a group of agricultural animals as defined in § 3.2-6500, or bees as defined in § 3.2-4400, and a client who is the owner or other caretaker of the animal, group of agricultural animals, or bees has consented to such treatment and agreed to follow the instructions of the veterinarian. Evidence that a veterinarian has assumed responsibility for making medical judgments regarding the health of and providing medical treatment to an animal, group of agricultural animals, or bees shall include evidence that the veterinarian (A) has sufficient knowledge of the animal, group of agricultural animals, or bees to provide a general or preliminary diagnosis of the medical condition of the animal, group of agricultural animals, or bees; (B) has made an examination of the animal, group of agricultural animals, or bees, either physically or by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically or has become familiar with the care and keeping of that species of animal or bee on the premises of the client, including other premises within the same operation or production system of the client, through medically appropriate and timely visits to the premises at which the animal, group of agricultural animals, or bees are kept; and (C) is available to provide follow-up care.*

*C. A prescription shall only be issued for a medicinal or therapeutic purpose in the usual course of treatment or for authorized research. A prescription not issued in the usual course of treatment or for authorized research is not a valid prescription. A practitioner who prescribes any controlled substance with the knowledge that the controlled substance will be used otherwise than for medicinal or therapeutic purposes shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the distribution or possession of controlled substances.*

*D. No prescription shall be filled unless a bona fide practitioner-patient-pharmacist relationship exists. A bona fide practitioner-patient-pharmacist relationship shall exist in cases in which a practitioner prescribes, and a pharmacist dispenses, controlled substances in good faith to a patient for a medicinal or therapeutic purpose within the course of his professional practice.*

*In cases in which it is not clear to a pharmacist that a bona fide practitioner-patient relationship exists between a prescriber and a patient, a pharmacist shall contact the prescribing practitioner or his agent and verify the identity of the patient and name and quantity of the drug prescribed.*

*Any person knowingly filling an invalid prescription shall be subject to the criminal penalties provided in § 18.2-248 for violations of the provisions of law relating to the sale, distribution or possession of controlled substances.*

*E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, for the close contact except for the physical examination required in clause (iii) of subsection B; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona-fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.*

*F. A pharmacist may dispense a controlled substance pursuant to a prescription of an out-of-state practitioner of medicine, osteopathy, podiatry, dentistry, optometry, or veterinary medicine, a nurse practitioner, or a physician assistant authorized to issue such prescription if the prescription complies with the requirements of this chapter and the Drug Control Act (§ 54.1-3400 et seq.).*

*G. A licensed nurse practitioner who is authorized to prescribe controlled substances pursuant to § 54.1-2957.01 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*H. A licensed physician assistant who is authorized to prescribe controlled substances pursuant to § 54.1-2952.1 may issue prescriptions or provide manufacturers' professional samples for controlled substances and devices as set forth in the Drug Control Act (§ 54.1-3400 et seq.) in good faith to his patient for a medicinal or therapeutic purpose within the scope of his professional practice.*

*I. A TPA-certified optometrist who is authorized to prescribe controlled substances pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32 may issue prescriptions in good faith or provide manufacturers'*

*professional samples to his patients for medicinal or therapeutic purposes within the scope of his professional practice for the drugs specified on the TPA-Formulary, established pursuant to § 54.1-3223, which shall be limited to (i) analgesics included on Schedule II controlled substances as defined in § 54.1-3448 of the Drug Control Act (§ 54.1-3400 et seq.) consisting of hydrocodone in combination with acetaminophen; (ii) oral analgesics included in Schedules III through VI, as defined in §§ 54.1-3450 and 54.1-3455 of the Drug Control Act (§ 54.1-3400 et seq.), which are appropriate to relieve ocular pain; (iii) other oral Schedule VI controlled substances, as defined in § 54.1-3455 of the Drug Control Act, appropriate to treat diseases and abnormal conditions of the human eye and its adnexa; (iv) topically applied Schedule VI drugs, as defined in § 54.1-3455 of the Drug Control Act; and (v) intramuscular administration of epinephrine for treatment of emergency cases of anaphylactic shock.*

*J. The requirement for a bona fide practitioner-patient relationship shall be deemed to be satisfied by a member or committee of a hospital's medical staff when approving a standing order or protocol for the administration of influenza vaccinations and pneumococcal vaccinations in a hospital in compliance with § 32.1-126.4.*

*K. Notwithstanding any other provision of law, a prescriber may authorize a registered nurse or licensed practical nurse to approve additional refills of a prescribed drug for no more than 90 consecutive days, provided that (i) the drug is classified as a Schedule VI drug; (ii) there are no changes in the prescribed drug, strength, or dosage; (iii) the prescriber has a current written protocol, accessible by the nurse, that identifies the conditions under which the nurse may approve additional refills; and (iv) the nurse documents in the patient's chart any refills authorized for a specific patient pursuant to the protocol and the additional refills are transmitted to a pharmacist in accordance with the allowances for an authorized agent to transmit a prescription orally or by facsimile pursuant to subsection C of § 54.1-3408.01 and regulations of the Board.*

# Virginia Board of Pharmacy
# Pharmacy Inspection Deficiency Monetary Penalty Guide

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location | 54.1-3434 and 18VAC110-20-110 | must have documentation | 2000 |
| 2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe | 54.1-3434 and 18VAC110-20-110 | | 1000 |
| 3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program | 54.1-3321 and 18VAC110-20-111 | per individual | First documented occurrence = no penalty<br>Repeat = $ penalty<br>250 |
| 4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration | ~~18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105~~<br>18VAC110-21-60, 18VAC110-21-110, and 18VAC110-21-170 | per individual | First documented occurrence = no penalty<br>Repeat = $ penalty<br>100 |
| 5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists | 54.1-3320<br>18VAC110-20-112 | | 500 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 6. Exceeds pharmacist to pharmacy technician ratio | 54.1-3320<br>18VAC110-20-112 | per each technician over the ratio | First documented occurrence = no penalty<br>Repeat = $ penalty<br>100 |
| 7. Change of location or remodel of pharmacy without submitting application or Board approval | 18VAC110-20-140 | must submit an application and fee | 250 |
| 8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit. | 18VAC110-20-150 and 18VAC110-20-10 | determined using inspector's or pharmacy's calibrated thermometer | First documented occurrence = no penalty; drugs may be embargoed<br>Repeat = $ penalty<br>100<br>Drugs may be embargoed |
| 9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty. | 18VAC110-20-180 and 18VAC110-20-190 | | 1000 |
| 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. The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy. | 18VAC110-20-180 | | First documented occurrence and no drug loss = no penalty<br>Drug loss or repeat = $ penalty<br>250 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 10. Unauthorized access to alarm or locking device to the prescription department | 18VAC110-20-180 and 18VAC110-20-190 | | 1000 |
| 11. Insufficient enclosures or locking devices | 18VAC110-20-190 | | First documented occurrence and no drug loss = no penalty<br>Drug loss or repeat = $ penalty<br>500 |
| 12. Storage of prescription drugs not in the prescription department | 18VAC110-20-190 | | 500 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 12a. Schedule II drugs are not dispersed with other schedules of drugs, ~~or~~ maintained in a securely locked cabinet, drawer, or safe, or maintained in a manner that combines the two methods. | 18VAC110-20-200 | ~~Do not cite if stored in a combination method as allowed in Guidance Document 110-40.~~ | First documented occurrence and no drug loss of Schedule II = no penalty<br>Drug loss or repeat = $ penalty<br>250 |
| 13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V. | 54.1-3404 and 18VAC110-20-240 | Cite Deficiency 113 if only expired drugs not included in inventory. | Over 30 days late and first documented occurrence = no penalty<br>Over 30 days late and repeat = $ penalty<br>500 |
| 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 | 54.1-3434 and 18VAC110-20-240 | Per occurrence. Cite Deficiency 113 if only expired drugs not included in inventory. | 500 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 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~~<br><br>Perpetual inventory not being maintained as required as it does not:<br><br>Include all Schedule II drugs received and dispensed;<br>Accurately indicate the physical count of each Schedule II drug "on-hand" at the time of performing the inventory;<br>Include a reconciliation of each Schedule II drug at least monthly; or<br>Include a written explanation for any difference between the physical count and the theoretical count.<br><br>Monthly perpetual inventory is performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required. | 18VAC110-20-240 | Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant. | 250 |
| 16. Theft/unusual loss of drugs not reported to the Board as required | 54.1-3404 and 18VAC110-20-240 | per report/theft-loss | 250 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 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) | 54.1-3404 and 18VAC110-20-240 | | 250 |
| 18. Records of dispensing not maintained as required | 54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425 | | 250 |
| 19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions | 18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425 | 10% threshold for documentation | 500 |
| 20. Pharmacist not checking and documenting repackaging or bulk packaging | 54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425 | Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant. | 250 |
| 20a. Pharmacist not documenting verification of accuracy of non-sterile compounding process and integrity of compounded products | 54.1-3410.2, 18VAC110-20-355 | 10% threshold | 500 |
| 20b. Pharmacist not documenting verification of accuracy of sterile compounding process and integrity of compounded products | 54.1-3410.2, 18VAC110-20-355 | | 5000 |
| 21. No clean room | 54.1-3410.2 | | 10000 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 21a. Performing sterile compounding outside of a clean room. | 54.1-3410.2 | Compliant clean room present but not utilized for preparation of compounded sterile drug products. | 3000 |
| 21b. Presterilization procedures for high-risk level CSPs, such as weighing and mixing, are completed in areas not classified as ISO Class 8 or better. | 54.1-3410.2 | | 500 |
| 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. | 54.1-3410.2 | Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification | 3000 |
| 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. | 54.1-3410.2 | Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification | 1000 |
| 24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas | 54.1-3410.2 | | 2000 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 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) | 54.1-3410.2 | | 5000 |
| 25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved fingertip testing for persons performing high-risk level compounding of sterile preparations. | 54.1-3410.2 | Review 2 most recent reports. Media-fill testing and gloved fingertip testing must be performed no later than the last day of the sixth month from the date the previous media-fill test and gloved fingertip testing was initiated. | 5000 |
| 25b. High-risk compounded sterile preparations intended for use are improperly stored | 54.1-3410.2 | | 5000 |
| 25c. Documentation that a person who failed a media-fill test or gloved fingertip 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 and gloved fingertip test | 54.1-3410.2 | | 5000 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 26. No documentation of initial and annual (12 months) media-fill testing or gloved fingertip testing for persons performing low and medium-risk level compounding of sterile preparations. | 54.1-3410.2 | Review 2 most recent reports. Media-fill testing and gloved finger-tip testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test and gloved fingertip testing was initiated. | 500 |
| 26a. Documentation that a person who failed a media-fill test or gloved fingertip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved fingertip test | 54.1-3410.2 | | 500 |
| 27. Compounding using ingredients in violation of 54.1-3410.2. | 54.1-3410.2 | | 1000 |
| 28. Compounding copies of commercially available products | 54.1-3410.2 | per Rx dispensed up to maximum of 100 RX or $5000 | 50 |
| 29. Unlawful compounding for further distribution by other entities | 54.1-3410.2 | | 500 |

| Deficiency | Law/Reg Cite | Conditions | $ Monetary Penalty |
|---|---|---|---|
| 30. Security of after-hours stock not in compliance | 18VAC110-20-450 | | First documented occurrence and no drug loss = no penalty<br>Drug loss or repeat = $ penalty<br>500 |
| 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. | 18VAC110-20-555 | Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C) | First documented occurrence and no known patient harm = no penalty<br>Repeat = $ penalty<br>250 |
| 32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling | 54.1-3410.2 | | 2000 |
| 33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD) | 54.1-3410.2 | | 1000 |
| 34. Combined with Deficiency 142 – 12/2013. | | | |
| 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 | 18VAC110-20-395 | | 250 |

## Other Deficiencies

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

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 101. Repealed 6/2011 | | |
| 102. Special/limited-use scope being exceeded without approval | 18VAC110-20-120 | |
| 103. Repealed 12/2013 | | |
| 104. Sink with hot and cold running water not available within the prescription department. | 18VAC110-20-150 | |
| 105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit | 18VAC110-20-150 and 18VAC110-20-10 | determined using inspector's calibrated thermometer |
| 106. Prescription department substantially not clean and sanitary and in good repair | 18VAC110-20-160 | must have picture documentation |
| 107. Current dispensing reference not maintained | 18VAC110-20-170 | |
| 108. Emergency access alarm code/key not maintained in compliance | 18VAC110-20-190 | |
| 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 | 54.1-3457<br>18VAC110-20-200<br>18VAC110-20-355 | 10% threshold |

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| stock container) | | |
| 110. Storage of paraphernalia/Rx devices not in compliance | 18VAC110-20-200 | |
| 111. Storage of prescriptions awaiting delivery outside of the prescription department not in compliance | 18VAC110-20-200 | |
| 112. Biennial taken late but within 30 days | 54.1-3404 and 18VAC110-20-240 | |
| 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. | 54.1-3404, 54.1-3434 and 18VAC110-20-240 | |
| 114. Records of receipt (e.g. invoices) not on site or retrievable | 54.1-3404 and 18VAC110-20-240 | |
| 115. Other records of distributions not maintained as required | 54.1-3404 and 18VAC110-20-240 | |
| 116. Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.) | 54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285 18VAC110-20-270 | 10% threshold |
| 117. Deficiency 117 combined with Deficiency 116 – 6/2011 | | |
| 118. Schedule II emergency oral prescriptions not dispensed in compliance | 54.1-3410 and 18VAC110-20-290 | >3 |
| 119. Not properly documenting partial filling of prescriptions | 54.1-3412, 18VAC110-20-255,18VAC110-20-310, and 18VAC110-20-320 | |

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 120. Offer to counsel not made as required | 54.1-3319 | |
| 121. Prospective drug review not performed as required | 54.1-3319 | |
| 122. Engaging in alternate delivery not in compliance | 18VAC110-20-275 | |
| 123. Engaging in remote processing not in compliance | 18VAC110-20-276 and 18VAC110-20-515 | |
| 124. Labels do not include all required information | 54.1-3410, 54.1-3411 and 18VAC110-20-330 | 10% Threshold<br>Review 25 prescriptions |
| 125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages | 18VAC110-20-340 | |
| 126. Special packaging not used or no documentation of request for non-special packaging | 54.1-3426, 54.1-3427 and 18VAC110-20-350 | 10% threshold<br>Review 25 prescriptions |
| 127. Repackaging records and labeling not kept as required or in compliance | 18VAC110-20-355 | 10% threshold |
| 128. Unit dose procedures or records not in compliance | 18VAC110-20-420 | |
| 129. Robotic pharmacy systems not in compliance | 18VAC110-20-425 | |
| 130. Required compounding/dispensing/distribution records not complete and properly maintained | 54.1-3410.2 | |
| 130a Compounded products not properly labeled | 54.1-3410.2 | |

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained | 54.1-3410.2 | |
| 132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements | 54.1-3410.2 | |
| 133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2 | 54.1-3410.2 | |
| 134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured | 18VAC110-20-440 | |
| 135. Policies and procedures for drug therapy reviews not maintained or followed | 18VAC110-20-440 | |
| 136. After hours access to a supply of drugs or records not in compliance | 18VAC110-20-450 | 10% threshold |
| 137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done | 18VAC110-20-460 | 10% threshold |
| 138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance | 54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555 | Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements. |
| 139. Emergency medical services procedures or records not in compliance | 18VAC110-20-500 | 10% threshold |

| Deficiency | Law/Regulation Cite | Conditions |
|---|---|---|
| 140. Emergency kit or stat-drug box procedures or records not in compliance | 18VAC110-20-540 and 18VAC110-20-550 | 10 % threshold |
| 141. Maintaining floor stock in a long-term care facility when not authorized | 18VAC110-20-520 and 18VAC110-20-560 | |
| 142. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization | 18VAC110-20-418 | |
| 143. Repealed 6/21/2018 | | |
| 144. Repealed 6/21/2018 | | |
| 145. Repealed 6/21/2018 | | |
| 146. Repealed 6/21/2018 | | |
| 147. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions. | 54.1-3410.2 | |
| 148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy | 54.1-3404 and 18VAC110-20-240 | |

**NOTE:** A "repeat" deficiency is a deficiency that was cited during the routine or focused inspection performed immediately prior to the current routine inspection and after July 1, 2018.

**Examples:**
Routine inspection on 7/1/18 – Cited for Deficiency 3. No monetary penalty.
Routine inspection on 7/1/20. Cited for Deficiency 3. Monetary penalty.

Routine inspection on 7/1/18 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/20 – No deficiency.
Routine inspection on 7/1/22 – Cited for deficiency 3. No monetary penalty.
Routine inspection on 7/1/24 – Cited for deficiency 3. Monetary penalty.

Guidance document: 110-14

Adopted: December 9, 2019
Effective: February 6, 2020

# VIRGINIA BOARD OF PHARMACY

## Statistically Valid Sample Size for Pharmaceutical Processors

The Board deems that a sample size consistent with the sampling requirements found in the United States Pharmacopeia Chapter < 561> *Articles of Botanical Origin* will satisfy the requirement in Regulation 18VAC110-60-300 for a "statistically valid sample."

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

*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.*

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

*An Act to amend and reenact § 54.1-3442.6 of the Code of Virginia, relating to cannabidiol oil and THC-A oil; sample testing.*

[S 1045]

Approved

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

**1. That § 54.1-3442.6 of the Code of Virginia is amended and reenacted as follows:**

**§ 54.1-3442.6. Permit to operate pharmaceutical processor.**

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

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

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing and delivering in person cannabidiol oil and THC-A oil to a registered patient, 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) a process for the wholesale distribution of and the transfer of cannabidiol oil and THC-A oil products between pharmaceutical processors.

*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. 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.*

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

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

~~F.~~ *G.* 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.

~~G.~~ *H.* 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.

~~H.~~ *I.* Every pharmaceutical processor shall adopt policies for pre-employment drug screening and

regular, ongoing, random drug screening of employees.

Guidance document: 110-14

Adopted: ~~December 9, 2019~~
Effective: ~~February 6, 2020~~

DRAFT

# VIRGINIA BOARD OF PHARMACY

## Statistically Valid Sample Size for Pharmaceutical Processors

The Board deems that a "statistically valid sample" shall be a sample consistent with provisions of subsection D of § **54.1-3442.6**, as amended by SB1045 of the 2020 General Assembly:

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

*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.*

*§* ***54.1-3442.6. Permit to operate pharmaceutical processor.***

*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. 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.*

# Virginia Board of Pharmacy

## PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

**New Pharmacies:**

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Additionally, the alarm must have at least one hard-wired communication method and a notification of any breach of the alarm must be communicated to the pharmacist-in-charge or a pharmacist working at the pharmacy. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.

- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a $150 reinspection fee will be assessed in order to schedule and conduct the reinspection.

- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must

ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.

- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

- Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, you must notify the board office, and a pharmacist shall continue to be on site on a daily basis.

- Once a permit has been issued, the pharmacy shall be fully operational within 90 days of issuance. For good cause shown, such as circumstances beyond the control of the permit holder, the board may grant an extension.

**Upon taking over responsibility as PIC:**

- A pharmacy permit application must be submitted to the Board indicating the effective date you intend to assume the role as PIC. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Assuming you are eligible to assume the role of PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on April 30th annually. Be sure that the permit is renewed each year. *Note: A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.*

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."

- Take an incoming change of PIC inventory of all Schedule II, III, IV, and V controlled substances, to include all expired drugs in Schedules II through V, prior to opening for business on the date you first assume the role as PIC, i.e., the effective date for the change of PIC indicated on the application. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business, if you performed the inventory the night before the effective date for the change of PIC. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or

distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm.

- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy.

- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board-approved training program for not more than nine months from the date the trainee began performing duties restricted to a pharmacy technician. When considering a person for employment as a pharmacy technician, verify through "License Lookup" at www.dhp.virginia.gov/pharmacy that the person has not been a registered pharmacy technician within the past 5 years. If the person has a pharmacy technician registration that expired less than 5 years ago, he or she must first renew or reinstate this registration before being authorized to perform the duties of a pharmacy technician in the pharmacy.

- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov . You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -13°F and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.

- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

**Safeguards against Diversion of All Controlled Substances:**

- The PIC "shall provide safeguards against diversion of all controlled substances". This responsibility should be taken very seriously. When an investigation involving the theft or loss of controlled substances is performed by the Board, the role of the PIC in providing safeguards against diversion is evaluated.

- It is the policy of the Board to include the name of the PIC (s) in the findings of fact in any disciplinary proceeding involving diversion of drugs.

- The PIC shall:

  - Ensure all security measures are in compliance and operational, e.g., locks to enclosures are functional, access to key and alarm code is restricted to pharmacists that practice at the location, emergency key and alarm code is securely stored;

  - Ensure the biennial inventory of **all** drugs in Schedules II, III, IV, and V, to include any expired drugs in Schedules II-V, is performed on any date which is within two years of the previous biennial inventory. Additional guidance on how to perform an inventory, e.g., which drugs must be physically counted, is found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Ensure the pharmacy is in compliance each month with the perpetual inventory requirement of Schedule II drugs found in Regulation 18VAC110-20-240. Be sure to include **all** Schedule II drugs in the monthly perpetual inventory requirement, to include any drugs on-hand that were not dispensed during that month and any expired drugs. Additional guidance on performing the monthly perpetual inventory of Schedule II drugs may be found in Guidance Document 110-16 at http://www.dhp.virginia.gov/pharmacy/pharmacy_guidelines.htm

  - Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.

  - Not permit access to the prescription department or controlled substances by a pharmacist, pharmacy intern, or pharmacy technician whose license or registration is currently suspended or revoked.

- The Board also offers the following *suggested* best practices to safeguard against diversion of controlled substances:

  - Perform state and federal criminal background checks on all personnel with access to controlled substances;

- Require periodic urine drug screening of all personnel with access to controlled substances;
- Prohibit personnel from bringing smocks or bags into the prescription department;
- Prior to leaving the pharmacy, perform routine bag checks of all personnel with access to controlled substances;
- Ensure all personnel with access to controlled substances are routinely made aware of policies and procedures to prevent, identify, and address internal and external theft, to include armed robberies, and loss of controlled substances;
- In addition to the biennial inventory and perpetual inventory of Schedule II drugs, perform inventories, at least quarterly, of drugs at-risk for diversion and appropriately reconcile all discrepancies;
- Do not delegate the management of drug inventory to solely one individual;
- Review the amount of drugs received and drugs dispensed to ensure no suspicious activity exists, and monitor any adjustments made to the ongoing inventory and any excessive ordering;
- Install surveillance cameras to prevent and/or identify theft or loss of controlled substances; and
- Have full and timely access to all reports relating to inventories, invoices, and audits
- In addition to the reporting requirements in §54.1-2400.6, notify the Board of any separation of employee for known or suspected drug diversion.

**Upon leaving as PIC:**

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a **copy** with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.
- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately.

For your protection, we would suggest that you return it by certified mail, return receipt requested.

# VIRGINIA BOARD OF PHARMACY

## GUIDANCE ON VIRGINIA PRESCRIPTION REQUIREMENTS

**Written Prescriptions:**

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

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

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

- As of March 4, 2020, nurse practitioners are no longer issued a separate license for prescriptive authority. Nurse practitioners who have been granted prescriptive authority will have an additional designation of 'RX Authority' clearly displayed on their license to practice nursing which begins with the numbers 0024. Nurse practitioners who are authorized for autonomous practice or who are authorized by a practice agreement with a collaborating physician to prescribe Schedule II-VI drugs are not required to include the prescriptive authority number issued to them by the Boards of Nursing and Medicine, if their DEA registration number is included on the prescription. Nurse practitioners who are authorized by a practice agreement to only prescribe Schedule VI drugs and who do not have a DEA number must include the prescriptive authority number issued to them by the Boards of Nursing and Medicine.

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

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

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

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

- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or

authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

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

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

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

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

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

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

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

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

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

**Oral Prescriptions:**

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

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

**Faxed Prescriptions:**

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

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

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

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

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

**Electronically transmitted prescriptions:**

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

longer an electronic prescription and must follow the guidelines of a written prescription to include bearing the prescriber's manual signature.

- Schedule II - VI prescriptions may be transmitted electronically. Schedule II – V prescriptions must meet all federal requirements including required security and authenticity features, as well as required recordkeeping for the prescriber and pharmacy.

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

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

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

- Please refer to the federal regulations for additional guidance.

Guidance Document: 110-48

Adopted: March 24, 2020
Effective: May 13, 2020

# Virginia Board of Pharmacy

## Verification Sources for a Pharmaceutical Processor

To assist pharmacists and pharmacy technicians practicing at a pharmaceutical processor in complying with §54.1-3442.7 and 18VAC110-60-310 to verify current board registration of the patient, registered agent, parent, or legal guardian obtaining cannabidiol oil or THC-A oil, the Board of Pharmacy will provide the pharmacist-in-charge (PIC) of each pharmaceutical processor with access to the Virginia Cannabis Patient Registration Lookup (VCPRL).

The registration information contained in the VCPRL is confidential and includes the following information: name of patient; name of registered agent, parent, or legal guardian, as applicable; registration number; and expiration date of registration. The PIC is responsible for granting, monitoring, maintaining, and denying access to the VCPRL for all pharmacist and pharmacy technician staff that have, as part of their job, the responsibility to verify that a patient, parent, legal guardian or registered agent is currently registered with the Board of Pharmacy.

As instructed in the VCPRL, the PIC must provide information to the pharmacist or pharmacy technician to complete his own request for access to the Lookup system. Once the request has been submitted, an email will be sent to the PIC for granting access to the pharmacist or pharmacy technician. The PIC should verify the necessity of the employee to have access to the VCPRL prior to approving the request. The approved pharmacist or pharmacy technician will receive an email alerting them that their access request has been granted. The PIC should regularly audit the list of employees with access to the VCPRL to ensure it remains accurate. Upon termination of employment of a pharmacist or pharmacy technician, or a change in employment responsibilities that does not warrant access to the VCPRL, the PIC should immediately terminate the employee's access to the VCPRL.

Verification of a practitioner's registration or a pharmaceutical processor permit may be completed through the Department of Health Professions' online License Lookup feature at www.dhp.virginia.gov as this registration and permit information is considered public information.

To assist in ensuring no pharmaceutical processor dispenses more than a 90-day supply for any patient during any 90-day period, the pharmacist or pharmacy technician, who is an authorized delegate of the pharmacist, should verify the quantity and last dates of dispensing of cannabidiol oil or THC-A oil by accessing the Prescription Monitoring Program.

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

*A. A pharmaceutical processor shall dispense or deliver cannabidiol oil or TIIC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3, (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 and is registered with the Board pursuant to § 54.1-3408.3. Prior to the initial dispensing of each written certification, the pharmacist or pharmacy technician at the location of the pharmaceutical processor shall 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 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 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 for Courts of Justice on the operation of pharmaceutical processors 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 shall ensure that such concentration in any THC-A onsite is within such range and shall establish a stability testing schedule of THC-A oil.*

*Excerpt from 18VAC110-60-310:*

***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, 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, legal guardian, or registered agent and shall maintain record of such viewing in accordance with policies and procedures of the processor.*

*Excerpt from 18VAC110-60-10:*

***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.*

# Virginia Board of Pharmacy

## Performing Inventories

Various sections of law or regulation, to include §§ 54.1-3404 and 54.1-3434 of the Code of Virginia and 18 VAC 110-20-240 of the Regulations of the Board of Pharmacy, address requirements for performing an inventory of drugs in Schedules I-V. However, it is unclear whether certain individuals are required to perform a physical count of the drugs when performing the inventories. Recently, the Board concluded the following:

- ~~Those persons required in law to perform an inventory of drugs shall physically count the drugs in Schedules I-V when a theft or any other unusual loss has occurred, and he is unable to determine the exact kind and quantity of the drug loss;~~

- Dispensers, researchers, and reverse distributors may otherwise perform the inventory in a manner consistent with federal allowances, as listed in 21 CFR 1304.11 (attached to this document), which require a physical count of drugs in Schedules I and II, but allow for an estimation of drugs in Schedules III-V unless the container contains greater than 1,000 tablets/capsules; and

- Nothing shall prohibit a person from choosing to perform a physical count of all drugs listed in Schedules I-V when performing an inventory.

Drugs that have been separated from the working stock that may be expired or earmarked for return or destruction must be included in an inventory of drugs in Schedules I-V.

~~Additionally, to comply with the requirement to perform a perpetual inventory of Schedule II drugs as stated in Regulation 18 VAC 110-20-240, the perpetual inventory record must accurately indicate the physical count of each Schedule II drug "on hand" at the time of performing the inventory. Furthermore, to comply with the requirement to perform the required "reconciliation" of the perpetual inventory, an explanation for any difference between the physical count and the theoretical count must be noted.~~

***from 21 CFR 1304.11***

**~~Section 1304.11 Inventory Requirements~~**

~~(a)*General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.~~

~~(b)*Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.~~

~~(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.~~

~~(d)*Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to §§1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.~~

~~(e)*Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by §1301.13 or §§1307.11–1307.13 of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to §1304.03 shall include in the inventory the information listed below.~~

~~(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:~~

~~(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:~~

~~(A) The name of the substance and~~

~~(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.~~

~~(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:~~

~~(A) The name of the substance;~~

~~(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and~~

~~(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.~~

~~(iii)For each controlled substance in finished form the inventory shall include:~~

~~(A) The name of the substance;~~

~~(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);~~

~~(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and~~

~~(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).~~

~~(iv)For each controlled substance not included in paragraphs (e)(1)~~
~~(i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:~~

~~(A) The name of the substance;~~

~~(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and~~

~~(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.~~

~~(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.~~

~~(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:~~

~~(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or~~

~~(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.~~

~~(4)*Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).~~

~~(5)*Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.~~

**§1304.11 Inventory requirements**

(a) *General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the

substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b) *Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d) *Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to **§§1308.45**, **1308.46**, or **1308.47** of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

(e) *Inventories of manufacturers, distributors, registrants that reverse distribute, importers, exporters, chemical analysts, dispensers, researchers, and collectors.* Each person registered or authorized (by **§§1301.13**, **1307.11**, **1307.13**, or **part 1317** of this chapter) to manufacture, distribute, reverse distribute, dispense, import, export, conduct research or chemical analysis with controlled substances, or collect controlled substances from ultimate users, and required to keep records pursuant to **§1304.03** shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate

identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii) For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv) For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) *Inventories of registrants that reverse distribute.* Each person registered or authorized to reverse distribute controlled substances shall include in the inventory, the following information:

(i) The name of the substance, and

(ii) The total quantity of the substance:

(A) For controlled substances in bulk form, to the nearest metric unit weight consistent with unit size;

(B) For each controlled substance in finished form: Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and the number of commercial containers of each such finished form (e.g., four 100-tablet bottles or six 3-milliliter vials); and

(C) For controlled substances in a commercial container, carton, crate, drum, or other receptacle that has been opened: If the substance is listed in Schedule I or II, make an exact count or measure of the contents;

or if the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents shall be made; or

(iii) For controlled substances acquired from collectors and law enforcement: The number and size (e.g., five 10-gallon liners, etc.) of sealed inner liners on hand, or

(iv) For controlled substances acquired from law enforcement: the number of sealed mail-back packages on hand.

(4) *Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5) *Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs (e)(1) (iii) and (iv) of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

(6) *Inventories of dispensers and researchers.* Each person registered or authorized to dispense or conduct research with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser or researcher shall do as follows:

(i) If the substance is listed in Schedules I or II, make an exact count or measure of the contents; or

(ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(7) *Inventories of collectors.* Each registrant authorized to collect controlled substances from ultimate users shall include in the inventory the following information:

(i) For registrants authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail-back package on hand awaiting destruction:

(A) The date of the inventory;

(B) The number of mail-back packages; and

(C) The unique identification number of each package on hand, whether unused or awaiting destruction.

(ii) For registrants authorized to collect through a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

(A) The date of the inventory;

(B) The number and size of inner liners (e.g., five 10-gallon liners, etc.);

(C) The unique identification number of each inner liner.

Guidance Document: 110-19 ~~Re-adopted: June 21, 2018~~ REPEALED 3/24/2020

**REPEALED – now in 18VAC110-20-680**

# ~~Virginia Board of Pharmacy~~

## ~~Transferring Valid Orders between Medical Equipment Suppliers~~

~~A valid order authorizing the dispensing of drugs or devices may be transferred from one medical equipment supplier to another medical equipment supplier provided the order can be filled or refilled. The transfer should be communicated either orally by direct communication between an individual at the transferring medical equipment supplier and the receiving medical equipment supplier, or by facsimile machine or by electronic transmission.~~

~~The transferring medical equipment supplier should:~~

~~a. Record the word "VOID" on the face of the invalidated order;~~

~~b. Record on the reverse of the invalidated order the name and address of the medical equipment supplier to which it was transferred, the date of the transfer, and for an oral transfer, the name of the individual receiving the prescription information and the name of the individual transferring the information; and,~~

~~The receiving medical equipment supplier should:~~

~~a. Write the word "TRANSFER" on the face of the transferred prescription.~~

~~b. Provide all information required to be on a valid order to include:~~

~~(1) Date of issuance of original order;~~

~~(2) Original number of refills authorized on the original order;~~

~~(3) Date of original dispensing, if applicable;~~

~~(4) Number of valid refills remaining and date of last dispensing;~~

~~(5) Medical equipment supplier name and address from which the order information was transferred; and~~

~~(6) Name of transferring individual, if transferred orally.~~

~~Both the original and transferred order should be maintained for a period of two years from the date of last refill. In lieu of recording the required information on the hard copy of a valid order, a medical~~

~~equipment supplier may record all required information in an automated data processing system used for storage and retrieval of dispensing information.~~

~~*Related statute and regulation:*~~

~~***§ 54.1-3435.2. Permit to act as medical equipment supplier; storage; limitation; regulations.***~~

~~*A. Unless otherwise authorized by this chapter or Chapter 33 (§ 54.1-3300 et seq.) of this title, it shall be unlawful for any person to act as a medical equipment supplier, as defined in § 54.1-3401, in this Commonwealth without a valid unrevoked permit issued by the Board. The applicant for a permit to act as a medical equipment supplier in this Commonwealth shall apply to the Board for a permit, using such form as the Board may furnish; renew such permit, if granted, annually on a date determined by the Board in regulation; and remit a fee as determined by the Board.*~~

~~*B. Prescription drugs received, stored, and distributed by authority of this section shall be limited to those Schedule VI controlled substances with no medicinal properties which are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water and saline for irrigation.*~~

~~*C. Distribution of any Schedule VI drug or device or of any hypodermic needle or syringe, or medicinal oxygen by authority of this section is limited to delivery to the ultimate user upon lawful order by a prescriber authorized to prescribe such drugs and devices.*~~

~~*D. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs, devices and controlled paraphernalia by medical equipment suppliers as it deems necessary to implement this section, to prevent diversion of prescription drugs and devices and controlled paraphernalia, and to protect the public.*~~

~~***18VAC110-20-680. Medical equipment suppliers.***~~

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

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

~~*C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an*~~

~~*electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.*~~

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

~~*1. Name and address of patient;*~~

~~*2. Item dispensed and quantity, if applicable; and*~~

~~*3. Date of dispensing.*~~

# Virginia Board of Pharmacy

## Practice by a Pharmacy Technician Trainee

Regulations of the Board of Pharmacy allow a person enrolled in a Board-approved pharmacy technician training program to perform duties restricted to pharmacy technicians, for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia, for no more than nine months without that person becoming registered as a pharmacy technician. (*See Regulations 18VAC110-~~20-10~~21-140, 18VAC110-20-111, and definition of "pharmacy technician trainee" in 18VAC110-~~20~~21-10*)

The Board interprets the restriction of nine months of practice for a pharmacy technician trainee to mean **nine consecutive months** from the date the pharmacy technician trainee begins performing duties restricted to a pharmacy technician as part of a Board-approved pharmacy technician training program. For example, a pharmacy technician trainee completes the didactic or classroom portion of a training program and begins performing tasks restricted to a pharmacy technician on January 1st. The technician may conduct tasks restricted to a pharmacy technician until October 1st of that year. If she/he ceases enrollment in the pharmacy technician training program in March and enrolls in a second pharmacy technician training program in July, she/he may still only perform tasks restricted to a pharmacy technician until October 1st of that year. By that date, the trainee must either be registered with the Board as a pharmacy technician or cease performing any tasks restricted to pharmacy technicians.

~~***18VAC110-20-101. Application for registration as a pharmacy technician.***~~

~~*D. A pharmacy technician trainee may perform tasks restricted to pharmacy technicians* ***for no more than nine months*** *without becoming registered as a pharmacy technician.*~~

***18VAC110-21-140 Application for registration as a pharmacy technician.***

*D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.*

***18VAC110-20-111. Pharmacy technicians.***

*C. Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians* ***for no more than nine months*** *without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for*

*inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training.*

***18VAC110-201-10 Definitions.***

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

***§ 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 that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.*
*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 of continued competency as a condition of renewal of a registration as a pharmacy technician.*
*F. 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.*

# Virginia Board of Pharmacy

## Use of Dispensing Records to Identify Pharmacist Responsible for Dispensing Error

To improve compliance with regulations and assist in determining which pharmacist to hold responsible for a dispensing error, the Board offers the following guidance on current dispensing practices and required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product.

**Dispensing Scenario #1**

One pharmacist verifies the accuracy of the prescription product in all respects and assumes responsibility for the entire transaction. Per Regulation 18VAC110-20-270 ~~C~~ B, he shall place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained for the required time period of two years. Additionally, if the pharmacist makes use of an automated data processing system, he shall document the fact that the information entered into the computer is correct in compliance with Regulation 18VAC110-20-250.

**Dispensing Scenario #2**

More than one pharmacist at the same pharmacy location verifies the accuracy of individual tasks associated with the dispensing of a prescription product and assumes responsibility for these individual tasks, i.e., one pharmacist may verify accuracy of the data entry while another may verify accuracy of product selection. Per 18VAC110-20-270 ~~C~~ B, if more than one pharmacist is involved in verifying the accuracy of the prescription product, a record shall be maintained identifying the date of dispensing, each pharmacist involved in the process, and the individual task for which he is responsible for verifying the accuracy. If the pharmacy's record of dispensing is non-compliant and inappropriately only captures one set of pharmacist initials on the record and this is the only record of dispensing maintained, then that pharmacist shall be responsible for the entire transaction and any resulting dispensing errors.

To identify more than one pharmacist responsible for individual tasks when the pharmacy's record of dispensing is incapable of capturing more than one set of pharmacist initials, an alternative record shall be used in compliance with Regulation 18VAC110-20-255. The alternative record shall indicate the date of dispensing and the identity of the other pharmacist(s) involved in the dispensing. An example of an alternative record could be a manual log. Such alternative record shall be maintained for a period of two years on premises. A pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted, i.e., which set of pharmacist initials is associated with verifying the accuracy of which dispensing function. For example, the policy and procedure manual could indicate that the pharmacist whose initials are on the record of dispensing maintained in the computer is responsible for verifying the validity of the prescription, drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, noncompliance and duplication of therapy, and prospective drug review. Additionally, the manual could indicate that the pharmacist whose initials



~~Adopted: June 12, 2012~~
Revised: ~~December 12, 2013~~ March 24, 2020
~~Re-adopted: June 21, 2018~~ Effective: _____

are captured on the manual log is responsible for product verification and ensuring that the correct quantity of the correct drug and strength has been placed in the properly labeled container.

**Dispensing Scenario #3**

More than one pharmacist at different pharmacy locations participate in central or remote processing pursuant to Regulation 18VAC110-20-276 or 18VAC110-20-515. The pharmacist and/or pharmacies must be properly licensed in compliance with regulations. Retrievable records shall be maintained at the participating pharmacies which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performed a processing function and the pharmacist who checked the processing function, if applicable. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board. The Virginia-licensed pharmacist identified on these records who assumed responsibility for checking an individual function which resulted in a dispensing error shall be held responsible for that dispensing error, i.e., if the dispensing error resulted from incorrect data entry, then the pharmacist identified on the record for checking the data entry shall be responsible for the error and if the dispensing error resulted from incorrect product selection, then the pharmacist identified on the record for checking the product selection shall be responsible for the error.

***Note Regarding Partial Filling of a Prescription:** When a prescription is partially-filled, a record of each dispensing shall be maintained. The records shall indicate the date a partial quantity was dispensed, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of the dispensing. If the pharmacy's record of dispensing is maintained in an automated dispensing system capable of capturing only the total quantity dispensed and not each partial dispensing, then the pharmacy's records are out of compliance. To improve compliance with recordkeeping requirements, the pharmacy shall maintain another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in the data processing system concerning such prescription can be found. An example of an alternative record could be a manual log that indicates the date of dispensing for each partial quantity, the quantity dispensed, and the initials of the pharmacist verifying the accuracy of each dispensing. Pursuant to Regulation 18VAC110-20-255, a pharmacy using such alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.***

***Relevant sections of law and regulation:***

**§ 54.1-3412. Date of dispensing; initials of pharmacist; automated data processing system.**

Pursuant to regulations promulgated by the Board, the pharmacist dispensing any prescription shall record the date of dispensing and his initials on the prescription in (i) an automated data processing system used for the storage and retrieval of dispensing information for prescriptions or (ii) on another record that is accurate from which dispensing information is retrievable and in which the original prescription and any information maintained in such data processing system concerning such prescription can be found.

**18VAC110-20-250. Automated data processing records of prescriptions.**

A. An automated data processing system may be used for the storage and retrieval of original and refill dispensing information for prescriptions instead of manual record keeping requirements, subject to the following conditions:

1. A prescription shall be placed on file as set forth in 18VAC110-20-240 B with the following provisions:

a. In lieu of a hard copy file for Schedule VI prescriptions, an electronic image of a prescription may be maintained in an electronic database provided it preserves and provides an exact image of the prescription that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information. Storing electronic images of prescriptions for Schedule II-V controlled substances instead of the hard copy shall only be authorized if such storage is allowed by federal law.

b. If the pharmacy system's automated data processing system fields are automatically populated by an electronic prescription, the automated record shall constitute the prescription and a hard copy or electronic image is not required.

c. For Schedule II-V controlled substances, electronic prescriptions shall be maintained in accordance with federal law and regulation.

2. Any computerized system shall provide retrieval (via computer monitor display or printout) of original prescription information for those prescriptions which are currently authorized for dispensing.

3. Any computerized system shall also provide retrieval via computer monitor display or printout of the dispensing history for prescriptions dispensed during the past two years.

4. Documentation of the fact that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct shall be provided by the individual pharmacist who makes use of such system. If a printout is maintained of each day's prescription dispensing data, the printout shall be verified, dated and signed by the individual pharmacist who dispensed the prescription. The individual pharmacist shall verify that the data indicated is correct and then sign the document in the same manner as his name appears on his pharmacist license (e.g., J. H. Smith or John H. Smith).

If a bound log book, or separate file is maintained rather than a printout, each individual pharmacist involved in dispensing shall sign a statement each day in the log, in the manner previously described, attesting to the fact that the dispensing information entered into the computer that day has been reviewed by him and is correct as shown.

B. Printout of dispensing data requirements. Any computerized system shall have the capability of producing a printout of any dispensing data which the user pharmacy is responsible for maintaining under the Drug Control Act (§54.1-3400 et seq. of the Code of Virginia) and such printout shall be provided within 48 hours of a request of an authorized agent.

**18VAC110-20-255. Other dispensing records.**

Pursuant to §54.1-3412 of the Code of Virginia, any other record used to record the date of dispensing or the identity of the pharmacist dispensing shall be maintained for a period of two years on premises. A pharmacy using such an alternative record shall maintain a current policy and procedure manual documenting the procedures for using the record, how the record is integrated into the total dispensing record system, and how the data included in the record shall be interpreted.

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

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

~~the dispensing involves central or remote processing, records of pharmacist verification shall be maintained in a manner consistent with 18VAC110-20-276 and 18VAC110-20-515.~~

**18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions.**

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

**18VAC110-20-276. Central or remote processing.**

A. Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a non-dispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing

central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records which show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

**18VAC110-20-515. Remote prescription order processing for hospitals and long term care facilities.**

A. Remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review to include an evaluation of a prescription order and patient records for over- or under-utilization of medication, therapeutic duplication of medication, drug-disease contraindications, drug interactions, incorrect drug dosage or duration of drug treatment, or clinical abuse or misuse of medication;
5. Obtaining substitution authorizations, or otherwise communicating with the prescriber concerning a patient's order;
6. Interpreting or acting on clinical data;
7. Performing therapeutic interventions;
8. Providing drug information to the medical or nursing staff of the hospital or long term care facility; or

9. Authorizing the administration of the drug to the patient by appropriate hospital or long term care facility staff.

B. The primary pharmacy providing pharmacy services to a hospital or long term care facility may outsource certain order processing functions as described in subsection A to another pharmacy in Virginia or a registered non-resident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties which are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. Any pharmacist participating in remote prescription order processing shall be a Virginia licensed pharmacist; and
4. The pharmacies shall share a common electronic file or have technology which allows sufficient information necessary to process a prescription order.

C. A policy and procedure manual that relates to remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in remote processing;
3. Procedures for protecting the confidentiality and integrity of patient information;
4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

D. A pharmacy involved in remote prescription order processing shall maintain a record that identifies each person who performed a processing function for every order.

1. The record shall be available by prescription order or by patient name.
2. The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a task involved in processing a prescription order and the location where the task was processed.
3. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

E. Nothing in this section shall prohibit an individual employee licensed as a pharmacist in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

**REPEAL – language now found in 18VAC110-20-270(F)

# ~~Virginia Board of Pharmacy~~

## ~~The Use of a Drop Box for the Collection of Prescriptions~~

~~A pharmacy may utilize a drop box for the collection of written prescriptions and refill requests. The drop box must be located in a visible area within the permitted facility and must be locked at all times with access to the items placed in the drop box restricted to pharmacists practicing at the pharmacy or an authorized pharmacy technician practicing at the pharmacy when a pharmacist is on duty. The drop box shall be constructed in a manner to prevent the theft or loss of a written prescription or confidential information and shall be bolted to the floor or a fixed structure. At no time shall a patient be allowed to leave containers to be refilled which contain drug.~~

Guidance document: 110-40 Re-adopted: ~~December 18, 2018~~March 24, 2020

# **REPEALED- now in 18VAC110-20-200

## ~~Virginia Board of Pharmacy~~

### ~~Storage of Schedule II Drugs in a Pharmacy~~

~~Regulations governing the practice of pharmacy provide in subsection B of 18VAC110-20-200 that:~~

~~*Dispersion of Schedule II drugs. Schedule II drugs shall either be dispersed with other schedules of drugs or shall be maintained within a securely locked cabinet, drawer, or safe. The cabinet, drawer, or safe may remain unlocked during hours that the prescription department is open and a pharmacist is on duty.*~~

~~The Board interprets the regulation to mean that Schedule II drugs in a pharmacy may be dispersed with other schedules of drugs on the shelves, maintained within a securely locked cabinet, drawer, or safe, or maintained in a manner which combines the two methods for storage.~~

# Virginia Board of Pharmacy

## Guidance for Continuous Hours Worked by Pharmacists and Breaks

***Regulations Governing the Practice of Pharmacy***

***18VAC110-20-110. Pharmacy permits generally.***

*B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.*

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

**Excerpt from *Regulations Governing the Practice of Pharmacy*, December 11, 2019**

**18VAC110-20-110. Pharmacy permits generally.**

D. A pharmacist shall not be eligible to serve as PIC until after having obtained a minimum of two years of experience practicing as a pharmacist in Virginia or another jurisdiction in the United States. The board may grant an exception to the minimum number of years of experience for good cause shown.

**From *The Pharmacy Act and The Drug Control Act with Related Statutes*, July 1, 2019**

**§ 54.1-3434. Permit to conduct pharmacy.**

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

The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy and who will be fully engaged in the practice of pharmacy at the location designated on the application.

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

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

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

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

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within 15 days of receipt of this notice. At the conclusion of the 15-day period, the Director or his authorized agent, or any law-enforcement officer in coordination with the Director, shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and the Director shall notify the owner of such seizure. The Director, his authorized agent, or the law-enforcement officer may properly dispose of the seized drugs and devices after 60 days from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board or law-enforcement agency shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

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

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

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

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

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

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

**Excerpt from *Regulations Governing the Practice of Pharmacy*, December 11, 2019**

**18VAC110-20-110**

H. 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 pharmacy 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.

## Agenda Topic: Consideration for requiring CE on a specific topic in 2021

**Background information:**

Action item from December 9, 2019 board meeting. Refer to draft minutes.

Statutory allowance:

**§ 54.1-3314.1. Continuing education requirements; exemptions; extensions; procedures; out-of-state licensees; nonpractice licenses.**

J. As part of the annual 15-hour requirement, the Board may require up to two hours of continuing education in a specific subject area. If the Board designates a subject area for continuing education, it shall publish such requirement no later than January 1 of the calendar year for which the specific continuing education is required.

Topics Required in the Past:

2015 – pharmacists - one hour on the topic of "opioid use or abuse"

2017 – pharmacists - one hour "in any of the following subject areas: proper opioid use, opioid overdose prevention, or naloxone administration"

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** |

# 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** | |

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

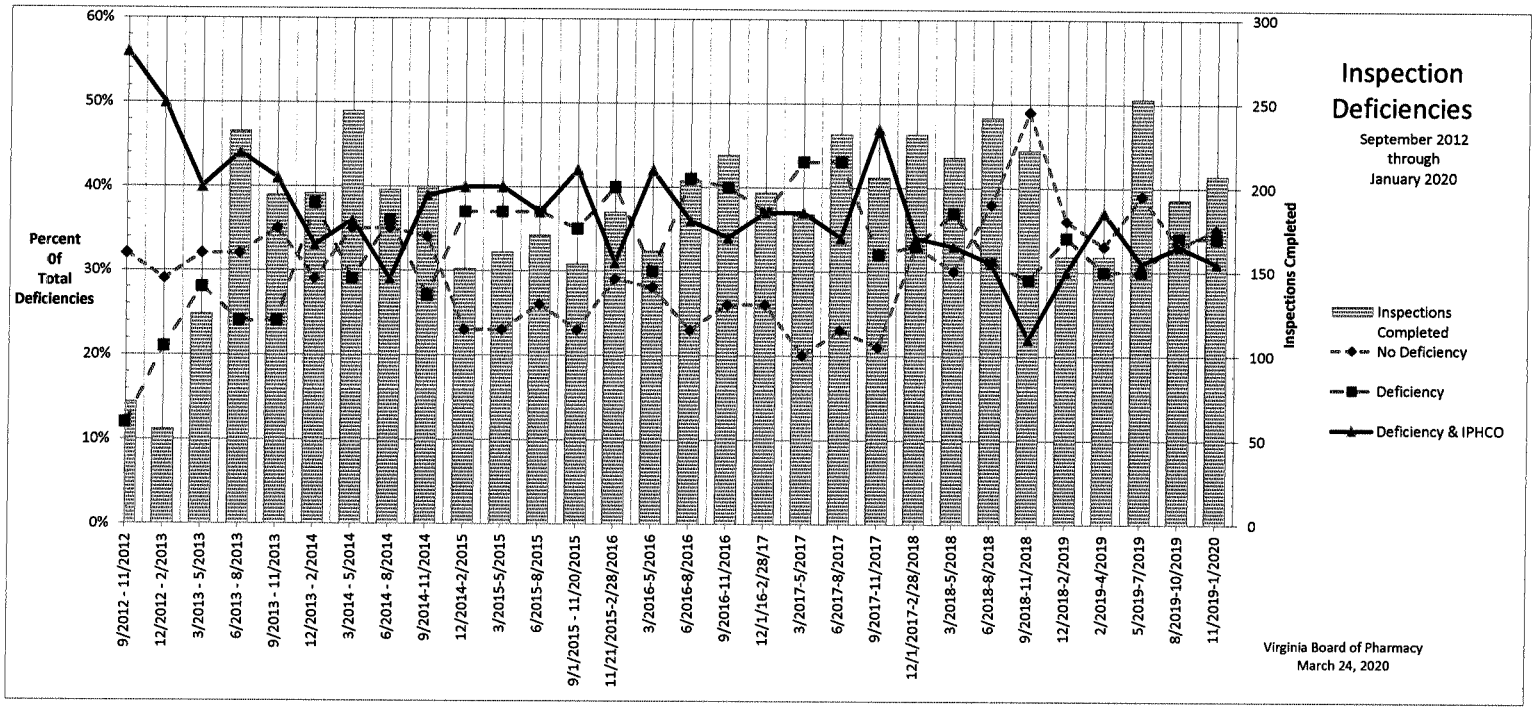
## Deficiencies Above 100
## (Formerly Minor Deficiency)

| | 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
Percent Of Total Deficiencies
Inspections Cmpleted
60%
50%
40%
30%
20%
10%
0%
300
250
200
150
100
50
0
Inspections Completed
No Deficiency
Deficiency
Deficiency & IPHCO
9/2012 - 11/2012
12/2012 - 2/2013
3/2013 - 5/2013
6/2013 - 8/2013
9/2013 - 11/2013
12/2013 - 2/2014
3/2014 - 5/2014
6/2014 - 8/2014
9/2014-11/2014
12/2014-2/2015
3/2015-5/2015
6/2015-8/2015
9/1/2015 - 11/20/2015
11/21/2015-2/28/2016
3/2016-5/2016
6/2016-8/2016
9/2016-11/2016
12/1/16-2/28/17
3/2017-5/2017
6/2017-8/2017
9/2017-11/2017
12/1/2017-2/28/2018
3/2018-5/2018
6/2018-8/2018
9/2018-11/2018
12/2018-2/2019
2/2019-4/2019
5/2019-7/2019
8/2019-10/2019
11/2019-1/2020
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 | CURRENT Q2 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Pharmacy** | **Number of Cases Received** | 119 | 179 | 146 | 143 | 160 | 171 | 213 | 148 | 126 | 133 | 223 | 211 | 111 |
| | **Number of Cases Open** | 386 | 355 | 309 | 302 | 271 | 287 | 319 | 303 | 306 | 262 | 259 | 310 | 251 |
| | **Number of Cases Closed** | 164 | 204 | 192 | 148 | 185 | 162 | 199 | 161 | 123 | 177 | 237 | 158 | 164 |
| **Physical Therapy** | **Number of Cases Received** | 9 | 7 | 21 | 6 | 15 | 9 | 4 | 13 | 10 | 9 | 7 | 26 | 4 |
| | **Number of Cases Open** | 24 | 28 | 39 | 36 | 44 | 48 | 50 | 46 | 44 | 37 | 32 | 46 | 39 |
| | **Number of Cases Closed** | 9 | 5 | 9 | 10 | 7 | 2 | 4 | 15 | 11 | 17 | 12 | 13 | 12 |
| **Psychology** | **Number of Cases Received** | 26 | 13 | 22 | 23 | 23 | 28 | 26 | 20 | 31 | 38 | 27 | 55 | 31 |
| | **Number of Cases Open** | 87 | 49 | 34 | 46 | 44 | 52 | 57 | 64 | 83 | 75 | 75 | 97 | 99 |
| | **Number of Cases Closed** | 17 | 52 | 38 | 16 | 24 | 19 | 24 | 13 | 11 | 46 | 29 | 34 | 30 |

Virginia Department of

# Health Professions

## Average Age of Cases Closed

## Quarterly Summary

Quarter 2 - Fiscal Year 2020

The average 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 specified.

| 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 |

| BOARD | Q2 2017 | Q3 2017 | Q4 2017 | Q1 2018 | Q2 2018 | Q3 2018 | Q4 2018 | Q1 2019 | Q2 2019 | Q3 2019 | Q4 2019 | Q1 2020 | CURRENT Q2 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Audiology | n/a | 135.3 | 259.8 | 255.7 | 192 | 179 | 463.3 | 97.4 | 190.3 | 149 | 208 | 241 | 291 |
| Counseling | 292.8 | 247.9 | 106.1 | 251.5 | 128.2 | 153.7 | 185 | 164.2 | 161.3 | 251 | 279 | 173 | 157 |
| Dentistry | 289.5 | 271.2 | 228.7 | 337.8 | 182.9 | 239.7 | 165 | 141.5 | 83.6 | 192 | 394 | 316 | 466 |
| Funeral Directing | 166.5 | 295 | 223.7 | 229.3 | 169.1 | 383.3 | 211.8 | 225.7 | 298.8 | 116 | 259 | 287 | 180 |
| Long Term Care Administrator | 260.5 | 282.8 | 395 | 171.2 | 350.6 | 424.1 | 395.5 | 253 | 396.8 | 400 | 433 | 291 | 385 |
| Medicine | 147.1 | 135.5 | 136.9 | 146.5 | 135 | 153.5 | 133.3 | 142.1 | 147.3 | 240 | 170 | 172 | 238 |
| Nurse aide | 198.6 | 191.4 | 223.8 | 297.4 | 273.3 | 200.7 | 235.3 | 150.1 | 201.7 | 204 | 147 | 164 | 226 |
| Nursing | 179.5 | 207.4 | 202.1 | 203.6 | 204.5 | 215.8 | 280.3 | 192.3 | 198.3 | 276 | 202 | 300 | 350 |
| Optometry | 216.2 | 95.3 | 106.3 | 557.6 | 268.1 | 240 | 190.7 | 194.2 | 506.5 | 379 | 129 | 275 | 380 |
| Pharmacy | 303.6 | 343.2 | 192.9 | 215.4 | 172.2 | 173.7 | 114.1 | 160.2 | 152.3 | 255 | 116 | 275 | 117 |
| Physical therapy | 273.7 | 102.4 | 291.3 | 239.4 | 112 | 152.5 | 412.8 | 389.3 | 366.5 | 467 | 322 | 280 | 174 |
| Psychology | 291.7 | 357.7 | 252.7 | 119.5 | 183.3 | 118.8 | 175.2 | 170.4 | 228.6 | 225 | 153 | 72 | 548 |
| Social Work | 407.6 | 366.2 | 228.8 | 292.7 | 123.6 | 277.5 | 237.2 | 113.8 | 200.7 | 263 | 211 | 271 | 377 |
| Veterinary Medicine | 301.2 | 283.5 | 295.6 | 223 | 357.7 | 278.7 | 376.7 | 321.9 | 261.9 | 293 | 423 | 285 | 79 |
| Agency total | 207.7 | 222.8 | 194.1 | 255.7 | 186.5 | 196.4 | 201.1 | 173.8 | 169.2 | 258 | 204 | 214 | 258.4 |

Virginia Department of
# Health Professions

## Cases Closed in Less than One Year
### Quarterly Summary
Quarter 2- Fiscal Year 2020

The percent 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 quarter specified.

| 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 |

| BOARD | Q2 2017 | Q3 2017 | Q4 2017 | Q1 2018 | Q2 2018 | Q3 2018 | Q4 2018 | Q1 2019 | Q2 2019 | Q3 2019 | Q4 2019 | Q1 2020 | CURRENT Q2 2020 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Audiology/Speech Pathology** | N/A | 100.0% | 90.0% | 90.9% | 100.0% | 80.0% | 33.3% | 100.0% | 71.4% | 100.0% | 84.6% | 87.5% | 62.5% |
| **Counseling** | 78.6% | 84.7% | 97.5% | 76.9% | 97.0% | 91.3% | 84.8% | 89.7% | 89.3% | 73.8% | 68.0% | 84.8% | 83.7% |
| **Dentistry** | 75.3% | 73.9% | 94.3% | 65.4% | 89.2% | 84.0% | 93.3% | 90.3% | 95.7% | 86.9% | 71.8% | 64.7% | 52.4% |
| **Funeral Directing** | 100.0% | 60.0% | 70.0% | 78.6% | 85.7% | 61.1% | 87.0% | 69.2% | 83.3% | 100.0% | 73.3% | 80.5% | 90.3% |
| **Long Term Care Administrator** | 72.7% | 69.2% | 55.0% | 80.0% | 50.0% | 25.0% | 29.0% | 64.3% | 36.4% | 42.6% | 64.3% | 64.4% | 41.9% |
| **Medicine** | 93.5% | 93.5% | 95.4% | 91.6% | 93.8% | 93.7% | 94.6% | 93.3% | 92.4% | 83.9% | 93.8% | 88.6% | 85.2% |
| **Nurse Aide** | 88.3% | 84.0% | 77.7% | 65.2% | 78.9% | 93.1% | 75.3% | 85.2% | 78.2% | 85.6% | 95.3% | 87.2% | 78.5% |
| **Nursing** | 89.2% | 85.8% | 86.4% | 83.4% | 84.5% | 81.0% | 62.3% | 79.2% | 72.5% | 69.9% | 79.3% | 59.6% | 49.5% |
| **Optometry** | 81.3% | 100.0% | 100.0% | 50.0% | 66.7% | 62.5% | 88.9% | 83.3% | 50.0% | 47.8% | 100.0% | 64.7% | 44.4% |
| **Pharmacy** | 69.5% | 71.6% | 85.4% | 83.1% | 87.1% | 91.4% | 94.0% | 90.3% | 92.6% | 83.4% | 95.8% | 64.7% | 95.8% |
| **Physical Therapy** | 77.8% | 100.0% | 44.4% | 90.0% | 100.0% | 100.0% | 25.0% | 46.7% | 45.5% | 32.7% | 54.5% | 54.8% | 78.6% |
| **Psychology** | 50.0% | 44.2% | 81.6% | 92.9% | 85.2% | 100.0% | 90.5% | 92.3% | 81.8% | 86.4% | 93.1% | 95.7% | 36.2% |
| **Social Work** | 62.5% | 41.3% | 92.3% | 73.3% | 100.0% | 81.8% | 66.7% | 84.2% | 78.3% | 50.9% | 70.8% | 46.7% | 47.9% |
| **Veterinary Medicine** | 68.8% | 73.7% | 75.5% | 86.0% | 51.2% | 74.3% | 53.8% | 64.5% | 73.8% | 67.1% | 44.6% | 64.6% | 93.8% |
| Agency Total | 85.1% | 81.7% | 86.7% | 82.2% | 86.7% | 87.6% | 80.6% | 85.5% | 84.0% | 76.4% | 82.3% | 78.2% | 72.9% |

Virginia Department of

# Health Professions

## Cases Closed in Less than One Year

## Fiscal Year Summary

Fiscal Year 2019

The percent 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 quarter specified.

| 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 |

| BOARD | 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 | FY 2019 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Audiology** | 100.0% | -3.2% | 96.8% | 3.3% | 100.0% | -10.5% | 89.5% | -10.6% | 80.0% | 9.3% | 88.2% |
| **Counseling** | 87.6% | -12.6% | 76.6% | -25.8% | 56.8% | 35.0% | 76.8% | 13.8% | 87.4% | -11.3% | 78.5% |
| **Dentistry** | 65.1% | 11.1% | 72.4% | 0.0% | 72.4% | 3.4% | 74.8% | 13.9% | 85.2% | -6.1% | 80.3% |
| **Funeral Directing** | 90.8% | 5.4% | 95.7% | -6.0% | 90.0% | -14.4% | 77.1% | 0.5% | 77.4% | 8.6% | 84.7% |
| **Long-Term Care Administrator** | 88.6% | 1.6% | 90.0% | -6.4% | 84.2% | -19.0% | 68.3% | -38.9% | 41.7% | -16.5% | 35.8% |
| **Medicine** | 91.7% | -1.0% | 90.8% | -1.7% | 89.3% | 5.0% | 93.7% | 0.1% | 93.8% | -9.6% | 85.6% |
| **Nurse Aide** | 96.1% | -0.1% | 96.0% | -2.2% | 94.0% | -9.4% | 85.1% | -3.0% | 82.5% | -0.4% | 82.2% |
| **Nursing** | 92.3% | -2.2% | 90.3% | -4.7% | 86.1% | 0.7% | 86.7% | -9.7% | 78.3% | -0.9% | 77.6% |
| **Optometry** | 83.3% | 4.0% | 86.7% | 4.9% | 90.9% | -1.4% | 89.7% | -29.4% | 63.3% | 1.1% | 64.0% |
| **Pharmacy** | 92.0% | -4.3% | 88.0% | 4.4% | 91.9% | -15.6% | 77.6% | 14.6% | 89.0% | 4.3% | 93.0% |
| **Physical Therapy** | 95.4% | -5.6% | 90.0% | 3.4% | 93.0% | -33.3% | 62.1% | 25.3% | 77.8% | -130.2% | 33.8% |
| **Psychology** | 93.7% | 0.1% | 93.8% | -49.5% | 47.3% | 21.8% | 57.6% | 60.0% | 92.2% | -8.2% | 85.2% |
| **Social Work** | 92.7% | -8.3% | 85.0% | -28.4% | 60.9% | -15.3% | 51.5% | 57.1% | 81.0% | -16.4% | 69.6% |
| **Veterinary Medicine** | 95.2% | 5.1% | 100.0% | -37.6% | 62.4% | 16.7% | 72.8% | -9.2% | 66.2% | -4.7% | 63.2% |
| **AGENCY** | **91.3%** | **-0.4%** | **90.9%** | **-1.6%** | **89.5%** | **-6.2%** | **83.9%** | **0.7%** | **84.5%** | **-5.6%** | **80.0%** |

# 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.

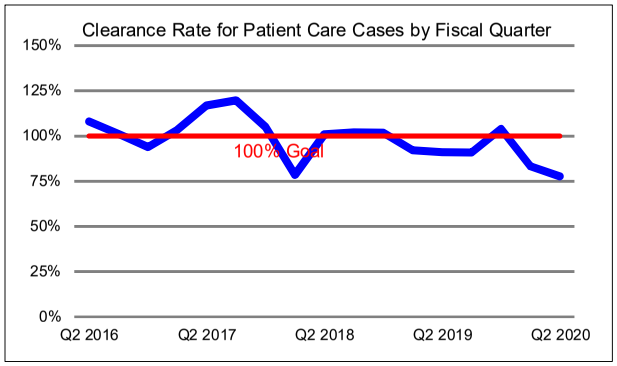
The current quarter's clearance rate is 78%, with 1209 patient care cases received and 940 closed.

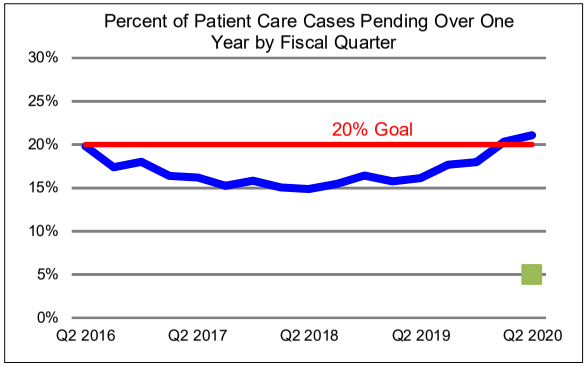
**Age of Pending Caseload** - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases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

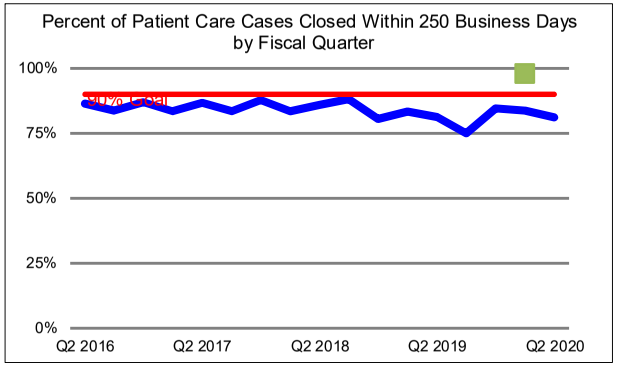
The current quarter shows 21% patient care cases pending over 250 business days with 3590 patient care cases pending and 757 pending over 250 business days. 192 Cases are pending over 415 business days for a percentage of 5%

**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

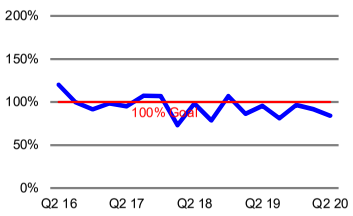
## Medicine

**Clearance Rate: 91%**
399 Cases Received
365 Cases Closed

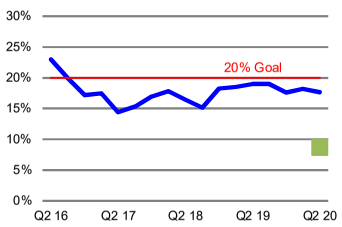
**Pending Caseload: 18%**
158 Cases Pending over 250 Days
**Pending Caseload Over 415: 9%**
78 Cases Pending over 415 Days

**Time to Disposition: 93%**
303 Cases Closed within 250 Days
**Time to Disposition within 415: 99%**
321 Cases Closed within 415 Days

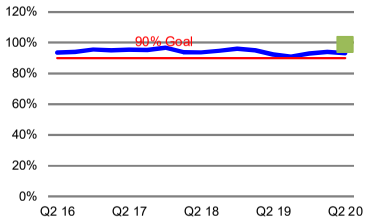
**Clearance Rate**




**Age of Pending Caseload**
(percent of cases pending over one year)




**Time to Disposition**

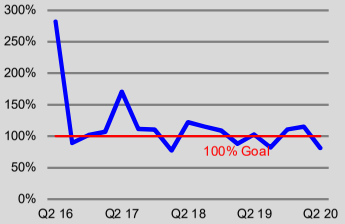


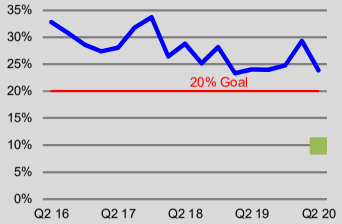

## Dentistry

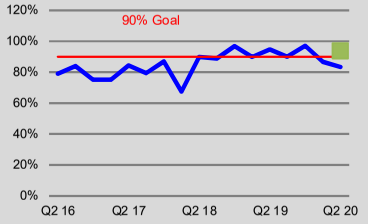
**Clearance Rate: 81%**
69 Cases Received
56 Cases Closed

**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



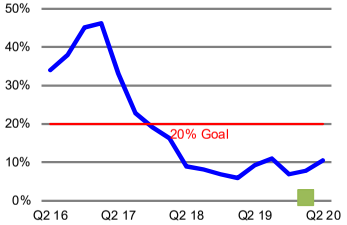



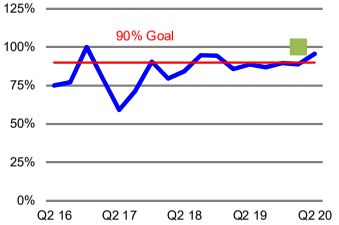

## Pharmacy

**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** – March 24, 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)

*Upcoming Meetings:*

- March 26, 2020, VCU School of Pharmacy
- April 3, 2020, VCU Researcher Presentation
- April 7, 2020, PMP InterConnect Steering Committee Meeting
- April 15, 2020, Food and Drug Law Institute (FDLI) Updates in Compounding Conference Presentation
- April 21, 2020, NABP Districts 1 & 2 Planning Committee Conference Call
- April 22, 2020, Formal Hearing
- April 27, 2020, Howard University (O'Halloran)
- May 11, 2020, Regulation Committee Meeting/Formal Hearing
- May 12-16, NABP Annual Meeting, Baltimore, MD
- 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