COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Full Board Meeting
December 6, 2023
9AM

TOPIC	**PAGES**
Call to Order of Public Hearing: Dale St.Clair, PharmD, Chairman	
• Welcome & Introductions	
Public Hearing:	
• Placing Certain Chemicals into Schedule I and Conforming Schedules to Federal Scheduling Actions	**69-75**
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Dale St.Clair, PharmD, Chairman	
• Approval of Agenda	
Approval of Previous Board Meeting Minutes:	**3-31**
• September 26, 2023, Full Board Meeting	
• September 26, 2023, Public Hearing for Scheduling	
• September 28, 2023, HB 2147 Workgroup	
• October 10, 2023, Formal Hearing	
• October 11, 2023, Innovative Pilot Program	
• October 20, 2023, Telephone Conference Call	
• November 8, 2023, Formal Hearing	
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, e.g., working condition regulations, or any pending disciplinary matters.	
DHP Director's Report: Arne Owens	
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh	
• Chart of Regulatory Actions	**32-34**
• Adoption of proposed regulations for pharmacy working conditions	**35-42**
• Consider recommendation of HB 2147 (Prescription Translation Services) Workgroup – St. Clair	**43-44**
• Repeal of guidance documents related to the medical cannabis program	**45-54**
• Repeal of Chapter 60 due to the transfer of the medical cannabis program	**55-58**
• Completion of periodic review of public participation guidelines contained in 18VAC110-11	**59-68**
• Adoption of exempt regulations – addition of drug to Schedule IV pursuant to federal changes	**69-73**
• Adoption of exempt regulations – addition of chemicals from Schedule I	**74-84**

New Business:

- Presentation on Use of Agency Subordinate **85-88**

Old Business:

- Citing of Deficiencies 13-16 within Guidance Document 110-9 **89**
- Reassess need for possible retreat **Verbal**
- Staff research on existing pharmacy location maps **Verbal**

Reports:

- Chairman's Report –Dale St.Clair, PharmD **Verbal**
- Report on Board of Health Professions – Sarah Melton, PharmD **Verbal**
- Report on Licensure – Ryan Logan, RPh **92-95**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **Handout**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **96**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **97-102**
- Executive Director's Report – Caroline D. Juran, RPh **Verbal**

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

Adjourn

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

*****A panel of the Board will tentatively convene at 1:00pm or immediately following adjournment of the board meeting, whichever is later.*****

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Tuesday, September 26, 2023

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

CALL TO ORDER:	A full board meeting was called to order at 9:15AM.
PRESIDING:	Dale St. Clair, PharmD, Chairman
MEMBERS PRESENT:	Cheri Garvin, RPh Larry Kocot, JD Ling Yuan, PharmD Wendy Nash, PharmD Kristopher Ratliff, DPh Sarah Melton, PharmD Shannon Dowdy, PharmD
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director Ryan Logan, Deputy Executive Director Beth O'Halloran, Deputy Executive Director Ellen B. Shinaberry, PharmD, Deputy Executive Director Arne W. Owens, DHP Agency Director Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs James Rutkowski, Senior Assistant Attorney General Sorayah Haden, Executive Assistant Yvonne Miller, Records Administrative Assistant Cecelia Robinson, Licensing Administrative Assistant
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	David Flammia - #0202011380 Yeh Ling Yuan Lee - #0202218262
QUORUM:	With 8 members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was provided listing a new item at the beginning of the "Legislative/Regulatory/Guidance" section entitled "Consideration of Fee Increase". The amended agenda was accepted as presented.

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

The Chairman reviewed with the Board DHP Policy 76.80-26 included in the agenda packet. Minutes for meetings held on June 13, 2023, June 27, 2023, August 11, 2023, and August 23, 2023 were approved as presented.

PUBLIC COMMENT:

Karen Winslow, PharmD, Interim Executive Director, Virginia Pharmacy Association (VPhA), provided public comment expressing how pleased VPhA is for the collaboration of the Board of Pharmacy, Board of Medicine, and Virginia Department of Health regarding recent development of statewide protocols. She stated VPhA has been working with DMAS on payment reimbursement issues. She encouraged the Board to have the Governor sign previously submitted working condition regulations, and appreciates the disciplinary action taken on unsafe conditions. She questioned the striking of language presented in Guidance Document 110-46 on page 113 of the agenda. She informed the Board that Jamie Fisher will be starting as the new Executive Director of VPhA. A handout summarizing her verbal comments was provided to the Board.

Natalie Nguyen, PharmD, provided public comment on behalf of the Virginia Society of Health-System Pharmacists. The public comment included: request that Board allow a 6-month transition period for enforcement of USP chapters <795> and <797> revisions similar to The Joint Commission; clarification regarding documentation for flavoring; recommendation that Board allow media-fill, gloved fingertip and garbing test requirements for multiple sites operating under same health system with same configuration of hoods; and request that the Board allow pharmacies to document shortage of testing supply, e.g., media-fill and agar plates, within the personnel file, allow 30 days for procurement of testing item in shortage, and allow compounding personnel to continue compounding in the interim. She additionally recommended the Board create a work group to monitor for necessary revisions of Guidance Document 110-36.

Cindy Warriner, RPh, provided public comment on behalf of the Community Pharmacy Enhanced Services Network. Ms. Warriner stated they are pleased that the Board provided preliminary maps of current pharmacy locations within the agenda packet. She expressed concern for patient access to needed medications and care, and encouraged the Board to address the issue and collaborate with other State agencies and professional associations to ensure awareness and developing strategy.

Chad Baker provided verbal comment on behalf of FLAVORx that mirrored written comment provided by Ursula Chizhik, PharmD with FLAVORx. Board staff provided copies of the written comment to the members and public. The comments included language in states addressing flavoring; he recommended reviewing Arizona and Iowa's language that provide basic

guard rales. Newly proposed or approved rules on flavoring, a state of flavoring regulatory map, and an overview of how FLAVORx program works were also provided.

DHP DIRECTOR'S REPORT: Arne Owens, DHP Agency Director, stated they are communicating with the Secretary regarding legislative proposals and will hear soon which ones may be introduced in the upcoming session. DHP's budget request has been submitted and the Board of Pharmacy will need an increase in fees. He commented that the Prescription Monitoring Program has applied to the Opioid Abatement Authority for funding to help sustain the program. Regarding workforce, he is aware of current pharmacy issues. He was informed by the Healthcare Workforce Development Authority that while pharmacists were not included in the current study, they will be included in future workforce studies. He stated that Ms. Juran has inserted pharmacy into workforce discussions of the Claude Moore Foundation and Deloitte.

LEGISLATIVE/ REGULATORY/GUIDANCE

CONSIDERATION OF FEE INCREASE

The Board reviewed and discussed a handout that included a memorandum from Arne Owens, DHP Director, to the Board regarding a revenue and expenditure analysis and the need for a fee increase. The handout included the following staff notes:

- The Board last raised fees in 2017. Prior to that time, the last fee increase was in 2002. In between 2002 and 2017, the Board instituted one-time fee reductions three times.
- At the time the Board increased fees in 2017, staff for the Board and agency communicated that another fee increase would be required. At the time of the previous increase, the following differences between 2002 and 2017 in Board operations were cited:
    - 283% increase in the number of licensees
    - 100% increase in employees of the Board (6 in 2002 to 12 in 2016)
    - 7 cost of living increases for staff
    - 5% increase in salary due to mandatory retirement system contribution
    - 84% increase in inspections and investigations
    - 40% increase in Administrative Proceedings Division hours and number of cases
    - 613% increase in mandated information technology costs

• As noted, the 30% increase in fees which took effect in 2020 could not cover these changes for more than a few years.

• In 2023, five compounded state salary increases have accelerated the need for a fee increase. When the General Assembly enacts salary increases, other state agencies receive increased allocations from the general fund through the budget process to cover the increase. As a special fund agency, DHP and its boards only receive funds from fees provided by licensees, which by statute

must be sufficient to cover the operating expenses of the board.
Additional operational increases affecting available funds:

- License counts have increased significantly over the years:
  - 2002: 12,861
  - 2018: 37,608
  - Q4 2023: 45,486
- Additional regulated categories:
  - In 2019 began registering nonresident third-party logistics providers; nonresident warehousers; limited-use physician selling;
  - In 2021 began registering pharmacy technician trainees
- Cases received regarding Board regulated individuals or entities has increased:
  - 2002: 269
  - 2018: 651
  - Q4 2023: 878
- Number of full-time employees has increased:
  - 2002: 6
  - 2018: 12
  - Q4 2023: 14
  - *Note: if FTE count had increased at a rate consistent with increase in licensees and cases, the Board should have 20-21 FTEs instead of 14.*
- Cash balance projections without a fee increase:
  - FY2023 (Actual): $2,270,363
  - FY2024 (Estimate): $1,446,128
  - FY2025 (Estimate): $434,063
  - FY2026 (Estimate): -$688,083
  - FY2027 (Estimate): -$1,926,100

MOTION:

The Board voted unanimously to adopt the Notice of Intended Regulatory Action to initiate a fee increase as presented. (motion by Ratliff seconded by Garvin)

CHART OF REGULATORY ACTIONS

Ms. Barrett reviewed the Chart of Regulatory Actions as of September 12, 2023 within the agenda packet.

ADOPTION OF EXEMPT FINAL REGULATION TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

The Board reviewed and discussed the recommendations and consultation from the Department of Forensic Science to place certain chemicals into Schedule I. Ms. Barrett stated that DFS provided her with recommended language for listing tianeptine in regulation and that she would revise the proposed amendment of 18 VAC110-20-322 by inserting the chemical nomenclature, if approved by the Board.

MOTION:

The Board voted unanimously to adopt exempt changes to 18VAC110-20-322 to add chemicals to Schedule I as follows:

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

1. **Synthetic opioid. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1- yl]ethanamine (other name: N-desethyl Isotonitazene), 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. **Cannabimimetic agent. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.**
3. **7-[(3-chloro-6-methyl-5,5-dioxo-11H-benzo[c][2,1]benzothiazepin-11-yl)amino]heptanoic acid (other name: Tianeptine), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.**

The placement of drugs listed in this subsection shall remain in effect until [May 1], 2025, unless enacted into law in the Drug Control Act. (motion by Kocot, seconded by Garvin)

INITIATION OF PERIODIC REVIEW OF PUBLIC PARTICIPATION GUIDELINES CONTAINED IN 18VAC110-11

The Board reviewed and discussed the Public Participation Guidelines contained in 18VAC110-11.

MOTION:

The Board voted unanimously to initiate periodic review of 18VAC110-11. (motion by Garvin, seconded by Yuan)

ADOPTION OF FAST-TRACK REGULATORY ACTION TO CHANGE "NURSE PRACTITIONER" TO "ADVANCED PRACTICE REGISTERED NURSE

The Board reviewed and discussed the changes to regulations in Chapter 30 to amend references to Nurse Practitioners to Advanced Practice Registered Nurse based on recent statutory changes.

The Board voted unanimously to adopt fast-track regulatory changes to

MOTION

Chapter 30 to amend references to "Nurse Practitioners" to "Advanced Practice Registered Nurses". (motion by Ratliff, seconded by Melton)

AMENDMENT OF GUIDANCE DOCUMENTS TO REFLECT TITLE CHANGE OF "NURSE PRACTITIONER" TO "ADVANCED PRACTICE REGISTERED NURSES"

The Board reviewed and discussed Guidance Documents 110-1, 110-7, 110-8, 110-13, and 110-29, all amended to change "Nurse Practitioner" to "Advanced Practice Registered Nurse" based on recent statutory changes.

MOTION

The Board voted unanimously to amend Guidance Documents 110-1, 110-7, 110-8, 110-13, and 110-29 to amend references to "Nurse Practitioners" to "Advances Practice Registered Nurses". (motion by Yuan, seconded by Garvin)

AMENDMENT TO GUIDANCE DOCUMENT 110-35 TO REFLECT TITLE CHANGE OF "NURSE PRACTITIONERS" TO "ADVANCED PRACTICE REGISTERED NURSES" AND ADDRESS DEA FINAL RULE FOR TRANSFERRING ELECTRONIC PRESCRIPTIONS

The Board reviewed and discussed Guidance Document 110-35 with suggested amendments to change "Nurse Practitioner" to "Advanced Practice Registered Nurse" and address the DEA's final rule regarding transferring electronic prescriptions between pharmacies for initial filling. Ms. Barrett stated that she will insert references into the document as a hyperlink.

MOTION

The Board voted unanimously to amend Guidance Document 110-35 as presented and amended by inserting DEA-related references as a hyperlink. (motion by Garvin, seconded by Dowdy)

AMENDMENT TO GUIDANCE DOCUMENT 110-36 TO INCLUDE ADDITIONAL FAQs RELATED TO REVISIONS OF USP CHAPTERS <795> AND <797>

The Board reviewed and discussed the excerpt from June 2008 board meeting minutes regarding flavoring that resulted in enforcement discretion of USP compounding standards when flavoring products, the excerpt from USP FAQs indicating that flavoring is considered compounding, and Guidance Document 110-36 with draft amendments. There was a robust discussion regarding draft FAQ #8 regarding flavoring found on page 99 of the agenda packet. It was noted that if flavoring is considered compounding, then a prescription is required. There was some discussion regarding risk of changing pH. Dr. Ratliff was supportive of flavoring not being considered compounding. Ms. Garvin suggested pharmacies use a resource to guide flavoring and have guardrails. There was some discussion regarding the phrasing of the draft FAQ.

MOTION

A motion to change the response of draft FAQ #8 "Is flavoring considered compounding?" to "No" failed by a vote of 3:5. (motion by Nash, seconded by Ratliff; opposed by Kocot, Garvin, Melton, St. Clair, and Yuan)

MOTION

The Board voted 7:1 to amend draft FAQ #8 to read "Does USP consider flavoring to be compounding?" and amend the response to read "Yes, but the Board will exercise enforcement discretion of USP compounding standards for flavoring." (motion by Garvin, seconded by Melton; opposed by Nash)

The Board discussed the draft language for FAQ #11 found on page 100 of the agenda packet regarding when the Board will begin enforcing USP revisions to chapters <795> and <797>. Ms. Garvin and Dr. Yuan recommended a delay in enforcement due to supply chain issues.

MOTION

The Board voted unanimously to:

- **amend the draft response to FAQ #11 in Guidance Document 110-36 to reflect that inspectors will begin citing deficiencies for noncompliance of USP revised standards as of November 1, 2023, but will exercise enforcement discretion for the first 6 months, e.g., through April 30, 2024, and not take disciplinary action unless egregious in nature, staff will consult with a committee of the Board for direction regarding possible disciplinary action for deficiencies that appear egregious**
- **adopt the remaining FAQs as presented and amended (recognizing that #8 was amended in the previous motion). (motion by Garvin, seconded by Kocot)**

AMEND GUIDANCE DOCUMENT 110-44, PROTOCOL FOR THE PRESCRIBING AND DISPENSING OF NALOXONE AND STATEWIDE PROTOCOL FOR NALOXONE

FDA recently approved two formulations of nalmefene, an opioid antagonist. Therefore, the Board reviewed and discussed amendments made to *Guidance Document 110-44 Naloxone Protocol* and the *Pharmacist Naloxone Statewide Protocol* to insert nalmefene. Ms. Juran stated that the nasal spray appears to be more appropriate for lay-person administration while the injectable formulation appears more appropriate for administration in a healthcare setting.

MOTION

The Board voted unanimously to amend *Guidance Document 110-44 Naloxone Protocol* and the *Pharmacist Naloxone Statewide Protocol* as presented to insert allowances for nalmefene. (motion by Melton, seconded by Yuan)

AMENDMENT OF GUIDANCE DOCUMENT

Based on discussions at the June board meeting, the Board reviewed amendments to Guidance Document 110-46 to include allowances for drone

110-46 REGARDING USE OF DRONES

delivery of drugs.

MOTION:

The Board voted unanimously to amend Guidance Document 110-46 as presented to include allowances for drone delivery of drugs. (motion by Garvin, seconded by Kocot)

NEW BUSINESS:

ADOPT STATEWIDE PROTOCOLS FOR COVID-19, STREP, UTI, AND INFLUENZA

The Board reviewed recommended protocols for pharmacist initiation of test and treat for COVID-19, Group A Streptococcal Bacteria, Influenza, and Urinary Tract Infections as developed by a workgroup composed of representatives from the Board of Pharmacy, Board of Medicine, and Department of Health.

MOTION

The Board voted unanimously to approve the statewide protocols for pharmacists to initiate test and treat for COVID-19, Group A Streptococcal Bacteria, Influenza, and Urinary Tract Infections as presented and amended as follows:

- **Page 120 of agenda packet on the Paxlovid Patient Assessment Form for Pharmacist, change "advanced nurse practitioner" to "advance practice registered nurse";**
- **Pages 141 and 146, change "Cefdanir" to "Cefdinir". (motion by Yuan, seconded by Melton)**

AMENDMENTS TO VACCINE PROTOCOLS FOR AGES 3-17 AND ADULTS TO INCLUDE EPINEPHRINE TO TREAT ANAPHYLAXIS

Ms. Juran indicated she had received multiple requests to insert an allowance for initiating epinephrine within the statewide vaccine protocols for treatment of anaphylaxis resulting from vaccine administration. She indicated that such an allowance would be consistent with standard of care and the PREP Act, that a statewide protocol to initiate epinephrine in adults already exists, and that 54.1-3408 D allows numerous individuals to possess and administer epinephrine such as pharmacists, and employees of public places and restaurants. She stated that she had consulted with staff from the Board of Medicine and Department of Health and that they were comfortable with the draft language in the interest of patient safety.

MOTION

The Board voted unanimously to amend the *Vaccine Statewide Protocol for Persons Ages 3-17* and the *Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older* as presented to insert an allowance to initiate epinephrine for treatment of anaphylaxis. (Motion by Ratliff, seconded by Garvin)

RESCISSION OF PHARMACEUTICAL PROCESSOR PERMIT RFA

Ms. Juran provided an overview of the Request for Application (RFA) process for awarding a pharmaceutical processor permit in Health Service Area I. The RFA was issued on September 25, 2020, but review of the

FOR HSA I

applications was halted by the court in 2021 pending PharmaCann's appeal. Although the Board of Pharmacy was successful in the Virginia Court of Appeals, staff indicated there is insufficient time to receive revised applications and award conditional approval of a permit prior to January 1, 2024, when the Cannabis Control Authority (CCA) will assume oversight of the Commonwealth's medical cannabis program. Board staff has been working closely with CCA staff over the last year. The CCA intends to open a new RFA after the January 1st transition. Ms. Garvin recused herself from discussions based on her involvement with an applicant prior to being appointed to the Board.

MOTION

The Board voted unanimously to rescind RFA No. PHR-2020-01 for awarding a pharmaceutical processor permit in Health Service Area I and direct staff to refund the application fee to the 26 applicants who submitted application prior to the RFA deadline of December 4, 2020. (motion by Ratliff, seconded by Nash; Garvin recused)

PRELIMINARY MAPS OF CURRENT PHARMACY LOCATIONS BASED ON PRACTICE TYPE

To facilitate the Board's recent discussion at the June board meeting regarding pharmacy locations, staff reviewed the list of current active pharmacy permits located in Virginia and assigned a practice type to each permit. The assigned practice type was not verified directly with permit holders. There was some discussion regarding how frequently these maps could be updated, whether staff has sufficient resources to address this issue or if public data could simply be provided to a researcher or school to further analyze, and if national data regarding pharmacy locations already exists.

ACTION ITEM

Staff to research ability to include a field on the pharmacy permit application for the applicant to designate a practice type/environment.

ACTION ITEM

Mr. Owens recommended gathering information from associations and stakeholders regarding concerns for patient access to pharmacies, taking this information forward, and letting the Board be part of the discussion.

ACTION ITEM

Staff to research access to national data regarding pharmacy locations such as through NABP, NCPA, or NACDS. Based on this information, the Board will decide in December the frequency of requesting staff to provide pharmacy location maps for its review.

REQUEST FROM MEMBER FOR RETREAT

Dr. Nash requested consideration for a half-day or full day board member retreat to brainstorm and prioritize meeting the needs of the "current situation in pharmacy". She requested the Board design a dashboard of metrics to monitor trends, determine which metrics need to be amended, and determine what things the Board should do. agenda topics pertaining to the current needs of the pharmacy industry. The Chairman indicated there is only one available date prior to the end of January 2024. Several board members expressed reservation for convening a retreat without specific agenda items.

MOTION **A motion to convene a retreat on January 11, 2024 and for members to bring agenda topics to the December board meeting failed for a lack of a second. (motion by Nash)**

ACTION ITEM **There was consensus that Board members will send agenda ideas to staff by November 15, 2023 (3 weeks prior to December full board meeting) and reassess at the December meeting if a retreat, possibly in the spring, should be convened.**

REPORTS:

APhA Substance Use Disorder Institute 2023

Dr. Nash presented a PowerPoint presentation (slides in agenda packet) documenting her experience at the APhA Institute on Substance Use Disorders Workshop in Salt Lake City, Utah. She explained the history and mission of the program, the wonderful people she met, her experience staying in the college dorms, and more. Dr. Nash encourages the board members to attend the next one. She informed the Board of that the American Society of Health-System Pharmacists (ASHP) and the American Pharmacists Association (APhA) have partnered together to establish Pharmacy Workforce Suicide Awareness Day, which will be observed annually on September 20, as part of Suicide Prevention Month.

CHAIRMAN'S REPORT

Dr. St. Clair provided the Chairman's Report. He welcomed Dr. Shannon Dowdy to the Board. The Board is still waiting on the fulfillment of the citizen board member position. Cheri Garvin provided an update from the NABP District 1&2 Meeting which she attended with Caroline Juran. Garvin detailed the Past, Present, and Future of Pharmacy presentation given. She commented hearing suggestions of offering virtual meeting attendance and holding full board meetings at Schools of Pharmacy throughout the state.

BOARD OF HEALTH PROFESSIONS

Dr. Melton provided an update regarding the Virginia Board of Health Professions. The Board has not met since the last full board meeting. The next meeting has been scheduled for October 27th.

LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES

Ryan Logan presented the Licensing Report of Individuals and In-State Facilities which included data from February 2022 – August 2023. Mr. Logan provided a resident and nonresident license count for pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician trainees.

LICENSURE OF NONRESIDENT FACILITIES

Beth O'Halloran presented the Licensing Report of Nonresident Facilities which included data from August 2022 – August 2023. As of August 2023, there are a total of 2,499 nonresident licenses consisting of manufacturers, medical equipment suppliers, outsourcing facilities, pharmacies, third-party logistics providers, warehousers, and wholesale distributors.

ACTION ITEM	**There was consensus that the Board only needs to review the report on page 201A annually, not quarterly, and that staff can delete the report found on page 202 and use the report on page 204 instead, going forward.**
INSPECTION PROGRAM	Beth O'Halloran presented the Inspections report on behalf of Melody Morton, Inspections Manager with the Enforcement Division. The report included statistics regarding the number of inspections completed, identified deficiencies, and the rate of deficiency occurrences.
PHARMACEUTICAL PROCESSORS	Caroline Juran presented the Pharmaceutical Processors Report on behalf of Annette Kelley. Three additional cannabis dispensing facilities have been permitted during the last quarter totaling 18 cannabis dispensing facilities. Board and agency staff continue to meet bimonthly with the Virginia Cannabis Control Commission to address the anticipated transition of the medical cannabis program to the VCCA on January 1, 2024. As of September 11, 2023 there are 7,425 registered patients, 37 registered parents/guardians, 108 registered agents, and 3,392 registered cannabis products.
DISCIPLINARY PROGRAM	Dr. Ellen Shinaberry presented the Disciplinary Program Report. As of September 6, 2023, the Discipline Program consists of 208 patient care cases and 210 non-patient care cases. The Board currently has two cases being appealed in the Circuit Court.
ACTION ITEM	**The Board enjoyed receiving the additional disciplinary reports included in the agenda packet and would like this information going forward.**
EXECUTIVE DIRECTOR'S REPORT	Caroline Juran provided the Executive Director's report. The report detailed previous meetings attended and reviewed upcoming meetings.
CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS	David Robinson, AAG offered a presentation for a possible summary suspension order for pharmacy technician registration issued to Whitney Gatewood.
DECISION	Upon a motion by Garvin, and duly seconded by Ratliff, the Board voted unanimously to summarily suspend the pharmacy technician registration issued to Whitney Gatewood.
MEETING ADJOURNED:	With all business concluded, the Board adjourned the meeting at 3:04PM.

Date	Caroline D. Juran, RPh Executive Director

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF PUBLIC HEARING TO PLACE CERTAIN CHEMICALS INTO SCHEDULE I

Tuesday, September 26, 2023
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: A meeting of the Board of Pharmacy ("Board") was called to order at 9:07am.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:
Cheri Garvin, RPh
Larry Kocot, JD
Sarah Melton, PharmD
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Ling Yuan, PharmD
Shannon Dowdy, PharmD

STAFF PRESENT:
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowski, Senior Assistant Attorney General
Arne W. Owens, Director, DHP
Caroline D. Juran, RPh, Executive Director
Sorayah Haden, Executive Assistant
Beth O'Halloran, RPh, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Ellen B. Shinaberry, PharmD, Deputy Executive Director
Yvonne Miller, Records Administrative Assistant
Cecelia Robinson, Licensing Administrative Assistant

QUORUM: With 8 members of the Board present, a quorum of the board was established.

PUBLIC COMMENT Dr. St.Clair invited members of the public to offer comment on the subject.

Pursuant to article § 54.1-3443(D), the Virginia Department of Forensic Science (DFS) identified the following compounds for recommended inclusion into Schedule I of the Drug Control Act.

The following compound is classified as a synthetic opioid. Compounds of this type have been placed in Schedule I (§ 54.1-3446(1)) in previous legislative sessions.

1. N-ethyl-2-[5-nitro-2-[(4-propan-2-yloxyphenyl)methyl]benzimidazol-1-yl]ethanamine (other

name: N-desethyl Isotonitazene), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation.

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

2. Ethyl-3,3-dimethyl-2-[(1-(pent-4-enylindazole-3-carbonyl)amino]butanoate (other name: EDMB-4en-PINACA), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Additionally, the Board consulted with DFS regarding its intention to place tianeptine into Schedule I. DFS indicated if placed into Schedule I, it would be best classified into § 54.1-3446(1).

PUBLIC COMMENT

Robyn Weimer from the Department of Forensic Science provided comment indicating the compounds being considered for placement into Schedule I are a risk to public safety and have no medical use.

ADJOURN:

With all business concluded, the meeting adjourned at 9:15AM.

Caroline Juran, RPh, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF WORK GROUP FOR TRANSLATED DIRECTIONS FOR USE OF PRESCRIPTIONS MEETING

Thursday, September 28, 2023

Department of Health Professions
Perimeter Center
Board Room 3
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER:	The work group meeting was called to order at 9:04AM.
PRESIDING:	Dale St. Clair, PharmD, Board of Pharmacy, Chairman
MEMBERS PRESENT:	Kristopher Ratliff, DPh, Board of Pharmacy, Member Cheri Garvin, RPh, Board of Pharmacy, Member Patricia Richards-Spruill, RPh, Board of Pharmacy, Member Joanne Dial, PharmD, Kaiser Permanente Mid-Atlantic States Lauren Linkenauger, PharmD, Virginia Association of Chain Drug Stores Tana Kaefer, PharmD, Virginia Pharmacy Association Cynthia Coffey, PharmD, Virginia Society of Health-System Pharmacists
STAFF PRESENT:	Caroline Juran, RPh, Board of Pharmacy, Executive Director Beth O'Halloran, RPh, Board of Pharmacy, Deputy Executive Director Ryan Logan, RPh, Board of Pharmacy, Deputy Executive Director Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP Sorayah Haden, Board of Pharmacy, Executive Assistant
QUORUM:	With all members of the workgroup present, a quorum was established.
APPROVAL OF AGENDA:	Agenda was accepted as presented.
PUBLIC COMMENTS:	No additional public comments were offered.
	Dr. St. Clair provided an overview of the work group's charge pursuant to HB 2147.
DISCUSSION	The workgroup reviewed and discussed the possible challenges and barriers the Commonwealth may face by requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. Related laws and information

from Nevada, Washington, California, Oregon, and New York were provided in the agenda packet to assist the discussion.

Among the possible challenges and barriers mentioned were:

- Financial burden for pharmacies to acquire the proper equipment to provide translated services.
- Pharmacies are already struggling financially to survive, and many are understaffed or have workforce shortages. Expense and additional workload may be burdensome.
- Difficulty and expense with Board developing and maintaining model language; will create fiscal impact for Board and its licensees.
- Model language cannot reasonably be developed for all directions of use for all types of drug formulations and therefore, model language may be restricted to oral tablets, similar to California, that would only benefit some.
- Burden associated with cutting language from a list of model language and adhering phrase to container.
- Interoperability between dispensing software and translation software may be a challenge particularly in smaller, independent pharmacies
- Inability for all software systems to provide dual languages on a single label.
- Possible risks of error and burden associated with having to retype information into a second software system and adhering a separate label to the container
- Patients potentially tearing off flagged labels if information gets in the way
- Inability for software to accommodate all directions of use, special characters, and lengthy directions for use, e.g, drug tapers or insulin
- Concerns with accuracy of translation based on various dialects
- Patient may not recall all significant details if only provided verbal translation without written translation (information overload).
- Identifying and selecting specific languages of the Commonwealth that would receive translated services
- Capacity of prescription label to include information in English and preferred translated language
- Limited space on small containers for multiple labels
- Font size for visually-impaired patients
- Possible inability for pharmacy staff to verbally counsel patient even if label contains translated language
- Limitation of patient access if a particular pharmacy is unable to comply with regulations
- Additional signs informing patients of language services provided may be overlooked due to the number of signs currently already in place
- Requiring too many changes in pharmacy workflow at one time may be burdensome and lead to patient harm

- Placing such requirements on in-state pharmacies without requiring it of nonresident pharmacies, e.g., mail order or specialty pharmacies, or physicians that dispense drugs
- Possible out-of-pocket expense to patient for service if not covered by insurance.

While the work group fully appreciated the need for patients to understand proper administration and possible side effects of medications, it acknowledged that federal laws already require minimum standards in certain situations and informing pharmacies may be beneficial in encouraging more pharmacies to provide translation services without creating additional mandates. The work group reviewed information compiled by the Washington Board of Pharmacy that identified the following federal laws: Title VI of the Civil Rights Act 1964 (42 U.S.C. 2000d) regarding discrimination based on race, color, or national origin by any program or activity receiving Federal financial assistance; Section 504 of the Rehabilitation Act (29 U.S.C. § 794) regarding discrimination based on a disability from any program or activity receiving federal financial assistance; and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189; 28 C.F.R. Pt. 36) regarding discrimination at a place of public accommodation which includes a pharmacy. The work group recommended that the Board of Pharmacy consider at its December full board meeting its ability to inform pharmacies and pharmacy personnel of these federal laws. It was further acknowledged that some pharmacies currently offer translation services for patients and that liability protections for pharmacy personnel are needed.

Other comments included:

- Pharmacies could be encouraged to offer resources to patients such as informing patients of translation applications for phones.
- Hiring pharmacists with language proficiencies appropriate to setting which some already do as reported by one member.
- Perhaps limit any possible efforts to Spanish and limit requirements to high-population density areas to avoid unnecessary burden across the Commonwealth.
- Consider grants for alleviating financial burden associated with any possible requirements.
- Administering a survey to identify which pharmacies currently offer language services to their patients.

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 11:10AM.

Date

Caroline D. Juran, RPh
Executive Director

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

Tuesday, October 10, 2023
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER:	A presentation for a Possible Summary Suspension was called to order at 9:12AM.
PRESIDING:	Dale St. Clair, PharmD, Chair
MEMBERS PRESENT:	Cheri Garvin, RPh Kristopher Ratliff, DPh Shannon Dowdy, PharmD Larry Kocot, JD Ling Yuan, PharmD
MEMBERS ABSENT:	Patricia Richards-Spruill, RPh Wendy C. Nash, PharmD Sarah Melton, PharmD
STAFF PRESENT:	Caroline Juran, RPh, Executive Director James Rutkowski, Senior Assistant Attorney General Ellen Shinaberry, PharmD, Deputy Executive Director Sorayah Haden, Executive Assistant
QUORUM	With 6 members of the Board present, a panel of the board was established.
RENEE TODD PHARMACY TECHNICIAN TRAINEE #0245-010573	David Robinson, Assistant Attorney General presented a possible summary suspension presentation via telephone for Board consideration regarding Renee Todd.
DECISION:	Upon a motion by Garvin, and duly seconded by Ratliff, the Board voted 8-0 to summarily suspend the Pharmacy Technician Trainee Registration, schedule a Formal Hearing, and offer a consent order in lieu of a formal hearing for Renee Todd.
ADJOURNED:	With all business concluded, the meeting adjourned at 9:25AM.
CALL TO ORDER:	A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:32AM.
PRESIDING:	Dale St. Clair, PharmD, Chair

MEMBERS PRESENT:	Kristopher Ratliff, DPh Shannon Dowdy, PharmD Larry Kocot, JD Ling Yuan, PharmD
MEMBERS ABSENT:	Patricia Richards-Spruill, RPh Wendy C. Nash, PharmD (recused) Cheri Garvin, RPh (recused) Sarah Melton, PharmD
STAFF PRESENT:	Caroline Juran, RPh, Executive Director James Rutkowski, Senior Assistant Attorney General Ellen Shinaberry, PharmD, Deputy Executive Director Sorayah Haden, Executive Assistant
QUORUM:	With 5 members of the Board present, a panel of the board was established.
CASE #210788 MIKDAD MAROUF PHARMACIST #0202-210485	A formal hearing was held in the matter of Mikdad Marouf to discuss allegations that he has violated certain laws and regulations governing the practice of pharmacy in Virginia. Jess Weber, DHP Adjudication Specialist for the Commonwealth, presented the case. Mikdad Marouf was not present and was not represented by counsel. Edward Haukrader, MD testified by telephone, and Katrina Trelease, RPh, DHP Senior Investigator, testified in person on behalf of the Commonwealth.
CLOSED MEETING:	Upon a motion by Ratliff, and duly seconded by Kocot, the Board 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 Mikdad Marouf. Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden 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 Yuan)
DECISION:	Upon a motion by Ling and duly seconded by Ratliff, the Board voted unanimously to approve the findings of fact and

	conclusions of law as presented by the Commonwealth and amended by the Board. Upon a motion by Dowdy and duly seconded by Kocot, the Board unanimously voted that with the evidence presented, to indefinitely suspend the Pharmacist license of Mikdad Marouf for no less than one year.
PRESIDING:	Dale St. Clair, PharmD, Chair
MEMBERS PRESENT:	Cheri Garvin, RPh Wendy C. Nash, PharmD Kristopher Ratliff, DPh Shannon Dowdy, PharmD Larry Kocot, JD Ling Yuan, PharmD
MEMBERS ABSENT:	Patricia Richards-Spruill, RPh Sarah Melton, PharmD
STAFF PRESENT:	Caroline Juran, RPh, Executive Director James Rutkowski, Ellen Shinaberry, PharmD, Deputy Executive Director Sorayah Haden, Executive Assistant
QUORUM:	With 7 members of the Board present, a panel of the board was established.
CASE #229127 JAKIY'YAH CANNON PHARMACY TECHNICIAN TRAINEE #0245-007487	A formal hearing was held in the matter of Jakiy'Yah Cannon to discuss allegations that she has violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia. Jess Weber, DHP Adjudication Specialist for the Commonwealth, presented the case. Jakiy'Yah Cannon was not present and was not represented by counsel. Shawn Ledger, DHP Senior Investigator, Christian Malone, Pharmacist in Charge, CVS Pharmacy #5986, and Rameshwar Singh, CVS District Asset Protection Leader, testified in person on behalf of the Commonwealth.
CLOSED MEETING:	Upon a motion by Ratliff, and duly seconded by Yuan, the Board voted 7-0, 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 Jakiy'Yah Cannon. Additionally, he moved that Caroline Juran, James Rutkowski, Ellen Shinaberry, and Sorayah Haden 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 Nash)
DECISION:	Upon a motion by Ling and duly seconded by Ratliff, the Board voted unanimously to approve the findings of fact and conclusions of law as presented by the Commonwealth and amended by the Board. Upon a motion by Dowdy and duly seconded by Garvin, the Board unanimously voted that with the evidence presented, to revoke the Pharmacy Technician Trainee Registration of Jakiy'Yah Cannon.
ADJOURN:	With all business concluded, the meeting adjourned at 2:04PM.

Caroline Juran, RPh, Executive Director

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, October 11, 2023
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of a Special Conference Committee (Innovative Pilot) of the Board of Pharmacy was called to order at 9:19 AM.
PRESIDING:	Dale St.Clair, Committee Chairman
MEMBER PRESENT:	Ling Yuan, Committee Member
STAFF PRESENT:	Caroline D. Juran, Executive Director Ellen Shinaberry, Deputy Executive Director Mykl Egan, Discipline Case Manager Jess Weber, DHP Adjudication Specialist Rebecca Ribley, DHP Adjudication Specialist
WALGREENS CENTRAL FILL #21420	Alice Kim, PharmD, Pharmacist, and Cheri Garvin, Pharmacist and Owner, appeared in person to discuss the proposed innovative pilot program "Remote Supervision Pilot" as stated in the September 22, 2023 Notice.
DISCUSSION:	Representatives of The Compounding Center in Leesburg, VA presented information related to their application for remote processing by pharmacy technicians.
DECISION:	Upon a motion by Dr. St. Clair, and duly seconded by Dr. Yuan, the Committee voted unanimously to approve the innovative pilot program for three years with certain terms and conditions.
ADJOURN:	With all business concluded, the meeting adjourned at 11:29 AM.

Caroline D. Juran
Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Friday, October 20, 2023

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 § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on October 20, 2023, at 08:31 AM, to consider the summary suspension in case no..

PRESIDING: Cheri Garvin, Vice Chair

MEMBERS PRESENT: Larry Kocot
Shannon Dowdy
Kristopher Ratliff
Sarah Melton
Patricia Richards-Spruill

STAFF PRESENT: Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
James Rutkowski, Senior Assistant Attorney General
David Robinson, Assistant Attorney General
Christine Andreoli, DHP Adjudication Specialist

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

ZACHARY AILSTOCK David Robinson, Senior Assistant Attorney General,

Registration No. 0230-032800	presented a summary of the evidence in case no. 231434 regarding the pharmacy technician trainee registration of Zachary W. Ailstock.
DECISION:	Upon a motion by Mrs. Richards-Spruill and duly seconded by Mr. Kocot, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician by Zachary Ailstock poses a substantial danger to the public; and therefore, the registration of Mr. Ailstock shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Mr. Ailstock for the revocation of his registration in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 8:51 AM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

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

Wednesday, November 8, 2023
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:58 a.m. for the purpose of two formal hearings.

PRESIDING: Dale St. Clair

MEMBERS PRESENT:
Mrs. Patricia Richards-Spruill
Ms. Cheri Garvin
Dr. Shannon Dowdy
Mr. Larry Kocot
Dr. Wendy Nash

STAFF PRESENT:
Ellen B. Shinaberry, Deputy Executive Director
James Rutkowski, Assistant Attorney General
Sorayah Haden, Executive Assistant

TARIQ AMIN
Registration No. 0230-010451

A formal hearing was held in the matter of Tariq Amin to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy technician in Virginia and to consider his application for reinstatement of his pharmacy technician registration as provided in the notice dated August 29, 2023.

Rebecca Ribley, Adjudication Specialist, presented on behalf of the Commonwealth.

Mr. Amin was present at the hearing and was represented by Nora Ciancio, Esq.

QUORUM: With six (6) members of the Board present, a panel of the board was established.
Rebecca Ribley, Adjudication Specialist, presented the case on behalf of the Commonwealth.

Katie Land, DHP Senior Investigator, testified on behalf of the Commonwealth.

Mr. Amin testified on his own behalf. Angela H. Spencer, Pharmacist in charge at Family Care RX, testified by telephone on behalf of Mr. Amin.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Dr. Dowdy, the Board 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 Tariq Amin. Additionally, she moved that Ellen Shinaberry, Jim Rutkowski, and Sorayah Hayden 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 Board reconvened an open meeting and announced the decision. (Garvin/Kocot)

DECISION:

Upon a motion by Dr. Dowdy, and duly seconded by Mrs. Richards-Spruill, the Board voted 6-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Dr. Nash, and duly seconded by Ms. Garvin, the board voted 6-0 to deny the reinstatement application of Mr. Amin to practice as a pharmacy technician.

Board member Garvin departed at 2:55 p.m.

Whitney Gatewood
Registration No. 0230-031284

A formal hearing was held in the matter of Whitney Gatewood to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as provided in the notice dated September 29, 2023.

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

David Robinson, Asst. Attorney General, presented the case. He was assisted by Rebecca Ribley, Adjudication Specialist.

Whitney Gatewood was not present and was not represented by counsel.

David Cowras, DHP Sr. Investigator, testified in person on behalf of the Commonwealth.

Cory Burke, Store Manager CVS Pharmacy #7581, Tamara Ferrel, Pharmacy Manager, CVS Pharmacy #7581, and Patrick Combs, District Leader CVS, testified in person on behalf of the Commonwealth.

Bradley Zaretsky, former District Asset Protection Leader, CVS Health, testified by telephone on behalf of the Commonwealth.

CLOSED MEETING: Upon a motion by Dr. Nash, and duly seconded by Mrs. Richards-Spruill, the Board 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 Whitney Gatewood. Additionally, she moved that Ellen Shinaberry, Jim Rutkowski, and Sorayah Hayden 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 Board reconvened an open meeting and announced the decision. (Nash/Dowdy)

DECISION: Upon a motion by Dr. Dowdy, and duly seconded by Mrs. Richards-Spruill, the Board voted 5-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Mr. Kocot, and duly seconded by Dr. Nash, the board voted 5-0 to revoke the pharmacy technician registration of Ms. Gatewood.

ADJOURNED: 3:14 PM

Caroline D. Juran
Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of November 17, 2023

In the Governor's Office

VAC	Stage	Subject Matter	Date submitted	Office; time in office	Notes
18VAC110-20	Final	Prohibition against incentives to transfer prescriptions	5/23/2018	Governor 2004 days; 6.6 years since submission for executive branch review	Addresses a patient safety concern.

In the Secretary's Office

VAC	Stage	Subject Matter	Date submitted	Office; time in office	Notes
18VAC110-20	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 593 days	Implementation of changes identified during 2021 periodic review of regulations governing the practice of pharmacy
18VAC110-21	NOIRA	Implementation of 2021 Periodic Review	4/3/2022	Secretary 593 days	Implementation of changes identified during 2021 periodic review of regulations governing the licensure of pharmacists and registration of pharmacy technicians
18VAC110-20	Proposed	Centralized warehouser or wholesale distributor verification of Schedule VI	8/31/2022	Secretary 443 days	Permits centralized warehousers or wholesale distributors to verify Schedule

		drugs for ADDs in hospitals			VI drugs for ADDs in hospitals
18VAC110-21	Emergency/ NOIRA	2023 pharmacists initiating treatment	7/25/2023	Secretary 115 days	Changes in pharmacists initiating treatment pursuant to legislation
18VAC110-21	Fast-Track	Repeal of outdated sections	8/16/2023	Secretary 93 days	Repeals outdated regulations regarding pharmacy technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	8/25/2023	Secretary 85 days	Implements changes identified during the periodic review process
18VAC110-20	Fast-Track	Amendment to clarify application of 18VAC110-20-735	8/29/2023	Secretary 80 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone
18VAC110-20	NOIRA	Increase in fees	9/29/2023	Secretary 32 days	The Board will consider increase of fees to fund Board activities as required by statute

At DPB/OAG

VAC	Stage	Subject Matter	Date submitted	Office; time in office	Notes
18VAC110-20	Exempt/ Final	September 2023 scheduling of chemicals in Schedule I	9/29/2023	OAG 49 days	Schedules chemicals in Schedule I pursuant

					to consultation with DFS
18VAC110-30	Fast-track	Name change of nurse practitioner to advanced practice registered nurse	9/29/2023	OAG 49 days	Changes reference from nurse practitioner to advanced practice registered nurse pursuant to legislation
18VAC110-20	Proposed	Exemption of automated dispensing devices stocked solely with emergency or stat-use medications from certain requirements of 18VAC110-20-555	6/21/2023	DPB 1 day	Response to a petition for rulemaking to allow certain ADDs exemption from requirements under regulations
18VAC110-21	Proposed	2022 pharmacists initiating treatment	6/21/2023	DPB 1 day	Implements 2022 legislation regarding pharmacists initiating treatment; replaces emergency regulations

Recently effective or awaiting publication

VAC	Stage	Subject Matter	Publication date	Effective date
18VAC110-21	Final	Implementation of 2021 legislation for pharmacists initiating treatment	10/9/2023	11/8/2023
18VAC110-20	Exempt/ Final	Removes chemicals from Schedule I pursuant to GA changes	10/9/2023	11/8/2023
18VAC110-20	Emergency/ NOIRA	Pharmacy working conditions	10/23/2023	9/29/2023

Agenda Item: Adoption of proposed regulations to replace emergency regulations for Pharmacy Working Conditions

Included in your agenda package:

- Proposed regulations regarding pharmacy working conditions;
- Ch. 628 of the 2022 General Assembly Session; and
- Public comment posted on Town Hall accessible at https://townhall.virginia.gov/L/ViewComments.cfm?stageid=9792 (and at your seat).

Staff notes: Public comment period ends 11/22/2023. Proposed regulations will begin the process to replace existing emergency regulations with permanent regulations.

Action needed:

- Motion to adopt the proposed regulations for pharmacy working conditions as presented or amended.

Project 7342 - Emergency/NOIRA

Board of Pharmacy

Pharmacy working conditions

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

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 may, however, volunteer to work longer than 12 continuous hours. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break. Breaks, including uninterrupted rest periods and meal breaks, shall be provided consistent with 18VAC110-20-113 B 5.

C. The PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

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.

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

F. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedules II through V controlled substances on hand on the date ~~he~~ the pharmacist 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.

G. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

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.

I. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

J. Before any permit is issued, the applicant shall attest to compliance with all federal, state, and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

18VAC110-20-113. Pharmacy working conditions.

A. A pharmacy permit holder shall protect the health, safety, and welfare of patients by consulting with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. A permit holder's decisions shall not override the control of the PIC or other pharmacist on duty regarding appropriate working environments for all pharmacy personnel necessary to protect the health, safety, and welfare of patients.

B. To provide a safe working environment in a pharmacy, a permit holder shall, at a minimum:

1. Ensure sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with reasonable competence and safety. Staffing levels shall not be solely based on prescription volume, but shall consider any other requirements of pharmacy staff during working hours;

2. Provide sufficient tools and equipment in good repair and minimize excessive distractions to support a safe workflow for a pharmacist to practice with reasonable competence and safety to address patient needs in a timely manner;

3. Avoid the introduction of external factors, such as productivity or production quotas or other programs, to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

4. Ensure staff are sufficiently trained to safely and adequately perform their assigned duties, ensure staff demonstrate competency, and ensure that pharmacy technician trainees work closely with pharmacists and pharmacy technicians with sufficient experience as determined by the PIC;

5. Provide appropriate opportunities for uninterrupted rest periods and meal breaks consistent with 18VAC110-20-110 and the following:

a. A pharmacy may close when a pharmacist is on break based on the professional judgment of the pharmacist on duty provided that the pharmacy has complied with the 14-day notice to the public pursuant to § 54.1-3434 of the Code of Virginia and 18VAC110-20-135;

b. If a pharmacy does not close while the pharmacist is on break, the pharmacist must ensure adequate security of drugs by taking a break within the prescription department or on the premises. The pharmacist on duty must determine whether pharmacy technicians or pharmacy interns may continue to perform duties and whether the pharmacist is able to provide adequate supervision; and

c. If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel any person filling a new prescription must be offered pursuant to § 54.1-3319 of the Code of Virginia. Persons who request to speak to the pharmacist shall be told that the pharmacist is on break and that they may wait to speak with the pharmacist or provide a telephone number for the pharmacist to contact them upon return from break. Pharmacists returning from break shall immediately attempt to contact persons who requested counseling and document when such counseling is provided;

6. Provide adequate time for a pharmacist to complete professional duties and responsibilities, including:

a. Drug utilization review;

b. Immunization;

c. Counseling;

d. Verification of prescriptions;

e. Patient testing; and

f. All other duties required by Chapter 33 (§ 54.1-3300 et seq.) and Chapter 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia and this chapter; and

7. Ensure that pharmacy technicians shall never perform duties otherwise restricted to a pharmacist.

C. A pharmacy permit holder shall not override the control of the pharmacist on duty regarding all aspects of the practice of pharmacy, including a pharmacist's decision not to administer vaccines when one pharmacist is on duty and, in the pharmacist's professional judgment, vaccines cannot be administered safely.

D. Staffing requests or concerns shall be communicated by the PIC or pharmacist on duty to the permit holder using a form developed by the board.

1. Executed staffing forms shall be provided to the immediate supervisor of the PIC or pharmacist on duty, with one copy maintained in the pharmacy for three years, and produced for inspection by the board.

2. The PIC or pharmacist on duty may report any staffing issues directly to the board if the PIC or pharmacist on duty believes the situation warrants immediate board review.

3. Under no circumstances shall a good faith report of staffing concerns by the PIC, pharmacist on duty, or notification of such issues by pharmacy personnel to the PIC or pharmacist on duty result in workplace discipline against the reporting staff member.

E. Permit holders shall review completed staffing reports and shall:

1. Respond to reporting staff member to acknowledge receipt of the staffing request or concern;

2. Resolve any issues listed in a timely manner to ensure a safe working environment for pharmacy staff and appropriate medication access for patients;

3. Document any corrective action taken, steps taken toward corrective action as of the time of inspection, or justification for inaction, which documentation shall be maintained on site or produced for inspection by the board within 48 hours of request; and

4. Communicate corrective action taken or justification for inaction to the PIC or reporting pharmacist on duty.

CHAPTER 628

An Act to direct the Board of Pharmacy to adopt regulations related to work environment requirements for pharmacy personnel.

[H 1324]

Approved April 11, 2022

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy shall adopt regulations related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients. Such regulations shall include provisions (i) addressing sufficient pharmacy staffing to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competence and safety; (ii) stating standards for uninterrupted rest periods and meal breaks for pharmacy personnel; (iii) stating standards that ensure adequate time for pharmacists to complete professional duties and responsibilities, including drug utilization reviews, immunization administration, patient counseling, and verification of prescription accuracy; and (iv) limiting external factors such as productivity or production quotas to the extent that such factors interfere with the ability to provide appropriate professional services to the public.*

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.

Agenda Topic: Consider recommendation of HB 2147 (Prescription Translation Services) Workgroup

Included in Agenda Packet:

- HB2147
- Refer to workgroup minutes from 9/28/23 on pages 17-19 of agenda packet

Action Needed:

- Motion to accept workgroup's recommendation to inform pharmacies and pharmacy personnel of the following federal laws and advise that they seek legal advice regarding applicability to their practice: Title VI of the Civil Rights Act 1964 (42 U.S.C. 2000d) regarding discrimination based on race, color, or national origin by any program or activity receiving Federal financial assistance; Section 504 of the Rehabilitation Act (29 U.S.C. § 794) regarding discrimination based on a disability from any program or activity receiving federal financial assistance; and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189; 28 C.F.R. Pt. 36) regarding discrimination at a place of public accommodation which includes a pharmacy.

CHAPTER 630

An Act to direct the Board of Pharmacy to convene a work group to evaluate the provision of translated directions for use of prescriptions; report.

[H 2147]

Approved March 26, 2023

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy (the Board) shall convene a work group of interested stakeholders to evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. The Board shall report the findings of the work group to the Governor and the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by December 1, 2023.*

Agenda Item: Repeal of guidance documents related to the medical cannabis program

Included in your agenda package:

- Guidance document 110-14;
- Guidance document 110-20;
- Guidance document 110-40;
- Guidance document 110-45;
- Guidance document 110-48; and
- Guidance document 110-51.

Staff note: With the transfer of the medical cannabis program to the Virginia Cannabis Control Authority, effective January 1, 2024, these guidance documents will be obsolete.

Guidance document 110-32 (Cannabis Drug Interactions) is not included in this list, as the subject matter of that document does not relate to the medical cannabis program, but to the use of cannabis by patients.

Action needed:

- Motion to repeal guidance documents 110-14, 110-20, 110-40, 110-45, 110-48, and 110-51, effective January 1, 2024.

Virginia Board of Pharmacy

Proximity of a School or Daycare to a Cannabis Dispensing Facility

Pursuant to 18VAC 110-60-135, a cannabis dispensing facility cannot be located within 1,000 feet of a school or daycare. At the time the dispensing facility application is submitted to the Board, the applicant must ensure that the proposed site at the address recorded on the application complies with this requirement and must attest that no school or daycare has been approved by the locality or licensed, registered, or regulated by the state to operate within 1,000 feet of the proposed site. A pending application is valid for up to 12 months from the date received by the Board.

Prior to issuing the dispensing facility permit, an agent of the Board will inspect the facility for compliance with the laws and regulations. In determining compliance with the requirement that a cannabis dispensing facility cannot be located within 1,000 feet of a school or daycare, the inspector will assess compliance as of the date the application was received by the Board.

Should a school or daycare locate within 1,000 feet of an already permitted cannabis dispensing facility or pharmaceutical processor, the Board will not hold the permit in violation of the 1,000 feet prohibition in 18VAC110-60-135.

VIRGINA BOARD OF PHARMACY

Criminal Background Checks of Material Owners for Pharmaceutical Processor or Cannabis Dispensing Facility Permits

The Board provides the following guidance for a material owner of an applicant for a pharmaceutical processor or cannabis dispensing facility permit who is also a material owner of another permitted pharmaceutical processor or cannabis dispensing facility and was previously subject to a criminal background check. Upon submission of an application for change of ownership of an existing pharmaceutical processor or cannabis dispensing facility or new application, the material owner(s) shall complete a background check if it has been more than 90 days since the previous background check was conducted. Board staff will provide the material owner(s) with the necessary documentation to complete the background check.

Notwithstanding 18VAC110-60-135, the Board interprets the requirement for material owners of a pharmaceutical processor or cannabis dispensing facility permit as referenced in Virginia Code § 54.1-3442.6 to mean those owners with 5.0% or greater ownership. For facilities that do not have owners with 5.0% or greater ownership, a criminal background check should be performed on the facility's executive leadership with ownership.

Virginia Board of Pharmacy

Contracted Employee Access to a Pharmaceutical Processor

In addition to the persons allowed on the premises of a pharmaceutical processor as identified in 18VAC110-60-220 (F), the Board of Pharmacy authorizes an employee of a business that is contracted by a pharmaceutical processor who needs to be allowed on the premises of the processor to perform his duties. The contract may be with an individual or with a service company such as security, cleaning, electrical, HVAC, plumbing, etc. A request for the Board to authorize these contracted employees to be allowed on the premises of the process is not required. To mitigate security risks, the pharmaceutical processor should apply the requirements for visitor access found in 18VAC110-60-220 (G) to the contracted employee.

Excerpt from 18VAC110-60-20

18VAC110-60-220. Pharmaceutical processor prohibitions.

F. No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian 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 or cannabis 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.

Virginia Board of Pharmacy

Approved Chemicals for use as Hydrocarbon or Other Flammable Solvents by Pharmaceutical Processors

Pursuant to 18VAC110-60-281(H), the Board approves the following chemicals for use as hydrocarbon or other flammable solvents in the cultivation, extraction, production, or manufacturing of cannabis products. These approvals are based on the availability of testing for residual material of individual solvents.

- Ethanol
- Ethyl acetate
- Ethyl ether
- Heptane
- Hexane
- Pentane
- 2-propanol (IPA)
- Butane*
- Propane*

*The Board recognizes butane and propane as class 3 solvents with a permissible daily exposure of 50mg/day.

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 cannabis 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 cannabis oil by accessing the Prescription Monitoring Program.

Code of Virginia as of July 1, 2020:

§ 54.1-3442.7. Dispensing cannabis oil; report.

A. A pharmaceutical processor or cannabis dispensing facility shall dispense or deliver cannabis 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 cannabis 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 cannabis 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 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 cannabis 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 cannabis oil on site is within such range. A pharmaceutical processor producing cannabis oil shall establish a stability testing schedule of cannabis oil.

Excerpt from 18VAC110-60-310 (as amended by the Board on June 16, 2020):

18VAC110-60-310. Dispensing of cannabis oil.

A. A pharmacist in good faith may dispense cannabis 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 cannabis 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 oil reasonably necessary to ensure an uninterrupted availability of supply for a 90-day period for registered patients.

Virginia Board of Pharmacy

Cannabis Product Packaging Requirements

In addition to packaging and labeling requirements found in 18VAC110-60-210, 18VAC110-60-290, 18VAC110-60-310 and pursuant to § 54.1-3442.6 and 18VAC110-60-285, the Board of Pharmacy interprets the term "advertising" (18VAC110-60-10) to include packaging in which cannabis products are marketed and dispensed. Therefore, cannabis product packages, including the brand name assigned to the cannabis product and appearing on the package label, should comply with the advertisement requirements of 18VAC110-60-215. Additional guidance is provided below to clarify acceptable packaging requirements.

Packaging should not:

- Promote over consumption or consumption for other than medical purposes;
- Include neon colors;
- Include psychedelic design; or,
- Include any color or design combinations that could be misconstrued to encourage the recreational use of cannabis.

Brand names assigned to cannabis products and included on the package label may include strain names, including those developed by pharmaceutical processors, that do not violate 18VAC110-20-215 or that are associated with movies, fictional characters, social media influencers, video games, illegal activities, or include derogatory, slang, or racial nomenclature. Descriptors such as flavors, colors, or minerals would be acceptable. Names comprised of a combination of letters or numbers would also be acceptable.

References:

Va. Code § 54.1-3442.6
18VAC110-60-10
18VAC110-60-210
18VAC110-60-215
18VAC110-60-285
18VAC110-60-290
18VAC110-60-310

Agenda Item: Repeal of Chapter 60 due to the transfer of the medical cannabis program

Included in your agenda package:

- 18VAC110-60, Regulations Governing Pharmaceutical Processors.

Staff note: With the transfer of the medical cannabis program to the Virginia Cannabis Control Authority, effective January 1, 2024, these regulations will be obsolete. Because the enacting legislation transferring the program takes effect January 1, 2024, the Board can repeal this Chapter by exempt action.

Action needed:

- Motion to repeal Chapter 60, Regulations Governing Pharmaceutical Processors, by exempt action effective January 1, 2024.

Commonwealth of Virginia

REGULATIONS

GOVERNING PHARMACEUTICAL PROCESSORS

Title of Regulations: 18 VAC 110-60-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34

of Title 54.1 of the *Code of Virginia*

Effective Date: August 16, 2023

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300 **Phone: 804-367-4456**
Henrico, VA 23233-1464 **Fax: 804-527-4472**

email: pharmbd@dhp.virginia.gov

Agenda Item: Completion of periodic review of public participation guidelines contained in 18VAC110-11

Included in your agenda packet:

- One comment received during public comment period
- 18VAC110-11

Staff Note: Agencies are required to conduct periodic reviews of regulatory chapters every four years. Although this particular chapter is only changed when the Department of Planning and Budget provides new model language, the Board was still required to conduct a periodic review. Now that the review is complete, the Board should not initiate any changes, but retain as is until DPB amends the model regulations.

The issue addressed in the public comment does not require a regulatory change and does not require a change to the public participation guidelines.

Action Needed:

- Motion to retain 18VAC110-11 as is.

Periodic Review: 2468			
Commenter	**Title**	**Comment**	**Date/ID**
Brad McDaniel, VSHP	Virtual Public Participation	The Virginia Society of Health-System Pharmacists appreciates the Board of Pharmacy's openness to public participation in Board items. VSHP requests the Board to consider the addition of virtual attendance and virtual participation in public meetings of the Board of Pharmacy. We are a large state and many stakeholders may wish to hear the conversation of the Board members which is not always captured in the meeting minutes. Additionally, outside the Town Hall opportunities for comment on specific items, a stakeholder may wish to make a virtual (verbal/audio) comment at the beginning of Board meetings and may not have representation available for the in-person option. VSHP kindly requests notification if this does not fall under the public participation guideline scope with insight into the appropriate avenue.	11/9/23 4:17 pm CommentID:220632

Commonwealth of Virginia

PUBLIC PARTICIPATION GUIDELINES

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-11-10 et seq.

Statutory Authority: §§ 54.1-2400 and 2.2-4007 of the *Code of Virginia*

Revised Date: December 15, 2016

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email: pharmbd@dhp.virginia.gov

TABLE OF CONTENTS

Part I
Purpose and Definitions

18VAC110-11-10. Purpose.

The purpose of this chapter is to promote public involvement in the development, amendment or repeal of the regulations of the Board of Pharmacy. This chapter does not apply to regulations, guidelines, or other documents exempted or excluded from the provisions of the Administrative Process Act (§2.2-4000 et seq. of the Code of Virginia).

18VAC110-11-20. Definitions.

The following words and terms when used in this chapter shall have the following meanings unless the context clearly indicates otherwise:

"Administrative Process Act" means Chapter 40 (§2.2-4000 et seq.) of Title 2.2 of the Code of Virginia.

"Agency" means the Board of Pharmacy, which is the unit of state government empowered by the agency's basic law to make regulations or decide cases. Actions specified in this chapter may be fulfilled by state employees as delegated by the agency.

"Basic law" means provisions in the Code of Virginia that delineate the basic authority and responsibilities of an agency.

"Commonwealth Calendar" means the electronic calendar for official government meetings open to the public as required by §2.2-3707 C of the Freedom of Information Act.

"Negotiated rulemaking panel" or "NRP" means an ad hoc advisory panel of interested parties established by an agency to consider issues that are controversial with the assistance of a facilitator or mediator, for the purpose of reaching a consensus in the development of a proposed regulatory action.

"Notification list" means a list used to notify persons pursuant to this chapter. Such a list may include an electronic list maintained through the Virginia Regulatory Town Hall or other list maintained by the agency.

"Open meeting" means any scheduled gathering of a unit of state government empowered by an agency's basic law to make regulations or decide cases, which is related to promulgating, amending or repealing a regulation.

"Person" means any individual, corporation, partnership, association, cooperative, limited liability company, trust, joint venture, government, political subdivision, or any other legal or commercial entity and any successor, representative, agent, agency, or instrumentality thereof.

"Public hearing" means a scheduled time at which members or staff of the agency will meet for the purpose of receiving public comment on a regulatory action.

"Regulation" means any statement of general application having the force of law, affecting the rights or conduct of any person, adopted by the agency in accordance with the authority conferred on it by applicable laws.

"Regulatory action" means the promulgation, amendment, or repeal of a regulation by the agency.

"Regulatory advisory panel" or "RAP" means a standing or ad hoc advisory panel of interested parties established by the agency for the purpose of assisting in regulatory actions.

"Town Hall" means the Virginia Regulatory Town Hall, the website operated by the Virginia Department of Planning and Budget at www.townhall.virginia.gov, which has online public comment forums and displays information about regulatory meetings and regulatory actions under consideration in Virginia and sends this information to registered public users.

"Virginia Register" means the Virginia Register of Regulations, the publication that provides official legal notice of new, amended and repealed regulations of state agencies, which is published under the provisions of Article 6 (§2.2-4031 et seq.) of the Administrative Process Act.

Part II
Notification of Interested Persons

18VAC110-11-30. Notification list.

A. The agency shall maintain a list of persons who have requested to be notified of regulatory actions being pursued by the agency.

B. Any person may request to be placed on a notification list by registering as a public user on the Town Hall or by making a request to the agency. Any person who requests to be placed on a notification list shall elect to be notified either by electronic means or through a postal carrier.

C. The agency may maintain additional lists for persons who have requested to be informed of specific regulatory issues, proposals, or actions.

D. When electronic mail is returned as undeliverable on multiple occasions at least 24 hours apart, that person may be deleted from the list. A single undeliverable message is insufficient cause to delete the person from the list.

E. When mail delivered by a postal carrier is returned as undeliverable on multiple occasions, that person may be deleted from the list.

F. The agency may periodically request those persons on the notification list to indicate their desire to either continue to be notified electronically, receive documents through a postal carrier, or be deleted from the list.

18VAC110-11-40. Information to be sent to persons on the notification list.

A. To persons electing to receive electronic notification or notification through a postal carrier as described in 18VAC110-11-30, the agency shall send the following information:

1. A notice of intended regulatory action (NOIRA).

2. A notice of the comment period on a proposed, a reproposed, or a fast-track regulation and hyperlinks to, or instructions on how to obtain, a copy of the regulation and any supporting documents.

3. A notice soliciting comment on a final regulation when the regulatory process has been extended pursuant to §2.2-4007.06 or 2.2-4013 C of the Code of Virginia.

B. The failure of any person to receive any notice or copies of any documents shall not affect the validity of any regulation or regulatory action.

Part III
Public Participation Procedures

18VAC110-11-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency; and (ii) be accompanied by and represented by counsel or other representative. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.

18VAC110-11-60. Petition for rulemaking.

A. As provided in §2.2-4007 of the Code of Virginia, any person may petition the agency to consider a regulatory action.

B. A petition shall include but is not limited to the following information:

1. The petitioner's name and contact information;

2. The substance and purpose of the rulemaking that is requested, including reference to any applicable Virginia Administrative Code sections; and

3. Reference to the legal authority of the agency to take the action requested.

C. The agency shall receive, consider and respond to a petition pursuant to §2.2-4007 and shall have the sole authority to dispose of the petition.

D. The petition shall be posted on the Town Hall and published in the Virginia Register.

E. Nothing in this chapter shall prohibit the agency from receiving information or from proceeding on its own motion for rulemaking.

18VAC110-11-70. Appointment of regulatory advisory panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

18VAC110-11-80. Appointment of negotiated rulemaking panel.

A. The agency may appoint a negotiated rulemaking panel (NRP) if a regulatory action is expected to be controversial.

B. A NRP that has been appointed by the agency may be dissolved by the agency when:

1. There is no longer controversy associated with the development of the regulation;

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act; or

3. The agency determines that resolution of a controversy is unlikely.

18VAC110-11-90. Meetings.

Notice of any open meeting, including meetings of a RAP or NRP, shall be posted on the Virginia Regulatory Town Hall and Commonwealth Calendar at least seven working days prior to the date of the meeting. The exception to this requirement is any meeting held in accordance with §2.2-3707 D of the Code of Virginia allowing for contemporaneous notice to be provided to participants and the public.

18VAC110-11-100. Public hearings on regulations.

A. The agency shall indicate in its notice of intended regulatory action whether it plans to hold a public hearing following the publication of the proposed stage of the regulatory action.

B. The agency may conduct one or more public hearings during the comment period following the publication of a proposed regulatory action.

C. An agency is required to hold a public hearing following the publication of the proposed regulatory action when:

1. The agency's basic law requires the agency to hold a public hearing;

2. The Governor directs the agency to hold a public hearing; or

3. The agency receives requests for a public hearing from at least 25 persons during the public comment period following the publication of the notice of intended regulatory action.

D. Notice of any public hearing shall be posted on the Town Hall and Commonwealth Calendar at least seven working days prior to the date of the hearing. The agency shall also notify those persons who requested a hearing under subdivision C 3 of this section.

18VAC110-11-110. Periodic review of regulations.

A. The agency shall conduct a periodic review of its regulations consistent with:

1. An executive order issued by the Governor pursuant to §2.2-4017 of the Administrative Process Act to receive comment on all existing regulations as to their effectiveness, efficiency, necessity, clarity, and cost of compliance; and

2. The requirements in §2.2-4007.1 of the Administrative Process Act regarding regulatory flexibility for small businesses.

B. A periodic review may be conducted separately or in conjunction with other regulatory actions.

C. Notice of a periodic review shall be posted on the Town Hall and published in the Virginia Register.

Agenda Item: Adoption of exempt regulations – addition of drug to Schedule IV pursuant to federal changes

Included in your agenda package are:

- Excerpts of DEA scheduling change published October 31, 2023.
- Amendments to 18VAC110-20-323.

Action needed:

- Motion to adopt exempt changes to 18VAC110-20-323 pursuant to federal scheduling action.

Schedules of Controlled Substances: Placement of Zuranolone in Schedule IV

A Rule by the Drug Enforcement Administration on 10/31/2023

This document has a comment period that ends in 15 days. (11/30/2023)

DOCUMENT DETAILS

Printed version:
PDF (https://www.govinfo.gov/content/pkg/FR-2023-10-31/pdf/2023-23982.pdf)

Publication Date:
10/31/2023 (/documents/2023/10/31)

Agencies:
Drug Enforcement Administration (https://www.federalregister.gov/agencies/drug-enforcement-administration)

Dates:
This rule is effective October 31, 2023. Comments must be submitted electronically or postmarked on or before November 30, 2023.

Effective Date:
10/31/2023

Comments Close:
11/30/2023

Document Type:
Rule

Document Citation:
88 FR 74347

Page:
74347-74352 (6 pages)

CFR:
21 CFR 1308

Agency/Docket Number:

Docket No. DEA1258

Document Number:
2023-23982

DOCUMENT DETAILS

DOCUMENT STATISTICS

Page views:
343
as of 11/15/2023 at 2:15 pm EST

DOCUMENT STATISTICS

ENHANCED CONTENT

regulations.gov

Placement of Zuranolone in Schedule IV (DEA1258)

DEA-2023-0149 (https://www.regulations.gov/docket/DEA-2023-0149)

Supporting Documents:

- ASH to DEA Letter and 8FA Zuranolone 12Jul2023 (https://www.regulations.gov/document?D=DEA-2023-0149-0003)
- DEA1258 Zuranolone Eight Factors of Analysis September 2023 (https://www.regulations.gov/document?D=DEA-2023-0149-0002)

ENHANCED CONTENT

PUBLISHED DOCUMENT

AGENCY:

Drug Enforcement Administration, Department of Justice.

ACTION:

Interim final rule; request for comments.

SUMMARY:

On August 4, 2023, the United States Food and Drug Administration approved a new drug application for ZURZUVAE (zuranolone) capsules for the treatment of post-partum depression. The Department of Health and Human Services provided the Drug Enforcement Administration (DEA) with a scheduling recommendation to place zuranolone and its salts in schedule IV of the Controlled Substances Act (CSA). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA is hereby issuing an interim final rule placing zuranolone, including its salts, in schedule IV of the CSA. This action facilitates the public availability of zuranolone as a schedule IV controlled substance.

DATES:

This rule is effective October 31, 2023. Comments must be submitted electronically or postmarked on or before November 30, 2023.

Determination To Schedule Zuranolone

On July 12, 2023, DEA received from HHS a scientific and medical evaluation entitled "Basis for the Recommendation to Control Zuranolone and its Salts in Schedule IV of the Controlled Substances Act" and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) (https://www.govinfo.gov/link/uscode/21/811) and (c) (https://www.govinfo.gov/link/uscode/21/811), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of zuranolone, along with HHS's recommendation to control zuranolone and its salts under schedule IV of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c) (https://www.govinfo.gov/link/uscode/21/811). DEA concluded that zuranolone meets the 21 U.S.C. 812(b)(4) (https://www.govinfo.gov/link/uscode/21/812) criteria for placement in schedule IV of the CSA.

Pursuant to subsection 811(j), and based on HHS's scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule zuranolone as a schedule IV controlled substance under the CSA.

Included below is a brief summary of each factor as analyzed by HHS and DEA, and as considered by DEA in its scheduling action. Please note that both DEA and HHS analyses are available in their entirety under "Supporting Documents" in the public docket for this IFR at *https://www.regulations.gov (https://www.regulations.gov),* under Docket Number "DEA1258." Full analysis of, and citations to, the information referenced in the summary may also be found in the supporting and related material.

1. Its Actual or Relative Potential for Abuse

Zuranolone is a new molecular entity that has not been marketed in the United States or any country. Thus, evidence regarding its diversion, illicit manufacturing, or deliberate ingestion is currently lacking. DEA notes that there are no reports of law enforcement encounters of zuranolone in the National Forensic Laboratory Information System (NFLIS)-Drug database.[5] Zuranolone has sedative effects and is likely to have abuse potential, similar to schedule IV sedatives such as alprazolam. Thus, it is reasonable to assume that zuranolone may be diverted from legitimate channels, used contrary to or without medical advice, and capable of creating hazards to the users and to the safety of the community. In human abuse potential studies, zuranolone produced positive subjective responses that are similar to those produced by alprazolam (schedule IV). Zuranolone produces rewarding effects that are comparable to those produced by schedule IV sedatives; therefore, zuranolone is likely to be abused for its sedative effects contrary to medical advice.

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2. Scientific Evidence of Its Pharmacological Effects, If Known

Zuranolone is a selective neuroactive steroid that potentiates synaptic (γ subunit-containing) and extra synaptic (δ-subunit containing) $GABA_A$ receptor activity. Zuranolone acts on $GABA_A$ receptors to enhance the effects of GABA, a major inhibitory neurotransmitter in the CNS. Zuranolone acts directly through the $GABA_A$ receptor-channel complex to increase the probability that the channel will enter into naturally occurring open states of relatively long duration and allow the influx of chloride. Zuranolone was found to potentiate GABA-evoked current in cells expressing human $GABA_A$ receptor subtypes. HHS noted that these data are consistent with a mechanism of action of zuranolone that is similar to other schedule IV neurosteroids (*e.g.,* brexanolone) as a positive allosteric modulator of $GABA_A$ sites.

In animal studies, zuranolone's effect on the general behavioral profile in male rats showed that it produced behavioral activities, such as decreased activity, ataxia, hypersensitivity to touch and/or sound, and impaired righting reflex at supratherapeutic plasma concentrations. The observations were generally limited to the highest dose test (22.5 mg/kg), although some animals exhibited slight impairments at the lower doses tested (3 and 10 mg/kg).

In a drug discrimination study using male rats trained to discriminate midazolam and saline, intraperitoneally administered zuranolone (0.1, 0.3, 0.5, 1, and 3 mg/kg) produced dose-dependent effects and full substitution to midazolam discriminative stimulus effect at the highest dose tested when considering lever presses over the entire session and not just the first reinforcer (75 percent). However, 3 mg/kg zuranolone produced behavioral impairment, such that only five of ten rodents completed the session. In female rats, intraperitoneally administered zuranolone (0.1, 0.3, 0.5, 1, and 2 mg/kg) also produced dose-dependent effects and full substitution to midazolam discriminative stimulus effect at the highest dose tested when considering lever presses over the entire session and not just the first reinforcer (72.5 percent).

Zuranolone reinforcing properties were assessed by determining whether self-administration behavior was maintained when the drug was substituted for cocaine (schedule II). As stated by HHS in their scientific and medical evaluation, the study found that the selected doses of zuranolone did not maintain robust self-administration in animals with a previous history of cocaine self-administration.

In clinical trials, zuranolone produced significantly greater mean drug liking than placebo. The low (30 mg) and middle (60 mg) doses of zuranolone produced significantly less mean drug liking scores than both alprazolam (schedule IV) doses (1.5 and 3 mg). However, the highest dose of zuranolone produced mean drug liking scores that were similar to both doses of alprazolam (schedule IV).

Zuranolone produced euphoria-related adverse events that are supportive of zuranolone having an abuse potential. However, the abuse-related treatment emergent AE profile of zuranolone was slightly lower than that of alprazolam (a schedule IV benzodiazepine) at a supratherapeutic dose of zuranolone.

Zuranolone produced incidence of euphoria-related adverse events supportive of its abuse potential in animals and humans similar to those of benzodiazepines in schedule IV. These data are consistent with the fact that both drugs share a common mechanism of action involving positive allosteric modulation of the $GABA_A$ receptors.

3. The State of Current Scientific Knowledge Regarding the Drug or Other Substance

Zuranolone, chemically known as 1-[2-[(3 *R,* 5 *R,* 8 *R,* 9 *R,* 10 *S,* 13 *S,* 14 *S,* 17 *S*)-3-hydroxy-3,13-dimethyl-2,4,5,6,7,8,9,10,11,12,14,15,16,17-tetradecahydro-1 *H* -cyclopenta[*a*]phenanthren-17-yl]-2-oxoethyl]pyrazole-4-carbonitrile, is a new molecular entity.

Zuranolone is a drug product formulated as 20, 25, and 30 mg colored hard-gelatin capsules. The powder is white to off-white in color. Zuranolone is available as an immediate-release formulation and is absorbed with a time to maximum effect of approximately 6 hours and a half-life of 20 hours.

As discussed in the background section, zuranolone has an accepted medical use in the United States.

Agenda Item: Adoption of exempt regulations – addition of chemicals from Schedule I

Included in your agenda package are:

- Recommendation from the Department of Forensic Science to place certain chemicals in Schedule I.
- Amendments to 18VAC110-20-322.

Action needed:

- Motion to adopt exempt changes to 18VAC110-20-322 to add chemicals to Schedule I.

COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
A Nationally Accredited Laboratory

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To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: October 13, 2023
RE: **Recommendation for Expedited Scheduling of Controlled Substances**

Ms. Juran,

Pursuant to article § 54.1-3443(D), The Virginia Department of Forensic Science (DFS) has identified two (2) compounds for recommended inclusion into the Code of Virginia.

Based on their chemical structures, the following compounds are expected to have hallucinogenic properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. **1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA; 3C-P; 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine)**, 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.

2. **2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT),** its salts, isomers (optical, position, and geometric), and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

Robyn Weimer
Chemistry Program Manager

Project 7717 - Exempt Final

Board of Pharmacy

December 2023 scheduling of chemicals in Schedule I

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. 1-(4-cinnamyl-2,6-dimethylpiperazin-1-yl)propan-1-one (other name: AP-238), 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. Compounds expected to have hallucinogenic properties.

a. 4-methallyloxy-3,5-dimethoxyphenethylamine (other name: Methallylescaline), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. Alpha-pyrrolidino-2-phenylacetophenone (other name: alpha-D2PV), its salts, isomers (optical, position, and geometric), 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-pentyl-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: EDMB-PINACA), its salts, isomers, and salts of isomers whenever the existence of

such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-phenethyl-1H-indazole-3-carboxamide (other name: ADB-PHETINACA), 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 August 16, 2023, 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. Synthetic opioid. 2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole (other names: N-pyrrolidino etonitazene, etonitazepyne), 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. Compounds expected to have hallucinogenic properties.

a. 1-(1,3-benzodioxol-5-yl)-2-(propylamino)-1-butanone (other names: 3,4-Methylenedioxy-alpha-propylaminobutiophenone; N-propyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-1-phenylpentan-1-one (other names: N-ethylpentedrone, alpha-ethylaminopentiophenone), its salts, isomers (optical, position, and geometric), and

salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

c. 3,4-methylenedioxy-alpha-cyclohexylaminopropiophenone (other name: Cyputylone), its salts, isomers (optical, position, and geometric), 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-cyclohexylmethylaminopropiophenone (other name: 3,4-Methylenedioxy-N,N-cyclohexylmethcathinone), its salts, isomers (optical, position, and geometric), 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-alpha-isopropylaminobutiophenone (other name: N-isopropyl butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

f. 4-chloro-N-butylcathinone (other names: 4-chlorobutylcathinone, para-chloro-N-butylcathinone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

g. 4-hydroxy-N-methyl-N-ethyltryptamine (other names: 4-hydroxy MET, Metocin), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Central nervous system stimulant. 4-methylmethamphetamine (other names: N-alpha,4-trimethyl-benzeneethanamine, 4-MMA), including its salts, isomers, and salts of isomers.

4. Cannabimimetic agent. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1H-indole-3-acetamide (other names: ADB-FUBIATA, AD-18, FUB-ACADB), 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 March 14, 2024, 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 opioid. N,N-diethyl-2-[5-nitro-2-(4-propoxybenzyl)-1H-benzimidazol-1-yl]ethanamine (other name: Protonitazene), 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. Compounds expected to have hallucinogenic properties. 1-(1,3-benzodioxol-5-yl)-2-(cyclohexylamino)butan-1-one (other names: Cybutylone, N-cyclohexyl Butylone), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compounds expected to have depressant properties. 8-bromo-6-(2-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: Clobromazolam, Phenazolam), its salts, isomers (optical, position, and geometric), and salts of isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Cannabimimetic agents.

a. 5-bromo-N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1H-indazole-3-carboxamide (other name: ADB-5Br-INACA), 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. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-5-bromo-1-butylindazole-3-carboxamide (other name: ADB-5'Br-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 July 31, 2024, 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 opioid. 2-methyl-N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]butanamide (other name: 2-methyl butyryl 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. Compounds expected to have hallucinogenic properties.

a. 1-(7-methoxy-1,3-benzodioxol-5-yl)propan-2-amine (other names: 5-methoxy-3,4-methylenedioxyamphetamine, 3-methoxy MDA, MMDA), its salts, isomers (optical,

position, and geometric), 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-chlorophenyl)cyclohexyl]-piperidine (other names: 3-Chloro Phencyclidine, 3Cl-PCP, 3-chloro PCP), its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

3. Compound expected to have depressant properties. 7-bromo-5-phenyl-1,3-dihydro-1,4-benzodiazepin-2-one (other names: Desalkylgidazepam, Bromonordiazepam), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

4. Compound classified as a cannabimimetic agent. Methyl N-[(5-bromo-1H-indazol-3-yl)carbonyl]-3-methyl-valinate (other name: MDMB-5Br-INACA), 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 12, 2024, unless enacted into law in the Drug Control Act.

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

1. Synthetic opioids:

a. 2-(4-isopropoxybenzyl)-5-nitro-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other name: N-Pyrrolidino Isotonitazene), 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. 5-nitro-2-(4-propoxybenzyl)-1-[2-(pyrrolidin-1-yl)ethyl]-1H-benzo[d]imidazole (other names: N-Pyrrolidino Protonitazene, Protonitazepyne), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

c. N-phenyl-N-(1-propionyl-4-piperidinyl)-propanamide (other name: N-propionyl 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. Synthetic compounds.

a. N-(4-fluorophenyl)-N-(1-phenethylpiperidin-4-yl)pentanamide (other names: para-fluoro valeryl fentanyl, para-fluoro pentanoyl fentanyl), its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation.

b. N-(4-fluorophenyl)-N-[1-(2-phenylethyl)piperidin-4-yl]acetamide (other name: para-fluoroacetyl 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.

3. Compounds expected to have hallucinogenic properties.

a. 1-[1-(3-fluorophenyl)cyclohexyl]piperidine (other names: 3-fluoro Phencyclidine, 3F-PCP), its salts, isomers (optical, position, and geometric), and salts of isomers

whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 2-(ethylamino)-2-(2-fluorophenyl)-cyclohexanone (other names: 2-fluoro-2-oxo PCE, 2-fluoro NENDCK), 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.

4. Compounds expected to have depressive properties:

a. 6-(4-chlorophenyl)-1-methyl-4H-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine (other names: 4'-chloro Deschloroalprazolam, 4'Cl-Deschloroalprazolam), its salts, isomers (optical, position, and geometric), and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

b. 7-chloro-5-(2-chlorophenyl)-1-methyl-3H-1,4-benzodiazepin-2-one (other names: Diclazepam, 2-Chlorodiazepam), 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.

5. Central nervous system stimulant. 2-(3-chlorophenyl)-3-methylmorpholine (other name: 3-chlorophenmetrazine), its salts, isomers (optical, position, and geometric), and salts of isomers.

The placement of drugs listed in this subsection shall remain in effect until March 27, 2025, unless enacted into law in the Drug Control Act.

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

1. 1-(3,5-Dimethoxy-4-propoxyphenyl)-2-propanamine (other names: 4-propoxy-3,5-DMA; 3C-P; 1-(3,5-Dimethoxy-4-propoxyphenyl)propan-2-amine), 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.

2. 2-(5-methoxy-1H-indol-3-yl)ethanamine (other names: 5-methoxytryptamine, 5-MeOT), its salts, isomers (optical, position, and geometric), 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 25, 2025], unless enacted into law in the Drug Control Act.

Virginia Department of Health Professions

Overview of the Agency Subordinate Process

Board of Pharmacy

December 6, 2023

1

Virginia Department of Health Professions

What is an agency subordinate?

- An agency subordinate is an individual to whom the Board has delegated certain fact-finding duties.
- Agency subordinates are hired employees of the Boards they serve.
- Agency subordinates are often former Board members or retired Board employees
- Used by other Boards within DHP (Nursing, Psychology, Counseling, Social Work, Funeral)
- Used by other agencies within the Commonwealth (VDH, DBHDS, DSS)

2

Virginia Department of Health Professions

Current informal conference process

- For Boards that do not use agency subordinates, Board members staff informal conferences
- The Board of Pharmacy scheduled 18 informal conferences on Town Hall from November 17, 2022 – November 16, 2023 (not all occurred)
- 2-3 Board members needed to staff each
- Board members agree to schedule, appear at hearing, review evidence and produce a decision based on the fact-finding of the committee
- Respondent can appeal IFC order to a formal administrative hearing

3

Virginia Department of Health Professions

Agency subordinate process

- The Board hires an agency subordinate as an employee, generally individuals who are familiar with the Board, process of discipline
- The agency subordinate is provided a docket of IFCs
- Scheduling is more flexible, as the agency subordinate does not have to take time away from practice to volunteer time
- The agency subordinate reviews evidence and speaks to the respondent, the same way a special conference committee would
- Agency subordinate fills out sanction reference points worksheet

4

Virginia Department of Health Professions

Agency subordinate process, cont.

- Rather than an IFC order (such as that produced by a special conference committee of board members), the agency subordinate produces a recommended decision
- The recommended decision includes recommended findings of fact, conclusions of law, and recommended sanction or decision
- A panel of at least 5 Board members reviews the agency subordinate recommendation and the SRP worksheet
- Respondents can appear to speak to the recommended decision, but cannot present new information (i.e., they cannot address issues not included in the recommended decision)

5

Virginia Department of Health Professions

Agency subordinate process, cont.

- The panel of the Board has three options
  - Accept the decision (recommended decision then becomes an Order)
  - Modify the decision (panel may change sanction, for example)
  - Reject the decision (sends the matter to a formal administrative hearing)
- The respondent can appeal this decision to a formal administrative hearing, the same as an IFC order produced by a 2 or 3 member committee
- The process is the same once the matter reaches formal administrative hearing

6

Virginia Department of Health Professions

Benefits to using agency subordinates

- Biggest benefit is easing pressure on Board members and staff to schedule IFCs
  - Less need to obtain available Board member schedule for informal conferences throughout the year
  - As number of cases increase, Board member requirements increase without use of agency subordinate
- Following 2023 General Assembly Session, agency subordinates can now hear disciplinary cases and application (credential) cases
  - Previously agency subordinates were limited by statutory language to hearing only disciplinary cases
  - DHP requested the change to allow agency subordinates to hear application cases. No other agency was subject to limitation and it was nonsensical.

7

Virginia Department of Health Professions

Questions?

8

Agenda Topic: Citing of Deficiencies 13-16 within Guidance Document 110-9

Included in Agenda Packet:

- Excerpt from 5/23/23 Regulation Committee Meeting Minutes
- Inspection Deficiencies Related to Controlled Substance Inventories and Theft/Unusual Loss of Drugs Not Reported to the Board (Def #13-16) for routine inspections performed 4-1-2023 to 9-30-2023

During the discussion of draft amendments to Guidance Document 110-9, Dr. Yuan recommended a new deficiency for those with oversight of compounding personnel, but who do not compound.

The committee voted unanimously to recommend to the full Board that it amend Guidance Document 110-9 as presented and amended by inserting a new deficiency 26b to read, "No documentation of initial and at least every 12 months media-fill testing or gloved fingertip testing for persons who have direct oversight of compounding personnel, but do not compound.", citing 54.1-3410.2 with a suggested monetary penalty of $500. (motion by Yuan, seconded by Richards-Spruill)

DISCUSSION OF MONETARY PENALTIES IN GUIDANCE DOCUMENT 110-9 AS COMPARED TO OTHER STATES

The committee discussed the current monetary penalties associated with the deficiencies within Guidance Document 110-9. Discussion focused on those deficiencies related to theft and loss of drugs. In addition to the information from DC, TN, and PA provided in the agenda packet, Ms. Juran reported that IL imposes a non-disciplinary fee of up to $3,000 for any identified violation. Specifically, it imposes $200 for the first violation, $300 for the second violation, $500 for the third violation, and greater than 3 violations is subject to further discipline.

ACTION ITEM

The Committee requested staff to identify how often Deficiencies #13, 14, 15, and 16 within Guidance Document 110-9 have been cited or repeatedly cited for quarters ending in June 2023 and September 2023 and report back during the next Regulation Committee meeting in November 2023.

DISCUSSION OF ACCEPTANCE OF OUTSOURCING FACILITY INSPECTIONS PERFORMED BY OTHER STATES

The committee discussed the acceptance of outsourcing facility inspections performed by Florida and California to assess cGMP compliance when the outsourcing facility does not have a current FDA inspection report to provide for initial application or renewal pursuant to 54.1-3434.05 and 54.1-3434.5. It was noted that an inspection report resulting from an FDA inspection must be considered by the Board and that an inspection performed by another entity would not preclude this requirement.

MOTION:

The committee voted unanimously to recommend to the full board that it accept an inspection report indicating compliance with current Good Manufacturing Practices performed by the California Board of Pharmacy or Florida Department of Health for licensure purposes of outsourcing facilities when the FDA has not performed an inspection within the required timeframe for a current inspection report pursuant to 54.1-3434.05 and 54.1-3434.5 of the Code of Virginia. (motion by Nash, seconded by Yuan)

Inspection Deficiencies Related to Controlled Substance Inventories and Theft/Unusual Loss of Drugs Not Reported to the Board (Def #13-16)

Deficiency #13: n=8
No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.

Deficiency #14: n=22
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.

Deficiency #15: n = 0
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.

Deficiency #16: n=19
Theft/unusual loss of drugs not reported to the Board as required

For routine inspections performed 4-1-2023 to 9-30-2023

Virginia Board of Pharmacy
December 6, 2023
Licenses Issued

	5/1/22 - 7/31/22	8/1/22 - 10/31/22	11/1/22 - 1/31/23	2/1/23 - 4/30/23	5/1/23 - 7/31/23	8/1/23 - 10/31/23	License Count 11/1/2023
Business CSR	30	32	25	26	38	29	1,523
CE Courses	0	0	0	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	4	3	3	6	12	2	222
Non-restricted Manufacturer	2	1	1	1	0	0	35
Outsourcing Facility	0	0	1	0	0	0	1
Permitted Physician	0	0	0	0	0	0	0
Pharmacist	265	252	164	144	237	273	16,712
Pharmacist Volunteer Registration	0	2	1	0	4	1	0
Pharmacy	11	10	11	11	11	11	1,747
Pharmacy Intern	56	96	179	91	71	133	1,256
Pharmacy Technician	531	430	311	339	469	327	13,476
Pharmacy Technician Trainee	777	1,226	1,185	789	1,074	1,069	7,930
Physician Selling Controlled Substances	33	27	43	16	15	37	614
Limited Use Practitioner Dispensing	1	1	0	0	0	1	4
Nonresident Manufacturer	4	6	6	9	2	7	232
Nonresident Medical Equipment Supplier	7	11	4	11	6	10	370
Nonresident Outsourcing Facility	2	2	1	1	0	0	31
Nonresident Pharmacy*	27	18	21	23	21	27	925
Nonresident Third Party Logistics Provider	8	11	10	15	11	12	236
Nonresident Warehouser	0	8	7	7	3	10	128
Nonresident Wholesale Distributor	7	9	2	11	12	12	637
Physician Selling Drugs Location	6	2	3	3	5	3	135
Pilot Programs	1	1	0	0	2	1	13
Registered Practitioner For Medical Cannabis	56	147	84	89	35	0	1,051
Repackaging Training Program	0	0	0	0	0	0	2
Restricted Manufacturer	0	0	0	0	0	0	32
Third Party Logistics Provider	1	0	0	0	0	0	6
Warehouser	1	0	2	3	1	2	127
Limited Use Facility Dispensing	0	0	2	1	0	0	3
Wholesale Distributor	0	0	0	0	0	2	62
Total	**1,830**	**2,295**	**2,066**	**1,596**	**2,029**	**1,969**	**47,526**

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2024

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

*** Veterinary Establishments are now grouped together, as the board works on designating existing establishments as "Ambulatory" or "Stationary", instead of "Full Service" or "Restricted Service".

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	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Audiology/Speech Pathology	5,375	5,527	5,662	5,114	5,432	5,605	5,756	5,894	5,671	5,809	5,975	6,117	5,963
Counseling	34,028	35,176	34,246	31,769	33,693	35,020	36,141	37,436	36,097	37,512	38,791	40,118	39,278
Dentistry	14,982	15,133	15,286	14,768	15,171	15,290	15,284	15,238	15,421	15,275	15,037	15,186	15,190
Funeral Directing	3,161	3,205	3,190	3,114	3,187	3,247	3,295	3,182	3,254	3,308	3,379	3,287	3,351
Long-Term Care Administrators	2,190	2,226	2,274	2,152	2,226	2,293	2,352	2,146	2,232	2,288	2,345	2,159	2,225
Medicine	75,040	74,654	75,929	76,642	78,312	79,452	80,957	82,857	83,193	83,804	85,497	87,470	88,629
Nurse Aide	51,407	50,753	51,820	49,909	50,322	49,967	49,911	50,189	50,085	50,216	50,278	50,817	51,449
Nursing	171,004	170,050	172,380	172,263	174,791	174,984	176,169	177,138	179,221	179,997	181,279	181,581	183,596
Optometry	2,010	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871
Pharmacy	38,167	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374
Pharmaceutical Processing	7,162	9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238
Physical Therapy	14,588	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411
Psychology	6,016	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168
Social Work	11,051	11,443	11,805	11,302	11,868	12,405	12,799	13,138	12,952	13,598	14,241	14,913	15,089
Veterinary Medicine	8,384	7,894	8,181	8,442	8,615	8,723	8,429	8,648	8,826	8,947	8,711	9,016	9,192
Agency Total	444,565	441,815	457,898	464,278	482,398	494,685	505,753	518,191	514,037	512,996	505,591	499,117	495,024

Virginia Department of Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2024

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

*** Veterinary Establishments are now grouped together, as the board works on designating existing establishments as "Ambulatory" or "Stationary", instead of "Full Service" or "Restricted Service".

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	Occupation	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Optometry	Optometrist	87	87	88	77	77	77	78	65	65	65	65	49	50
	Optometrist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	-	-	1
	Professional Designation	260	-	-	-	-	-	-	-	-	-	-	-	-
	TPA Certified Optometrist	1,663	1,693	1,720	1,680	1,716	1,736	1,749	1,708	1,758	1,784	1,808	1,777	1,820
	Total	2,010	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826	1,871
Pharmacy	Business CSR	1,447	1,458	1,378	1,461	1,478	1,510	1,399	1,463	1,507	1,529	1,423	1,465	1,508
	CE Courses	9	9	9	9	9	9	9	9	9	9	9	9	9
	Humane Society	-	-	-	-	-	-	-	-	-	-	-	-	-
	Limited Use Facility Dispensing	-	-	-	-	-	-	-	-	-	1	2	3	3
	Limited Use Pharmacy Technician	11	7	8	8	8	8	7	7	7	7	7	7	7
	Limited Use Practitioner Dispensing	-	-	-	-	-	-	1	2	2	3	3	3	4
	Medical Equipment Supplier	233	233	224	223	230	229	209	217	223	226	213	220	226
	Non-Resident Manufacturer	199	200	194	202	209	215	206	213	218	224	217	226	231
	Non-Resident Medical Equipment Supplier	358	375	322	349	363	373	331	354	361	369	346	355	367
	Non Resident Outsourcing facility	32	33	33	33	34	33	30	29	32	33	35	33	32
	Non Resident Pharmacy	827	841	866	874	876	885	882	898	910	911	924	923	923
	Non-Resident Wholesale Distributor	629	634	604	635	644	660	624	634	643	641	610	624	635
	Non Restricted Manufacturer	32	32	28	28	29	30	31	32	34	34	35	35	35
	Non-Resident Third Party Logistics Prov.	146	161	169	182	186	191	181	181	194	206	207	219	229
	Non Resident Warehouser	69	78	79	91	96	101	98	99	105	115	109	114	123
	Outsourcing Facility	-	-	-	-	-	-	-	-	-	-	1	1	1
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	15,916	15,326	15,668	15,865	16,210	16,445	15,858	16,079	16,414	16,619	16,064	16,273	16,606
	Pharmacist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	-	1	-
	Pharmacy	1,772	1,769	1,772	1,771	1,770	1,767	1,773	1,768	1,765	1,765	1,762	1,755	1,751
	Pharmacy Intern	1,578	1,368	1,464	1,489	1,499	1,457	1,247	1,312	1,267	1,352	1,166	1,235	1,213
	Pharmacy Technician	13,699	11,838	12,751	13,248	13,689	14,042	12,421	12,924	13,522	13,875	12,312	12,871	13,310
	Pharmacy Technician Trainee	-	-	831	2,406	3,309	4,628	5,930	6,258	6,977	8,041	8,581	8,178	8,190

Virginia Department of Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 1 - Fiscal Year 2024

Current licenses by board and occupation as of the last day of the quarter.

** New Occupation

*** Veterinary Establishments are now grouped together, as the board works on designating existing establishments as "Ambulatory" or "Stationary", instead of "Full Service" or "Restricted Service".

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	Occupation	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Pharmacy	Pharmacy Technician Training Program	125	119	126	136	138	133	128	126	-	-	-	-	-
	Physician Selling Controlled Substances	662	526	558	571	614	631	537	571	600	645	543	565	596
	Physician Selling Drugs Location	172	139	163	165	168	167	160	160	160	164	125	131	135
	Pilot Programs	22	24	24	24	17	20	18	25	23	20	15	15	13
	Registered Physician for CBD/THC-A Oil	-	-	-	-	-	-	-	-	-	-	-	-	-
	Repackaging Training Program	2	2	2	2	2	2	2	2	2	2	2	2	2
	Restricted Manufacturer	44	43	39	41	41	41	36	36	36	36	33	32	32
	Third Party Logistics Provider	6	6	7	7	7	7	8	7	7	7	6	6	6
	Warehouser	111	115	119	120	121	122	117	121	121	122	123	125	127
	Wholesale Distributor	66	67	64	65	66	66	60	62	64	63	60	60	60
	Total	38,167	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486	46,374
Pharmaceutical Processing	Pharmaceutical Processor Permit	4	4	4	4	4	4	4	4	4	4	4	4	4
	Registered Agent For Medical Cannabis	11	20	65	103	141	162	180	179	181	166	158	137	109
	Registered Practitioner for CBD/THC-A Oil	528	633	685	797	920	997	720	873	1,059	1,164	938	1,051	1,051
	Registered Par/Guard For Medical Cannab	70	77	136	183	212	235	258	262	210	163	133	74	38
	Registered Patient For Medical Cannabis	6,535	8,754	17,257	26,136	33,204	39,468	47,466	52,903	45,434	38,071	29,214	16,201	7,547
	Registered Product	14	59	216	372	568	842	1,178	1,566	1,949	2,271	2,770	3,158	3,489
		7,162	9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625	12,238
Physical Therapy	Direct Access Certification	1,308	1,323	1,333	1,345	1,376	1,384	1,396	1,406	1,420	1,427	1,437	1,448	1,250
	Physical Therapist	9,380	8,372	8,603	8,901	9,161	9,245	9,382	9,634	9,906	10,022	8,878	9,146	9,403
	Physical Therapist Assistant	3,900	3,574	3,641	3,714	3,816	3,852	3,901	3,969	4,061	4,093	3,615	3,676	3,758
	Total	14,588	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270	14,411
Psychology	Applied Psychologist	28	29	29	24	26	27	27	28	25	25	25	25	23
	Clinical Psychologist	3,907	4,042	4,130	3,888	4,082	4,224	4,325	4,418	4,230	4,360	4,461	4,573	4,517
	Resident in School Psychology	10	11	11	11	12	13	13	13	21	24	26	27	29
	Resident In Training	795	370	373	368	376	376	380	380	397	395	392	392	404
	School Psychologist	93	97	102	90	97	98	99	100	96	96	100	103	98
	School Psychologist-Limited	615	633	648	560	622	640	658	673	550	569	583	598	577
	Sex Offender Treatment Provider	429	442	447	414	433	437	444	455	421	427	439	450	441
	SOTP Trainee	139	131	135	131	125	110	99	100	95	97	79	78	79
	Total	6,016	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246	6,168

Pharmaceutical Processors Report-December 6, 2023

- No additional cannabis dispensing facilities haves been permitted during the last quarter. There currently are 18 cannabis dispensing facilities.
- With the July 1, 2022 change to the requirement for patients/parents/legal guardians to register with the Board, the number of applications received has decreased significantly. The Board has seen an 88% decrease in patient applications. Registration renewals have also significantly decreased.
- The Medical Cannabis Program Portal became operational on September 27, 2023. Practitioners enrolled in the portal are able to complete and submit an electronic written certification and patients have access to the electronic written certification and a digital card validating that they have an active written certification. Patients may register with the Board through the new portal if they wish to do so, although Board registration is optional. Board and agency staff continue work to develop specific components of the product registration platform.
- All 26 applicants have been notified of the Board's decision to rescind the 2020 RFA for HSA I and all refunds have been issued.
- Board and agency staff continue to meet bi-monthly with the Virginia Cannabis Control Authority to address the transition of the medical cannabis program to the VCCA on January 1, 2024.

Pharmaceutical Processors Program-By the Numbers
As of 11/17/2023

Registered Patients	6,253
Registered Parents/Guardians	30
Registered Agents	91
Portal Issued Written Certifications	3,888
Portal Enrolled Practitioners	820
Registered Cannabis Products (cumulative)	3,695

Discipline Program Report

Open Cases as of 11/14/23:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	TOTALS
Patient Care Cases	77	16	100	2	12	1	0	11	219
Non-Patient Care Cases	73	20	35	5	9	1	16	0	159
						TOTAL:			**378**

- The Board has two cases currently being appealed in circuit court (Category: Other).

Upcoming Disciplinary Proceedings:

December 14, 2023	Ratliff/Nash	Informal Conferences
January 9, 2024	Yuan/Richards-Spruill	Informal Conferences
January 10, 2024	All members	Formal Hearings
January 23, 2024	Ratliff/Dowdy	Informal Conferences
February 6, 2024	Subordinate	Informal Conferences
February 7, 2024	All members	Formal Hearings
February 21, 2024	Garvin/Nash	Informal Conferences
March 12, 2024	Yuan/Richards-Spruill	Informal Conferences
March 21, 2024	St.Clair/Garvin	Pilot Committee
March 27, 2024	Ratliff/Dowdy	Informal Conferences
March 28, 2024	All members	Full Bord Meeting/Formal Hearings

Virginia Department of

Health Professions

Average Age of Cases Closed

Quarterly Summary

Quarter 1 - Fiscal Year 2024

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	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Audiology	569.5	458.4	N/A	223.0	306.0	691.9	257.9	231.0	309.4	291.0	216.7	278.0	137.6
Counseling	217.0	284.8	236.2	191.0	302.0	208.7	311.0	187.1	250.0	219.8	232.7	228.7	220.2
Dentistry	403.0	366.1	595.5	380.0	310.0	459.6	590.3	410.7	343.8	226.4	258.8	308.6	292.1
Funeral Directing	311.0	265.3	360.7	231.5	384.0	305.0	444.7	445.0	342.1	382.1	310.9	361.4	284.8
Long-Term Care Administrators	332.0	429.1	430.2	488.5	668.0	555.6	294.3	554.8	415.4	362.4	506.9	266.7	387.7
Medicine	255.0	209.5	206.5	165.0	189.0	205.4	178.1	233.6	256.3	275.0	186.9	203.7	169.2
Nurse aide	262.6	242.2	178.9	318.0	351.0	323.9	316.4	427.3	454.8	476.3	460.3	351.3	329.3
Nursing	325.9	438.0	350.3	443.0	386.0	428.5	352.1	494.1	380.6	384.7	430.9	380.7	329.5
Optometry	227.5	379.5	350.1	254.0	303.0	502.5	253.4	91.1	221.9	240.7	183.5	104.0	170.6
Pharmacy	142.3	165.0	116.7	254.0	169.0	127.1	123.6	130.7	124.3	147.6	197.5	104.6	135.8
Physical Therapy	340.3	395.2	198.8	286.3	516.0	250.1	477.7	436.4	238.2	405.8	202.7	580.3	366.6
Psychology	213.8	198.6	208.0	286.1	253.0	297.5	341.2	127.5	455.1	460.1	381.6	537.2	617.0
Social Work	111.8	340.4	101.4	71.6	173.0	213.5	181.5	136.5	130.9	63.7	204.3	95.9	211.3
Veterinary Medicine	543.2	337.9	313.0	419.9	376.0	347.6	263.3	298.6	205.9	209.6	214.6	207.0	173.5
Agency total	280.6	307.0	276.2	278.6	299.0	305.2	291.1	331.6	280.8	288.2	281.2	267.6	242.8

Virginia Department of
Health Professions

Average Age of Cases Closed
Fiscal Year Summary
Fiscal Year 2023

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 year 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 2018	Change Between FY 19 & FY 18	FY 2019	Change Between FY 20 & FY 19	FY 2020	Change Between FY 21 & FY 20	FY 2021	Change Between FY 22 & FY 21	FY 2022	Change Between FY 23 & FY 22	FY 2023
Audiology/Speech Pathology	264.5	-57.4%	168.0	18.1%	205.2	50.3%	412.9	-7.3%	384.7	-28.5%	275.0
Counseling	178.9	15.6%	212.0	31.7%	310.2	-34.6%	230.4	13.3%	265.9	-12.4%	233.0
Dentistry	216.5	2.5%	222.0	4.9%	233.5	22.9%	303.0	34.1%	460.1	-36.0%	294.6
Funeral Directing	260.7	-33.0%	196.0	53.5%	421.8	-39.3%	302.9	27.4%	417.2	-15.9%	351.0
Long-Term Care Administrators	353.3	18.4%	433.0	-111.4%	204.8	50.0%	409.6	22.9%	531.4	-25.0%	398.7
Medicine	139.9	31.8%	205.0	76.0%	854.0	-296.1%	215.6	-5.5%	204.3	15.8%	236.6
Nurse Aide	235.6	-11.1%	212.0	34.5%	323.5	9.9%	359.0	-3.0%	348.5	23.7%	431.2
Nursing	225.2	16.6%	270.0	20.8%	340.7	13.5%	393.9	5.1%	414.9	-5.0%	394.1
Optometry	367.4	-19.8%	306.8	-152.0%	121.7	61.7%	317.6	-5.8%	300.1	-36.3%	191.1
Pharmacy	167.9	-24.4%	135.0	51.5%	278.4	-94.3%	143.3	-4.8%	136.7	7.6%	147.1
Physical Therapy	238.5	47.4%	453.0	-30.9%	345.9	-6.5%	324.9	29.0%	457.5	-21.5%	359.3
Psychology	148.6	31.5%	217.0	36.7%	342.9	-35.4%	253.3	6.0%	269.6	75.6%	473.5
Social Work	223.1	-8.8%	205.0	15.0%	241.3	-37.0%	176.1	2.3%	180.2	-30.3%	125.6
Veterinary Medicine	311.8	3.8%	324.0	-74.8%	185.3	52.1%	386.5	-19.0%	324.9	-35.5%	209.6
Agency Total	198.4	11.8%	225.0	5.9%	239.0	17.8%	290.8	6.5%	311.0	-9.3%	282.2

Virginia Department of
Health Professions

Cases Closed in Less than One Year
Quarterly Summary
Quarter 1 - Fiscal Year 2024

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	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Audiology/Speech Pathology	25.0%	50.0%	N/A	88.9%	80.0%	11.1%	55.6%	50.0%	28.6%	50.0%	83.3%	80.0%	100.0%
Counseling	82.6%	61.3%	77.7%	84.2%	69.7%	94.7%	67.4%	90.2%	88.9%	86.4%	81.1%	81.3%	81.2%
Dentistry	61.4%	58.4%	50.9%	54.2%	65.0%	51.8%	32.2%	45.2%	62.1%	71.4%	72.8%	60.3%	75.8%
Funeral Directing	75.8%	87.0%	51.4%	69.2%	40.0%	76.0%	30.9%	43.8%	67.4%	61.8%	65.0%	46.7%	58.3%
Long-Term Care Administrators	50.0%	35.1%	40.0%	39.5%	30.2%	29.0%	51.4%	46.9%	45.5%	50.0%	23.5%	76.9%	31.3%
Medicine	80.3%	84.2%	82.9%	90.7%	89.2%	88.3%	93.5%	82.1%	99.3%	80.5%	88.9%	86.7%	91.9%
Nurse Aide	65.4%	69.7%	86.4%	65.5%	60.0%	63.8%	67.5%	53.3%	46.5%	41.4%	53.3%	64.7%	70.1%
Nursing	57.7%	37.7%	53.0%	37.0%	48.9%	53.2%	64.3%	43.4%	57.4%	56.0%	53.7%	56.9%	65.7%
Optometry	66.7%	56.0%	37.5%	70.0%	56.3%	66.7%	77.8%	100.0%	90.0%	80.0%	92.9%	100.0%	89.5%
Pharmacy	88.4%	89.6%	93.6%	82.4%	85.3%	90.9%	89.8%	93.2%	93.9%	93.2%	83.9%	93.0%	93.1%
Physical Therapy	48.5%	46.9%	88.2%	62.5%	38.3%	85.7%	32.4%	69.2%	62.5%	60.0%	100.0%	9.1%	53.8%
Psychology	76.9%	75.7%	71.4%	61.9%	73.0%	60.0%	59.6%	83.3%	57.9%	30.0%	55.2%	38.6%	25.0%
Social Work	100.0%	59.1%	96.8%	96.4%	97.0%	63.6%	94.7%	100.0%	88.2%	100.0%	79.2%	93.1%	86.7%
Veterinary Medicine	31.8%	66.3%	56.3%	50.9%	46.7%	70.4%	76.3%	73.0%	85.2%	82.5%	87.7%	73.6%	82.1%
Agency Total	70.1%	64.0%	71.1%	68.8%	66.0%	70.7%	71.9%	65.8%	74.5%	72.7%	73.9%	73.0%	79.2%

Virginia Department of

Health Professions

Cases Closed in Less than One Year

Fiscal Year Summary

Fiscal Year 2023

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 year 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 2018	Change Between FY 18 & FY 19	FY 2019	Change Between FY 19 & FY 20	FY 2020	Change Between FY 20 & FY 21	FY 2021	Change Between FY 21 & FY 22	FY 2022	Change Between FY 23 & FY 22	FY 2023
Audiology	80.0%	9.3%	88.2%	-12.2%	78.6%	-41.5%	55.6%	-22.9%	45.2%	31.1%	65.6%
Counseling	87.4%	-11.3%	78.5%	2.7%	80.7%	-4.7%	77.1%	0.9%	77.8%	7.5%	84.1%
Dentistry	85.2%	-6.1%	80.3%	-11.8%	71.8%	-26.6%	56.7%	-25.0%	45.4%	31.2%	66.0%
Funeral Directing	77.4%	8.6%	84.7%	-5.3%	80.4%	-16.7%	68.9%	-78.9%	38.5%	38.5%	62.6%
Long-Term Care Administrator	41.7%	-16.5%	35.8%	16.4%	42.8%	-1.3%	42.2%	-14.5%	36.9%	21.4%	46.9%
Medicine	93.8%	-9.6%	85.6%	0.9%	86.4%	-3.2%	83.7%	4.8%	87.9%	-3.7%	84.8%
Nurse Aide	82.5%	-0.4%	82.2%	2.7%	84.5%	-16.1%	72.8%	-17.6%	61.9%	-19.5%	51.8%
Nursing	78.3%	-0.9%	77.6%	-40.8%	55.1%	-21.1%	45.5%	12.6%	52.1%	6.2%	55.5%
Optometry	63.3%	1.1%	64.0%	-30.9%	48.9%	17.6%	59.3%	32.6%	88.0%	2.7%	90.5%
Pharmacy	89.0%	4.3%	93.0%	0.5%	93.5%	-3.8%	90.1%	0.0%	90.1%	0.6%	90.6%
Physical Therapy	77.8%	-130.2%	33.8%	43.0%	59.3%	-3.8%	57.1%	-17.1%	48.8%	8.7%	53.5%
Psychology	92.2%	-8.2%	85.2%	-39.0%	61.3%	9.4%	67.7%	0.3%	67.9%	-48.1%	45.8%
Social Work	81.0%	-16.4%	69.6%	-61.9%	43.0%	49.5%	85.1%	7.2%	91.7%	-2.1%	89.8%
Veterinary Medicine	66.2%	-4.7%	63.2%	18.3%	77.4%	-43.8%	53.8%	19.1%	66.5%	19.8%	82.9%
AGENCY	**84.5%**	**-5.6%**	**80.0%**	**-6.8%**	**74.9%**	**-10.9%**	**67.5%**	**0.6%**	**67.9%**	**6.9%**	**73.0%**

Virginia Department of
Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 1 – Fiscal Year 2024

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

		Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	CURRENT Q1 2024
Pharmacy	Number of Cases Received	127	138	145	160	212	208	220	185	215	210	204	249	206
	Number of Cases Open	289	263	300	332	350	329	399	409	416	437	384	442	390
	Number of Cases Closed	131	174	115	131	193	228	154	181	228	214	288	220	257
Physical Therapy	Number of Cases Received	8	12	12	20	11	9	15	3	15	13	10	4	10
	Number of Cases Open	33	29	33	47	46	47	46	39	35	34	36	35	31
	Number of Cases Closed	12	19	8	7	12	8	18	10	21	18	8	5	14
Psychology	Number of Cases Received	27	37	36	31	37	32	24	34	20	18	22	31	39
	Number of Cases Open	92	106	130	132	140	159	144	162	163	169	174	172	167
	Number of Cases Closed	25	26	13	32	29	13	39	22	26	16	24	49	44