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
September 26, 2023
9AM

TOPIC	PAGES
Call to Order of Public Hearing: Dale St.Clair, PharmD, Chairman	
• Welcome & Introductions	
Public Hearings:	
• Placing Certain Chemicals into Schedule I	**38-50**
Adjournment of Public Hearings	
Call to Order of Full Board Meeting: Dale St.Clair, PharmD, Chairman	
• Approval of Agenda	
Approval of Previous Board Meeting Minutes:	
• DHP Policy 76-80.26 Meeting Minutes Approval and Signatures	**3-4**
• June 13, 2023, Full Board Meeting	**5-17**
• June 13, 2023, Public Hearing	**18-20**
• June 27, 2023, Telephone Conference Call	**21-23**
• August 11, 2023, Statewide Protocol Workgroup Meeting	**24-28**
• August 23, 2023, Formal Hearing	**29-33**
Call for Public Comment: The Board will receive public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.	
DHP Director's Report: Arne Owens	
Legislative/Regulatory/Guidance: Erin Barrett, JD/Caroline Juran, RPh	
• Chart of Regulatory Actions	**34-37**
• Adoption of Exempt Final Regulation to Place Certain Chemicals into Schedule I	**38-50**
• Initiation of periodic review of public participation guidelines contained in 18VAC110-11	**51-59**
• Adoption of fast-track action to change "nurse practitioner" to "advanced practice registered nurse"	**60-65**
• Amendment of guidance documents to reflect title change of nurse practitioners to advanced practice registered nurses	**66-87**
• 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	**88-93**
• Amendment to guidance document 110-36 to include additional FAQs related to revisions of USP Chapters <795> and <797>	**94-100**
• Amend Guidance Document 110-44, *Protocol for the Prescribing and Dispensing of Naloxone* and *Statewide Protocol for Naloxone*	**101-110**
• Amendment of Guidance Document 110-46 regarding use of drones	**111-114**
New Business:	
• Adopt statewide protocols for COVID-19, Strep, UTI, Influenza	**115-147**

- Amendments to vaccine protocols for ages 3-17 and adults to include epinephrine to treat anaphylaxis **148-152**
- Rescission of pharmaceutical processor permit RFA for HSA I **153-172**
- Preliminary maps of current pharmacy locations based on practice type **173-176**
- Request from Board Member **177**

Reports:

- Report on APhA Substance Use Disorder Institute 2023 – Wendy Nash, PharmD **178-200**
- Chairman's Report –Dale St.Clair, PharmD
- Report on Board of Health Professions – Sarah Melton, PharmD
- Report on Licensure of Individuals and In-State Facilities – Ryan Logan, RPh **201-A**
- Report on Nonresident Facilities – Beth O'Halloran, RPh **202-205**
- Report on Inspection Program – Melody Morton, Inspections Manager, Enforcement Division **206-218**
- Report on Pharmaceutical Processors – Annette Kelley, M.S., C.S.A.C. **219**
- Report on Disciplinary Program – Ellen B. Shinaberry, PharmD **220-226**
- Executive Director's Report – Caroline D. Juran, RPh **227**

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.*****

Virginia Department of Health Professions Policy Library

76-80.26 Meeting Minutes Approval and Signatures

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Policy Name	Meeting Minutes Approval and Signatures			Policy Number	76-80.26
Section Title	Operational	Section Number	76-80	Former Policy No.	
Approval Authority	Agency Director			Effective Date	3/17/2022
Responsible Executive	Chief Operating Officer			Revised Date	3/5/2023
Responsible Office	Director's Office			Last Reviewed	3/6/2023
Responsible Reviewer	Barrett,Erin				

Purpose:

To establish a policy for the approval and signature of meeting minutes in compliance with relevant statutes and in accordance with the Department's mission to protect the public and to provide public information.

Policy:

The following provisions apply regarding minutes:

1. A copy of all meeting minutes are to be provided to all members of the body for review in advance of the next meeting.

2. Boards shall approve meeting and formal hearing minutes during their business meetings. For example:

The Board President/Chair refers Board members to the draft minutes as included in the agenda packet.

Chair: “Included in the agenda packet [or consent agenda] are draft minutes for meeting(s) held on _____. These minutes can be found on page ___.”

The Board President/Chair asks if there are any additions or corrections to the minutes.

If there are no additions or corrections, the Board President/Chair states that the minutes are approved as presented. This is known under Robert's Rules of Order as unanimous consent. No motion, second, or vote is needed.

If there are corrections, the Board President/Chair is to seek agreement among Board members as to the accuracy of the proposed corrections. If there is agreement, the body may proceed to approve the minutes as presented and amended by unanimous consent.

Chair: “With corrections as noted and agreed to by the body, the minutes are approved as presented and amended.”

If there is not a consensus on amendments to the minutes, a motion, second, and vote is required.

3. Approval of previous minutes shall be indicated in the minutes of the meeting at which they are approved.

4. Upon approval by the Board, final minutes are to be signed by the Executive Director or their designee on behalf of the Board and posted in accordance with the timeframes established by the Code.

5. Informal conference minutes do not require approval by the Board. Draft and final informal conference minutes are to be posted in accordance with the timeframes established by the Code.

6. The Boards shall post on the Department website (via the Virginia Town Hall website) all draft and approved final minutes from meetings and hearings in accordance with Virginia Code § 2.2-3707.1.

Nothing contained in this Policy shall modify the requirements for Boards to maintain original copies of minutes or the requirements related to the retention of minutes as public records.

Authority:

Va. Code § 2.2-3707(H)
Va. Code § 2.2-3707.1

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
MINUTES OF FULL BOARD MEETING

Tuesday, June 13, 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 full board meeting was called to order at 9:05am.
PRESIDING:	Dale St. Clair, PharmD, Chairman
MEMBERS PRESENT:	William Lee, DPh, Vice Chairman Cheri Garvin, RPh Larry Kocot, JD Sarah Melton, PharmD Wendy Nash, PharmD Kristopher Ratliff, DPh Patricia Richards-Spruill, RPh
MEMBERS ABSENT:	Ling Yuan, PharmD
STAFF PRESENT:	Caroline D. Juran, RPh, Executive Director Annette Kelley, Deputy 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 James Jenkins Jr, RN, DHP Chief Deputy Erin Barrett, JD, DHP Director of Legislative and Regulatory Affairs James Rutkowski, Senior Assistant Attorney General Sorayah Haden, Executive Assistant
PHARMACISTS AWARDED 1-HOUR OF LIVE OR REAL-TIME INTERACTIVE CONTINUING EDUCATION FOR ATTENDING MEETING:	Natalie Nguyen
QUORUM:	With 8 members present, a quorum was established.
APPROVAL OF AGENDA:	An amended agenda was provided to the Board as a handout. It included two new topics added under the Legislative/Regulatory/Guidance section: Amend

Electronic Participation Meeting Policy and Use of Drones to Deliver Prescription Drugs.

MOTION **The amended agenda was adopted as presented. (motion by Ratliff, seconded by Garvin)**

APPROVAL OF PREVIOUS BOARD MEETING MINUTES

MOTION: **The Board voted unanimously to adopt the minutes for the meetings held between March 21, 2023 and May 24, 2023 as presented and amended as follows:**

- **Name correction for meeting chair and header date for the Innovative Pilot Program meeting held on May 18, 2023 on page 28 (motion by Ratliff, seconded by Garvin)**

PUBLIC COMMENT: On behalf of the Virginia Society of Health-Systems Pharmacists (VSHP), Natalie Nguyen, PharmD, provided public comment regarding several matters. Staff provided a copy of her written comments to the Board members later during the meeting to review during discussions. Among her comments, she indicated VSHP is supportive of additional duties for pharmacy technicians, expressed concern for drug shortages, and provided feedback on Guidance Documents 110-36 and 110-9.

Karen Winslow, PharmD, Interim Executive Director, Virginia Pharmacists Association (VPhA), commented that VPhA hopes to fill the executive director position in September. She urged the Board to adopt a uniform credentialing process for reimbursement. She indicated that pharmacy access continues to be a concern and that VPhA is hosting the Pizza and Policy educational program that evening.

DHP DIRECTOR'S REPORT: Mr. Arne Owens, Director, DHP provided agency updates. The Conference Center has ongoing renovations taking place. There is ongoing budget prep for the time period of 2024-2026. He stated the agency is currently collecting legislative proposals for 2024. He indicated that the Commonwealth will soon receive healthcare workforce recommendations from a study performed by the Rand Corporation. James Jenkins, Jr, RN, DHP Chief Deputy has been working with the subject of healthcare workforce and behavioral health reform. He commented that the memorandum of understanding previously signed in November 2022 with the Department of Labor and Industry and Department of Education regarding work agreements for pharmacy technician trainees who are minors has been cancelled. If the pharmacy technician trainees who are minors do not mix drugs together to prepare a compounded drug and only learn compounding through simulation or the mixing of inert ingredients, then no work agreement is necessary.

LEGISLATIVE/
REGULATORY/GUIDANCE

CHART OF REGULATORY ACTIONS

Ms. Barrett briefly reviewed the chart in the agenda packet and provided updated information. She stated the Secretary's Office hopes to address any backlogs this summer.

RECOMMENDATION TO AMEND GUIDANCE DOCUMENT 110-45: APPROVED CHEMICALS FOR USE AS HYDROCARBON OR OTHER FLAMMABLE SOLVENTS BY PHARMACEUTICAL PROCESSORS

The Board discussed the recommended revision of the previously adopted, but not yet effective, guidance document on hydrocarbon solvents.

ACTION ITEM:

The Board voted unanimously to accept the amendment to Guidance Document 110-45 to include butane and propane as recommended by the Regulation Committee.

RECOMMENDATION TO ADOPT GUIDANCE DOCUMENT 110-50 CANNABIS PRODUCT PACKAGING REQUIREMENTS

The Board discussed the adoption of new Guidance Document 110-50 regarding cannabis product packaging requirements.

MOTION:

The Board voted unanimously to adopt Guidance Document 110-50 *Cannabis Product Packaging Requirements* as recommended by the Regulation Committee.

RECONSIDER AMENDMENT OF 18VAC110-20-555 REGARDING EXEMPTION OF ADDs STOCKED SOLELY WITH STAT-USE OR EMERGENCY DRUGS

The Board discussed the reconsideration of the amendment of 18VAC110-20-555. A handout consisting of a letter from PharmScript dated June 9, 2023 and recommended amendments to 18VAC110-20-555 were reviewed by the Board. Pharmscript's proposed amendments removed the requirement for the pharmacist to electronically authorize access to a drug that would be stocked in an emergency kit or stat drug box, but maintained the general requirement for the pharmacist to receive the prescription.

MOTION:

The Board voted unanimously to amend the proposed language of 18VAC110-20-555 regarding use of automated dispensing devices as follows:

- **In 4a, strike ", including a drug that would be stocked in a stat drug box pursuant to subsection B of 18VAC110-20-550,";**
- **In 4c, after "18VAC110-20-540", insert "or a stat drug box pursuant to subsection B of 18VAC110-20-550" and after "patients", insert "or a delay in the administration of the drugs could result in harm to the patient." (motion by Nash, seconded by Richards-Spruill)**

DISCUSSION REGARDING NUMBER AND LOCATION OF PHARMACY PERMITS IN RECENT YEARS

An update on the Regulation Committee's discussion on this topic was provided. Per the DHP Biennial Report, on June 30, 2012 there were 1,754 current active in-state pharmacy permits in Virginia. As of June 30, 2016, the number of pharmacy permits had increased by 100. Between June 30, 2016 and June 30, 2022, the number of in-state pharmacy permits had declined by 86 for a total of 1,768. Because the Board issues only one type of pharmacy permit and cannot easily discern the number of pharmacy permits operating as community pharmacies, the Regulation Committee had asked staff to research the ability for pharmacies to self-identify its practice setting during the renewal process. Ms. Juran reported that IT staff informed her that they would need to research further its ability to collect information on the renewal software platform and have it auto-populate into the licensing software platform. Additionally, the next renewal cycle for pharmacy permits would not open until March 2024. Alternatively, Ms. Juran stated that staff could attempt to identify the pharmacy practice settings, manually record the information in the licensing software, and ask pharmacies to self-identify on new pharmacy permit applications going forward. Mr. Kocot noted that the data represents net results for pharmacy permit openings and closings.

ACTION ITEM: **Send findings of the Virginia Health Workforce Development Authority study to the Board.**

ACTION ITEM: **Research ability to identify locations of the 86 closed pharmacy permits between 2016 and 2022 and new permits issued during this period.**

RECOMMENDATION OF 2024 LEGISLATIVE PROPOSALS:

- PHARMACY TECHNICIANS ACCEPTING REFILL AUTHORIZATIONS FOR SCHEDULES III-VI PRESCRIPTIONS AND CLARIFICATION OF QUANTITY/REFILLS

The Board discussed the recommendation of the Regulation Committee to adopt the legislative proposal as presented. Dr. Ratliff and Ms. Garvin suggested that an ability to electronically transfer prescriptions may be beneficial. Staff indicated the 2021 Pharmacy Technician Workgroup that met to consider additional duties for pharmacy technicians offered similar recommendations.

FOR SCHEDULE VI PRESCRIPTIONS

MOTION:

The Board voted unanimously to adopt the legislative proposal as presented and amended to 1) authorize pharmacy technicians to accept clarification of quantity or refills from a prescriber or prescriber's agent for a Schedule VI prescription, 2) insert a definition of "on hold prescription", and 3) allow pharmacy technicians to electronically transfer a prescription for a Schedule VI drug, that is not an on-hold prescription, when authorized by the pharmacist-in-charge or pharmacist on duty. (motion by Nash, seconded by Garvin)

- REQUIRING FEDERAL CRIMINAL BACKGROUND CHECK FOR RESIDENT AND NONRESIDENT WHOLESALE DISTRIBUTORS AND THIRD-PARTY LOGISTICS PROVIDERS

The Board discussed the Regulation Committee's recommendation to adopt a legislative proposal requiring the responsible party of a wholesale distributor, nonresident wholesale distributor, third-party logistics provider, and nonresident third-party logistics providers to submit a federal criminal history record check with the facility application. Staff indicated that while 18VAC110-50-80 C4 has required this for several years, the FBI will not perform such background check without authorizing language in the Virginia Code.

MOTION:

The Board voted unanimously to adopt a legislative proposal requiring the responsible party of a wholesale distributor, nonresident wholesale distributor, third-party logistics provider, and nonresident third-party logistics providers to submit a federal criminal history record check with the facility application. (motion by Ratliff, seconded by Melton)

- CLARIFYING COMPOUNDING OF ESSENTIALLY COPIES OF COMMERICALLY AVAILABLE DRUG PRODUCTS

The Board discussed the Regulation Committee's recommendation to adopt the legislative proposal regarding pharmacy compounding as presented. Ms. Garvin suggested that the pharmacist be also authorized to record the prescriber's indication regarding significant difference between the compounded drug and the comparable commercially available drug in the prescription notes since there is no ability for the pharmacist to record information on the prescription if transmitted electronically.

MOTION:

The Board voted unanimously to accept the Regulation Committee's recommendation to adopt the legislative proposal to clarify compounding of essentially copies of commercially available drug products as presented and amended by inserting an ability for the pharmacist to also record the prescriber's indication regarding significant difference between the compounded drug and the comparable commercially available drug in the prescription record. (motion by Ratliff, seconded

by Richards-Spruill)

RECOMMENDATION TO AMEND GUIDANCE DOCUMENTS 110-36 AND 110-9 REGARDING USP REVISIONS

The Board discussed the Regulation Committee's recommendation to amend Guidance Documents 110-36 and 110-9 based on USP revisions effective November 1, 2023. The Board also considered the written public comment provided by VSHP earlier in the meeting.

ACTION ITEM: **Staff to research with USP, if necessary, and determine if frequently asked questions are needed in Guidance Document 110-36 to clarify expectations for completing media-fill testing and gloved fingertip testing when providing direct oversight of compounding and under what conditions cameras can be used to verify product.**

ACTION ITEM: **Staff to research with USP if the pharmacist verifying the dispensing of a compounded product that was previously verified for compounding accuracy must complete any personnel testing related to compounding.**

MOTION **The Board voted unanimously to accept the Regulation Committee's recommendation to amend Guidance Document 110-36 as presented and amended as follows:**

- **Insert "gloved fingertip testing and garbing" in the newly proposed FAQ #3 to read, "Should compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test, gloved fingertip test, and garbing test at each pharmacy where they will prepare CSPs? Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, should pass a media-fill test, gloved fingertip test, and garbing test at each pharmacy prior to performing sterile compounding."; and,**
- **In the newly proposed FAQ #5 "May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?", the second paragraph of the response should be amended to conform to current law. (motion by Ratliff, seconded by Garvin)**

Ms. Garvin and Dr. St. Clair offered recommendations to Guidance Document 110-9 for consideration.

MOTION **The Board voted unanimously to accept the Regulation Committee's recommendation to amend Guidance Document 110-9 as presented and amended as follows:**

- **Deficiency #15 – Under "Conditions", in the third sentence, replace "drugs" with "reconciliations" so that it reads "Deficiency if more than 5 reconciliations not compliant.";**

- **Deficiency #25 – Under "Deficiency", replace "assigned inappropriate beyond use date (BUD)" with "when required by USP";**
- **Deficiency #25c – Insert a new deficiency 25c to read "Category 1 or 2 CSPs intended for use are improperly stored" and impose a $500 monetary penalty; change the numbering of the current 25c to 25d.**
- **Deficiency #33a – Insert new deficiency to read "Category 3 CSPs assigned inappropriate BUD" and impose $5,000 monetary penalty; and,**
- **#149 – Insert new deficiency to read "Surface sample testing not being performed". (motion by Garvin, seconded by Richards-Spruill)**

Based on public comment from VSHP recommending the formation of a workgroup to discuss the upcoming revised USP chapters, the Board decided to reassess if this was warranted later in the year. The Board encouraged the public to send questions, that are not already addressed in the FAQs published by USP, to the Board and staff will attempt to research the subject with USP.

USE OF DRONES TO DELIVER PRESCRIPTION DRUGS

Prior to a meeting break, the Board decided it would discuss use of drones next. The Board reviewed a handout consisting of 54.1-3420.2 (A) of the Code of Virginia and a 2015 Board Order issued to Mountain Care Center approving an innovative pilot program for delivering meds via drone. Ms. Juran reported that she has been contacted recently by parties interested in using drones to deliver prescription drugs. Staff is seeking guidance as to whether such activity warrants a pilot or if it is simply a "delivery service" as authorized in 54.1-3420.2 of the Code. She is aware of such activity in other states. Additionally, in Virginia, some pharmacies are currently using drones to deliver non-prescription items. There was discussion regarding FAA oversight of drones, that most drones have a limited flight radius, and pharmacy responsibility for reporting a theft or loss of drug, including when lost in transit, regardless of delivery method. It was also discussed that drug may not be stored overnight or for any significant length of time in an unlicensed facility during the delivery process but can pass through as part of the delivery process.

MOTION

The Board voted unanimously that use of a drone to deliver a dispensed prescription drug is a permissible "delivery service" as authorized in 54.1-3420.2 of the Code of Virginia and does not necessitate an innovative pilot when otherwise compliant with the Code of Virginia and Board regulation. (motion by Ratliff, seconded by Garvin)

RECOMMENDATIONS TO ACCEPT OUTSOURCING FACILITY INSPECTIONS PERFORMED BY CALIFORNIA AND FLORIDA

The Board discussed the Regulation Committee's recommendation to accept outsourcing facility inspections performed by California and Florida when a current FDA inspection was unavailable.

MOTION

The Board voted unanimously to approve the recommendation of the Regulation Committee to accept an outsourcing facility inspection report indicating compliance with cGMP when performed by Florida Department of Health or California Board of Pharmacy, if the outsourcing facility has not been inspected by the US Food and Drug Administration within the required period. (motion by Richards-Spruill, seconded by Nash)

ADOPTION OF EXEMPT REGULATIONS – ADDITION OF CHEMICALS FROM SCHEDULE I

MOTION

The Board voted unanimously to adopt exempt changes to 18VAC110-20-322 to add the following chemicals to Schedule I as recommended by the Department of Forensic Science:

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,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.**

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.

2. **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.**

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. **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.**

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. **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.**

5. **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. (motion by Nash, seconded by Kocot)**

ADOPTION OF PROPOSED REGULATIONS – IMPLEMENTATION OF 2022 LEGISLATION FOR PHARMACISTS INITIATING TREATMENT

The Board discussed the adoption of proposed regulations regarding the implementation of 2022 legislation for pharmacists initiating treatment.

MOTION

The Board voted unanimously to adopt proposed regulatory changes to 18VAC110-21-46 as presented to implement Chapter 791 of the 2022 Acts of Assembly regarding pharmacists initiating treatment which will replace the current emergency regulations once effective. (motion by Melton, seconded by Garvin)

AMEND NALOXONE PROTOCOL

The Board discussed the revision of Guidance Document 110-44, Naloxone Protocol, pursuant to the passing of SB1415 and SB1424. As required by law, the amendments were shared with VDH and the Board of Medicine. Revisions from VDH were shared as a handout with the Board and this

version was considered for adoption, in lieu of the version in the agenda packet.

MOTION **The Board voted unanimously to amend Guidance Document 110-44 as presented in the handout. (motion by Melton, seconded by Garvin)**

ADOPTION OF EXEMPT REGULATORY CHANGES PURSUANT TO 2023 SCHEDULING ACTIONS OF THE GENERAL ASSEMBLY

The Board discussed the adoption of exempt regulatory changes pursuant to 2023 scheduling actions of the General Assembly.

MOTION **The Board voted unanimously to adopt exempt regulatory changes as presented to remove drugs and chemicals from 18VAC110-20-322 that were placed in law pursuant to HB2364. (motion by Nash, seconded by Garvin)**

ADOPTION OF FAST-TRACK REGULATORY ACTION TO AMEND 18VAC110-20-735 Requirements for dispensing of naloxone by trained individuals

The Board discussed the adoption of fast-track regulatory action to amend 18VAC110-20-735 to clarify that the requirements in (A) apply only to individuals dispensing injectable formulations of naloxone under Virginia Code 54.1-3408(Y).

MOTION **The Board voted unanimously to adopt the proposed amendment to 18VAC110-20-735 as a fast-track regulatory action. (motion by Richards-Spruill, seconded by Kocot)**

AMEND ELECTRONIC PARTICIPATION MEETING POLICY

The Board discussed the adoption of a revised policy on meetings held with electronic participation pursuant to recent statutory changes. The proposed revised electronic participation policy and Virginia Code §2.2-3708.3 were provided as handouts.

MOTION **The Board voted unanimously to revise the policy on meetings held with electronic participation as presented (motion by Garvin, seconded by Ratliff)**

NEW BUSINESS:

ELECTIONS OF CHAIRMAN AND VICE-CHAIRMAN – JULY 1, 2023 THROUGH JUNE 30, 2024

NOMINATIONS FOR CHAIRMAN:	Mrs. Richards-Spruill nominated Dr. Dale St. Clair to be re-elected for 2023-2024 Chairman of the Virginia Board of Pharmacy. Dr. Ratliff nominated Dr. William Lee for 2023-2024 Chairman of the Virginia Board of Pharmacy.
MOTION:	**The Board voted unanimously to close the nominations for the position of Chairman. (motion by Garvin, seconded by Nash)**
ELECTION RESULTS:	**Ms. Juran and Ms. Hayden tallied the written ballots. Dr. St. Clair announced the results indicating that he had been re-elected Chairman of the Virginia Board of Pharmacy for the term July 1, 2023 through June 30, 2024. (motion by Garvin, seconded by Nash)**
NOMINATIONS FOR VICE-CHAIRMAN:	Dr. Melton nominated Ms. Garvin as the 2023-2024 Vice-Chairman of the Virginia Board of Pharmacy. Dr. Lee nominated Dr. Ratliff as 2023-2024 Vice-Chairman of the Virginia Board of Pharmacy.
MOTION	**The Board voted unanimously to close the nominations for the position of Vice-Chairman. (motion by Nash, seconded by Richards-Spruill)**
ELECTION RESULTS:	**Ms. Juran and Ms. Hayden tallied the written ballots. Dr. St. Clair announced the results indicating that Cheri Garvin had been elected Vice-Chairman of the Virginia Board of Pharmacy for the term July 1, 2023 through June 30, 2024.**
SCHEDULE 2024 FULL BOARD MEETING DATES	The Board chose the following dates for full board meetings in 2024: March 28, June 25, September 24, and December 17.
REPORTS:	
CHAIRMAN'S REPORT	Dr. St. Clair expressed appreciation for the opportunity to serve as Chairman over the past year. He additionally provided updates on his attendance at the NABP Annual Meeting in May in Nashville where he represented District 2 on the Resolution Committee.
BOARD OF HEALTH PROFESSIONS	Dr. Melton reported the Board of Health Professions has not met since she provided the last update.
LICENSURE OF INDIVIDUALS AND IN-STATE FACILITIES	Mr. Logan presented the Licensing Report of Individuals and In-State Facilities which included data from November 2021 through May 2023. As of May 1, 2023 the Virginia Board of Pharmacy has a total of 43,677 active individual and in-state facilities licensed.

LICENSURE OF NONRESIDENT FACILITIES	Ms. O'Halloran presented the Licensing Report of Nonresident Facilities which included data from November 2021 through May 2023. As of May 22, 2023, the Virginia Board of Pharmacy has a total of 2,487 active nonresident facilities licensed.
ACTION ITEMS:	**Dr. Nash and Dr. St. Clair requested staff research if they can provide licensing counts over the last 5 quarters to more easily detect trends, the number of pharmacists with Virginia addresses vs. out-of-state addresses, and if Virginia is seeing an increase in the number of nonresident pharmacy registrations vs. in-state pharmacy permits.**
INSPECTION PROGRAM	Enforcement was unable to provide an inspection report prior to the meeting. Ms. O'Halloran provided brief comments regarding recruitment.
PHARMACEUTICAL PROCESSORS	Ms. Kelley presented the Pharmaceutical Processors Report. Three additional cannabis dispensing facility haves been permitted during the last quarter, for a total of 16 cannabis dispensing facilities. The Virginia Court of Appeals ruled in favor of the Board of Pharmacy on the PharmaCann appeal. 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 89% decrease in patient applications. Registration renewals have also significantly decreased.
DISCIPLINARY PROGRAM	Dr. Shinaberry presented the Disciplinary Program Report. As of May 17, 2023, the Virginia Board of Pharmacy has a total of 424 open cases consisting of 188 patient care cases and 236 non-patient care cases.
EXECUTIVE DIRECTOR'S REPORT	Ms. Juran provided an Executive Director's report detailing recently attended and upcoming meetings. She provided an updated on the ongoing recruitment process to fill a vacant licensing administrative staff position and a new disciplinary administrative staff position. She indicated that certain staff members and inspectors will soon be completing training on the upcoming USP revisions on compounding. She stated that the transition of the medical cannabis program to the VCCA as of July 1, 2024 is a primary focus. She announced that the September 2023 board meeting will be rescheduled to September 26, 2023 and the tentative workgroup for translated directions for use of prescriptions will be scheduled for September 28, 2023. This is a change from what was listed in her report in the agenda packet.
CONSIDERATION OF CONSENT ORDERS, SUMARY SUSPENSIONS, OR SUMMARY RESTRICTIONS	

CVS PHARMACY #2691 0201-003705	Sean Murphy, Assistant Attorney General presented a consent order for Board consideration regarding CVS Pharmacy #2691.
CLOSED MEETING	Upon a motion by Lee, and duly seconded by Kocot, the Board voted unanimously to convene a closed meeting pursuant to §2.2-3711(A)(27) of the Code of Virginia ("Code") to reach a decision regarding the matter of CVS Pharmacy #2691. Additionally, he moved that Caroline Juran, James Rutkowski, Sorayah Haden and Ellen Shinaberry attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.
RECONVENE	Upon a motion by Lee, and duly seconded by Richards-Spruill, having certified that the matters discussed in the closed meeting met the requirements of §2.2-3712 of the Code, the Board voted 7:0 with one abstention (Kocot) to reconvene an open meeting and announce the decision.
DECISION	Upon a motion by Nash, and duly seconded by Melton, the Board voted 7-0 with one abstention (Kocot) to reject the consent order and authorize the Chair to negotiate for the Board, in lieu of a formal hearing for CVS Pharmacy #2691.
CAROLINE BENTLEY #0230-008523	David Robinson, Assistant Attorney General presented a possible summary suspension for Board consideration regarding Caroline Bentley (#0230-008523).
DECISION	Upon a motion by Ratliff, and duly seconded by Melton, the Board voted unanimously to summarily suspend the pharmacy technician registration issued to Caroline Bentley (#0230-008523) and offer her a consent order for indefinite suspension for no less than 2 years, in lieu of a formal hearing.
MEETING ADJOURNED:	With all business completed, the Board adjourned at 4:24pm.

_____
Caroline Juran, RPh
Executive Director

_____
DATE:

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

Tuesday, June 13, 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 9:04am.

PRESIDING: Dale St. Clair, PharmD, Chairman

MEMBERS PRESENT:
William Lee, DPh, Vice Chairman
Cheri Garvin, RPh
Larry Kocot, JD
Sarah Melton, PharmD
Wendy Nash, PharmD
Kristopher Ratliff, DPh
Patricia Richards-Spruill, RPh

MEMBERS ABSENT:
Ling Yuan, PharmD

STAFF PRESENT:
Caroline D. Juran, RPh, Executive Director
Erin Barrett, JD, Director of Legislative and Regulatory Affairs, DHP
James Rutkowski, Senior Assistant Attorney General
Arne W. Owens, Director, DHP
James Jenkins Jr, RN, Chief Deputy Director, DHP
Sorayah Haden, Executive Assistant
Beth O'Halloran, RPh, Deputy Executive Director
Annette Kelley, MS, CSAC, Deputy Executive Director
Ryan Logan, RPh, Deputy Executive Director
Ellen B. Shinaberry, PharmD, Deputy Executive Director

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 subjects.

Pursuant to article § 54.1-3443(D), the Virginia Department of Forensic Science (DFS) identified the following five 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,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.

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.

2. 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.

Based on its chemical structure, the following compound is expected to have depressant properties. Compounds of this type have been placed in Schedule I (§ 54.1-3446(4)) in previous legislative sessions.

3. 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.

The following compounds are classified as cannabimimetic agents. Compounds of this type have been placed in Schedule I (§ 54.1-3446(6)) in previous legislative sessions.

4. 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.

5. 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.

Robyn Weimer from the Department of Forensic Science provided comment indicating that the Department recommends the Board consider placing these chemicals into Schedule I.

ADJOURN: With all business concluded, the meeting adjourned at 9:12AM.

Caroline Juran, RPh, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Tuesday, June 27, 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 June 27, 2023, at 12:00 PM, to consider the summary suspensions in case no. 227102, case no. 227198, and case no. 227205.

PRESIDING: Dale St.Clair, Chair

MEMBERS PRESENT:
Cheri Garvin
William Lee
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
Sean J. Murphy, Assistant Attorney General
Jess Weber, DHP Adjudication Specialist
Rebecca Ribley, 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.

NIQUELLE A. MADDEN Sean Murphy, Senior Assistant Attorney General,

Registration No. 0245-007139

presented a summary of the evidence in case no. 227102 regarding the pharmacy technician trainee registration of Niquelle A. Madden.

DECISION:

Upon a motion by Dr. Ratliff and duly seconded by Mrs. Patricia Richards-Spruill, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Niquelle Madden poses a substantial danger to the public; and therefore, the registration of Ms. Madden shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Madden for the revocation of her registration in lieu of the formal hearing.

CLAUDIA YOUNG
Registration No. 0230-037763

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 227198 regarding the pharmacy technician registration of Claudia Young.

DECISION:

Upon a motion by Ms. Garvin and duly seconded by Mr. Ratliff, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician by Claudia Young poses a substantial danger to the public; and therefore, the registration of Ms. Young shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Young for the revocation of her registration in lieu of the formal hearing.

JENNIFER L. KARPIK
Registration No. 0245-007691

Sean Murphy, Senior Assistant Attorney General, presented a summary of the evidence in case no. 227205 regarding the pharmacy technician trainee registration of Jennifer L. Karpik.

Upon a motion by Dr. Ratliff and duly seconded by Ms. Garvin, and amended by Mrs. Richards-Spruill, the Board unanimously voted (6-0) that, with the evidence presented, the practice as a pharmacy technician trainee by Jennifer L. Karpik poses a substantial danger to the public; and therefore, the registration of Ms.

	Karpik shall be summarily suspended and with the Notice of formal hearing, a Consent Order shall be offered to Ms. Karpik for the revocation of her registration in lieu of the formal hearing.
ADJOURN:	With all business concluded, the meeting adjourned at 12:19 PM.

Ellen B. Shinaberry, PharmD
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF STATEWIDE PROTOCOL WORK GROUP MEETING

Friday, August 11, 2023

Department of Health Professions
Perimeter Center
Board Room 2
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A Statewide Protocol Work Group Meeting was called to order at 9:03AM.

PRESIDING: Dale St. Clair, PharmD, Board of Pharmacy, Chairman

MEMBERS PRESENT:
Kristopher Ratliff, DPh, Board of Pharmacy, Member
Ling Yuan, PharmD, Board of Pharmacy, Member
L. Blanton Marchese, Board of Medicine, Member
William T. Hutchens, MD, Board of Medicine, Member
Krishna P. Madiraju, MD, Board of Medicine, Member
Shaina Bernard, PharmD, Virginia Department of Health, Antibiotic Resistance Coordinator

STAFF PRESENT:
Caroline Juran, RPh, Board of Pharmacy, Executive Director
James Rutkowski, JD, Senior Assistant Attorney General, Board Counsel
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: Karen Winslow, RPh, Interim Executive Director of VPhA, expressed VPhA's excitement and support of the protocols being discussed. VPhA believes the protocols will allow pharmacists to practice at the top of their education.

Staff provided the work group members and the public with three handouts of written public comment that Ms. Juran received via email prior to the meeting. The three documents consisted of public comments from the Virginia Association of Health-System Pharmacists, the Medical Society of

Virginia, and the Virginia Association of Chain Drugstores.

Dr. St. Clair provided an overview of the work group's charge pursuant to SB 948 and HB 2274.

GROUP A STREPTOCOCCUS BACTERIA INFECTION

The workgroup reviewed and discussed recommended statewide protocols for Group A Streptococcus (GAS) bacteria infection for patients 18 and over. The agenda materials included Statewide Protocols from Arkansas, Iowa, and Kansas. There was discussion that use of the Centor Score Assessment as used in the Arkansas example may go beyond the legislation's allowance for use of a CLIA-waived test. The work group carefully reviewed each protocol and had a lengthy discussion regarding appropriate language to recommend for inclusion in Virginia's protocol.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt the Kansas Group A Streptococcus statewide protocol as presented and amended as follows:

- **Rearrange language in the protocol to conform with the general outline of existing Virginia statewide protocols to create uniformity;**
- **Under inclusion criteria on page 26 of agenda packet, strike "If testing positive, the patient must be willing to wait at the pharmacy until antibiotics are dispensed";**
- **Under exclusion criteria on page 27, strike "Resident of nursing home or long-term care facility" and "A patient being treated in a medical care facility or emergency department" and insert #2 from page 15 "If patient has taken antibiotics for sore throat or URI in the last 30 days"**
- **Regarding Antibiotic Therapy, insert notation that both azithromycin and clindamycin may have potential resistance and that clindamycin is preferred;**
- **On page 30, replace the paragraph for monitoring beginning with "The pharmacy shall ensure…." with requirement to counsel patient to follow-up with primary care provider (PCP) within 48 hours if symptoms worsen or are unresolved;**
- **On page 31, strike the requirement that training must be accredited by ACPE and insert reference to CDC guidelines following the reference to IDSA guidelines;**
- **On page 31, replace the paragraph under Notification with current statutory language for notifying PCP or counseling patient on importance of relationship with PCP as required in statute for use of statewide protocols;**
- **In Appendix A on page 33, insert question "Have you taken an antibiotic in the last 30 days? If yes, why?" and allow Appendix A to be used in an electronic format. (motion by Marchese, seconded**

by Ratliff)

INFLUENZA VIRUS INFECTION

The workgroup reviewed and discussed recommended statewide protocols for Influenza virus infection for patients 18 and over. The agenda materials included statewide protocols from Arkansas, Iowa, and Kansas. There was lengthy discussion regarding whether the protocol should authorize pharmacists to initiate prophylaxis therapy. The work group decided it would authorize treatment only for now, but that prophylaxis could be considered in the future in a separate protocol. It was discussed and determined that the law does not currently require pharmacists to report positive influenza tests to the Virginia Department of Health.

MOTION

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt the Kansas Influenza statewide protocol as presented and amended as follows:

- **Rearrange language in the protocol to conform with the general outline of existing Virginia statewide protocols to create uniformity;**
- **Under inclusion criteria on page 56 of agenda packet, strike "If testing positive, the patient must be willing to wait at the pharmacy until antiviral therapy is dispensed";**
- **Under exclusion criteria on page 57, strike "Resident of nursing home or long-term care facility" and "A patient being treated in a medical care facility or emergency department" and insert "If patient has taken antivirals in last 30 days"**
- **On page 59, replace the paragraph for monitoring beginning with "The pharmacy shall ensure…." with requirement to counsel patient to follow-up with primary care provider (PCP) within 48 hours if symptoms worsen or are unresolved;**
- **On page 60, strike the requirement that training must be accredited by ACPE;**
- **On page 60, replace the paragraph under Notification with current statutory language for notifying PCP or counseling patient on importance of relationship with PCP as required in statute for use of statewide protocols. (motion by Marchese, seconded by Ratliff)**

COVID-19 VIRUS INFECTION

The work group reviewed and discussed a recommended statewide protocol for COVID-19 virus infection for patients 18 and over. The agenda materials included the statewide protocol used in New Mexico. The work group acknowledged that the Paxlovid Emergency Use Authorization currently allows pharmacists to prescribe Paxlovid under certain conditions.

MOTION

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt a statewide protocol for COVID-19 that references allowances under the Paxlovid current emergency use

authorization and contains a checklist similar to page 67 to assist pharmacists. (motion by Marchese, seconded by Ratliff)

URINARY TRACT INFECTION

The workgroup reviewed and discussed recommended statewide protocols for Urinary Tract Infections for patients 18 and over. The agenda materials included statewide protocols from Kansas and Kentucky.

MOTION:

The work group voted unanimously to recommend to the Board of Pharmacy that it adopt the Kansas statewide protocol for urinary tract infections as presented and amended as follows:

- **Rearrange language in the protocol to conform with the general outline of existing Virginia statewide protocols to create uniformity;**
- **Under inclusion criteria on page 69, strike "and" between "nitrites and/or leukocytes";**
- **Under exclusion criteria on page 70, replace "stay at a medical care facility" with "or hospital stay" and strike "Resident of a nursing home or long-term care facility" and "A patient being treated in a medical care facility or emergency department";**
- **On page 71, regarding counseling for when to seek medical attention, change "three days" to "48 hours";**
- **Restructure antibiotic treatment on page 72, by inserting reference to "First-line Treatment" which shall then list first "Cephalexin 500mg PO BID for 5 days", secondly "Cefdanir 300mg PO BID for 5 days", thirdly "Nitrofurantoin monohydrate/macrocrystals 100mg PO BID for 5 days (for cephalexin allergy)", then insert reference to "Alternative Therapy" and list Fosfomycin trometamol 3gm PO single dose";**
- **On page 72, replace the paragraph for monitoring beginning with "The pharmacy shall ensure…." with requirement to counsel patient to follow-up with primary care provider (PCP) within 48 hours if symptoms worsen or are unresolved;**
- **Regarding recordkeeping, on page 73, strike reference to Kansas laws and change "10 years" to "6 years";**
- **On page 73, strike the requirement that training must be accredited by ACPE and insert requirement that training should include proper biohazard destruction;**
- **On page 73, replace the paragraph under Notification with current statutory language for notifying PCP or counseling patient on importance of relationship with PCP as required in statute for use of statewide protocols. (motion by Marchese, seconded by Ratliff). (motion by Marchese, seconded by Madiraju)**

MEETING ADJOURNED: Having completed all business on the agenda, the meeting was adjourned at 1:44PM.

Date

Caroline D. Juran, RPh
Executive Director

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
POSSIBLE SUMMARY SUSPENSION PRESENTATION & MINUTES OF A PANEL OF THE BOARD

Wednesday, August 23, 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 quorum of the Board of Pharmacy ("Board") was called to order at 9:11 a.m. for the purpose of a possible summary suspension presentation.
PRESIDING:	Dale St. Clair
MEMBERS PRESENT:	Dr. Krisopher Ratliff Mrs. Patricia Richards-Spruill Ms. Cheri Garvin Dr. Ling Yuan Mr. Larry Kocot Dr. Wendy Nash
STAFF PRESENT:	Caroline D. Juran, Executive Director Mykl Egan, Discipline Case Manager James Rutkowski, Assistant Attorney General Sorayah Haden, Executive Assistant
QUORUM:	With seven (7) members of the Board present, a quorum of the board was established.
PURPOSE: CASE NO. 229127	Sean J. Murphy, Assistant Attorney General, presented a summary of the evidence in this case. Mr. Murphy was assisted by Jess Weber, Adjudication Specialist.
DECISION:	Upon a motion by Ms. Garvin and duly seconded by Mr. Kocot, the Board unanimously voted (7-0) that with the evidence presented, Jakiy'Yah Cannon poses a substantial danger to the public; and therefore, the Board voted to summarily suspended Ms. Cannon's pharmacy technician trainee registration, to notice her for a formal hearing, and offer a consent order in lieu of the formal hearing.

NIQUELLE A. MADDEN
Registration No. 0245-007139

A formal hearing was held in the matter of Niquelle A. Madden to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia as provided in the notice dated June 27, 2023, and rescheduled by letter dated July 7, 2023.

With seven (7) members of the Board present, a quorum of the board was established.

Rebecca Ribley, Adjudication Specialist, presented the case.

Niquelle A. Madden was not present and was not represented by counsel.

Carlo Mirabelli, Pharmacist-in-Charge of Wal-Mart Pharmacy #10-1344, Kevin Chandler, Wal-Mart District Manager, and Brian Horowitz, DHP Sr. Investigator, testified in person on behalf of the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Dr. Ratliff, 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 Niquelle A. Madden. Additionally, she moved that Caroline Juran, Jim Rutkowski, Mykl Egan, 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/Ratliff)

DECISION:

Upon a motion by Dr. Yuan, and duly seconded by Mrs. Richards-Spruill, the Board voted 7-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the board voted 7-0 to revoke the pharmacy technician trainee registration of Ms. Madden.

CLAUDIA YOUNG Registration No. 0230-037763	A formal hearing was held in the matter of Claudia Young 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 June 27, 2023, and rescheduled by letter dated July 10, 2023. With seven (7) members of the Board present, a quorum of the board was established. Jess Weber, Adjudication Specialist, presented the case. Claudia Young was present and was not represented by counsel. Maria Joson, DHP Sr. Investigator, testified in person on behalf of the Commonwealth. Ryan Rhodes, Store Manager Walgreens Pharmacy, testified by telephone on behalf of the Commonwealth. Gloria Rine, Ms. Young's Grandmother, testified on behalf of the respondent. Claudia Young testified on her own behalf.
CLOSED MEETING:	Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, 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 Claudia Young. Additionally, she moved that Caroline Juran, Jim Rutkowski, Mykl Egan, 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. Yuan, and duly seconded by Dr. Nash, the Board voted 7-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Ms. Garvin, and duly seconded by Mrs. Richards-Spruill, the board voted 7-0 to suspend the pharmacy technician registration of Ms. Young for not less than two (2) years.

JENNIFER KARPIK
Registration No. 0245-007691

A formal hearing was held in the matter of Jennifer Karpik to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technician trainees in Virginia as provided in the notice dated June 27, 2023, and rescheduled by letter dated July 10, 2023.

With seven (7) members of the Board present, a panel of the board was established.

Jess Weber, Adjudication Specialist, presented the case.

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

Maria Joson, DHP Sr. Investigator and Michelle Newman, Walgreens Store Manager testified in person for the Commonwealth.

CLOSED MEETING:

Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, 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 Darrelle Moses. Additionally, she moved that Caroline Juran, Jim Rutkowski, Mykl Egan, 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/Richards-Spruill)

DECISION:

Upon a motion by Dr. Yuan, and duly seconded by Dr. Nash, the Board voted 7-0 to accept the Findings of Fact and Conclusions of law as presented by the Commonwealth and amended by the Board.

Upon a motion by Ms. Garvin, and duly seconded by Mr. Kocot, the board voted 7-0 to revoke the technician trainee registration of Jennifer Karpik.

3:25 PM

ADJOURNED:

Caroline D. Juran
Executive Director

Date

Board of Pharmacy
Current Regulatory Actions
As of September 12, 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 1,938 days; 6.5 years since submission for executive branch review	Addresses a patient safety concern.
18VAC110-20	Emergency/ NOIRA	Pharmacy working conditions	2/27/2023	Governor 197 days	Implements emergency regulations related to work environments for pharmacy personnel

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 527 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 527 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 drugs for ADDs in hospitals	8/31/2022	Secretary 377 days	Permits centralized warehousers or wholesale distributors to verify Schedule VI drugs for ADDs in hospitals
18VAC110-21	Emergency/ NOIRA	2023 pharmacists initiating treatment	7/25/2023	Secretary 49 days	Changes in pharmacists initiating treatment pursuant to legislation
18VAC110-21	Fast-Track	Repeal of outdated sections	8/16/2023	Secretary 27 days	Repeals outdated regulations regarding pharmacy technician registration
18VAC110-30	Proposed	Implementation of 2021 periodic review	8/25/2023	Secretary 18 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 14 days	Clarification that certain regulatory requirements only apply to individuals dispensing injectable formulations of naloxone

At DPB/OAG

VAC	Stage	Subject Matter	Date submitted*	Office; time in office	Notes
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	OAG 83 days	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	OAG 83 days	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	Exempt/ Final	March 2023 scheduling of chemicals in Schedule I	8/28/2023	9/27/2023
18VAC110-20	Exempt/ Final	June 2023 scheduling of chemicals in Schedule I	8/28/2023	9/27/2023

18VAC110-20	Exempt/ Final	March 2023 scheduling and de-scheduling of drugs and chemicals pursuant to federal scheduling actions July 7, 2022 – February 3, 2023	7/17/2023	8/16/2023
18VAC110-60	Exempt/ Final	Pharmaceutical processor regulations	7/17/2023	8/16/2023

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.
- Recommendation from the Department of Forensic Science to place tianeptine in Schedule I.
- Information regarding tianeptine.
- 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

700 NORTH 5TH ST.
RICHMOND, VIRGINIA 23219
(804) 786-2281 FAX (804) 786-6857

To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: July 21, 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.

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.

Robyn Weimer
Chemistry Program Manager

COMMONWEALTH of VIRGINIA

DEPARTMENT OF FORENSIC SCIENCE

OFFICE OF THE DIRECTOR
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To: Caroline Juran, Executive Director, Board of Pharmacy
From: Robyn Weimer, Chemistry Program Manager, Virginia Department of Forensic Science
Date: August 30, 2023
RE: **Placement of tianeptine into Schedule I**

Ms. Juran,

Pursuant to article § 54.1-3443(D), the Board of Pharmacy has notified the Department of Forensic Science (DFS) of its intention to consider tianeptine as a Schedule I compound and its placement into the Code of Virginia.

DFS records indicate the identification of tianeptine in a single case; the identification was pursued due to its involvement in a death investigation. Tianeptine is currently not controlled, and as such, would generally not be identified if present in seized drug submissions from across the state. Given the lack of controlled status, no accurate frequency of occurrence data can be provided.

If tianeptine is added into Schedule I, this compound would be best classified into § 54.1-3446(1). It is recognized, however, that there is not a consensus between states who have scheduled this compound as to the most appropriate schedule or compound classification, and therefore leave it to the Board's discretion.

Robyn Weimer
Chemistry Program Manager

Tianeptine

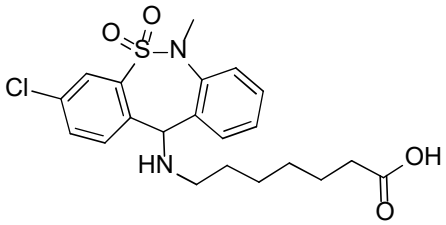
May 2023

Introduction:

Tianeptine has recently emerged on the illicit drug market in the United States. The Centers for Disease Control and Prevention (CDC) reviewed data from 2000 to 2017 from the National Poison Data System (NPDS) of the American Association of Poison Control Centers and noted a rapid and marked increase in tianeptine related calls during this time period. According to recent case reports, tianeptine is abused for its euphoric properties similar to other opioids, such as heroin. Severe adverse health effects, including respiratory depression, severe sedation, and death, have occurred from the misuse of tianeptine.

Chemistry:

The chemical structure for tianeptine[1] is shown below.



Tianeptine is often encountered in a salt form, such as its sodium or sulfate salt.

Pharmacology:

Data from preclinical studies show that tianeptine binds to and acts as an agonist at the mu opioid receptor. Additional studies demonstrated that tianeptine has no activity at NMDA glutamate (GluN1a/GluN2a) receptors or the dopamine, serotonin or norepinephrine transporters.

Licit Uses:

While tianeptine is available for use in other countries, tianeptine has not been approved by the United States Food and Drug Administration (FDA) for any medical use nor are there any commercial uses for tianeptine in the United States.

Illicit Uses:

Tianeptine has been encountered in the United States by law enforcement in various forms including bulk powder, counterfeit pills mimicking hydrocodone and oxycodone pharmaceutical products, and individual stamp bags commonly used to distribute heroin. Severe withdrawal symptoms in humans resulting in hospitalization following the use of tianeptine have been reported. Published case reports have provided evidence of adverse respiratory, neurological, cardiovascular, gastrointestinal, and withdrawal effects associated with the use of tianeptine.

User Population:

In August, 2018, the CDC published an analysis of the tianeptine-related calls to the NPDS between 2000 and 2017. During the first 14 years of the study period (2000-2013), NPDS reported a total of 11 tianeptine exposure calls, whereas 207 calls were reported from 2014 through 2017 (2014 – 5; 2015 – 38; 2016 – 83; 2017 – 81). There were 29 tianeptine withdrawal-associated calls reported to NPDS, of which 21 (72.4%) calls involved tianeptine only. The most commonly reported adverse effects among the 21 tianeptine withdrawal-associated calls consisted of: agitation, nausea, vomiting, tachycardia, hypertension, diarrhea, tremor, and diaphoresis. Amidst the current opioid crisis, this rapid and marked increase in calls to poison control centers related to tianeptine, an opioid-like drug, is of extreme public health concern. These data demonstrate that the abuse of tianeptine is increasing while contributing to the current opioid epidemic.

Illicit Distribution:

According to DEA's National Forensic Laboratory Information System (NFLIS) Drug database, which collects scientifically verified data on drug items and cases submitted to and analyzed by federal, state, and local forensic laboratories, there have been 84 reports of tianeptine since it was first reported in 2017.

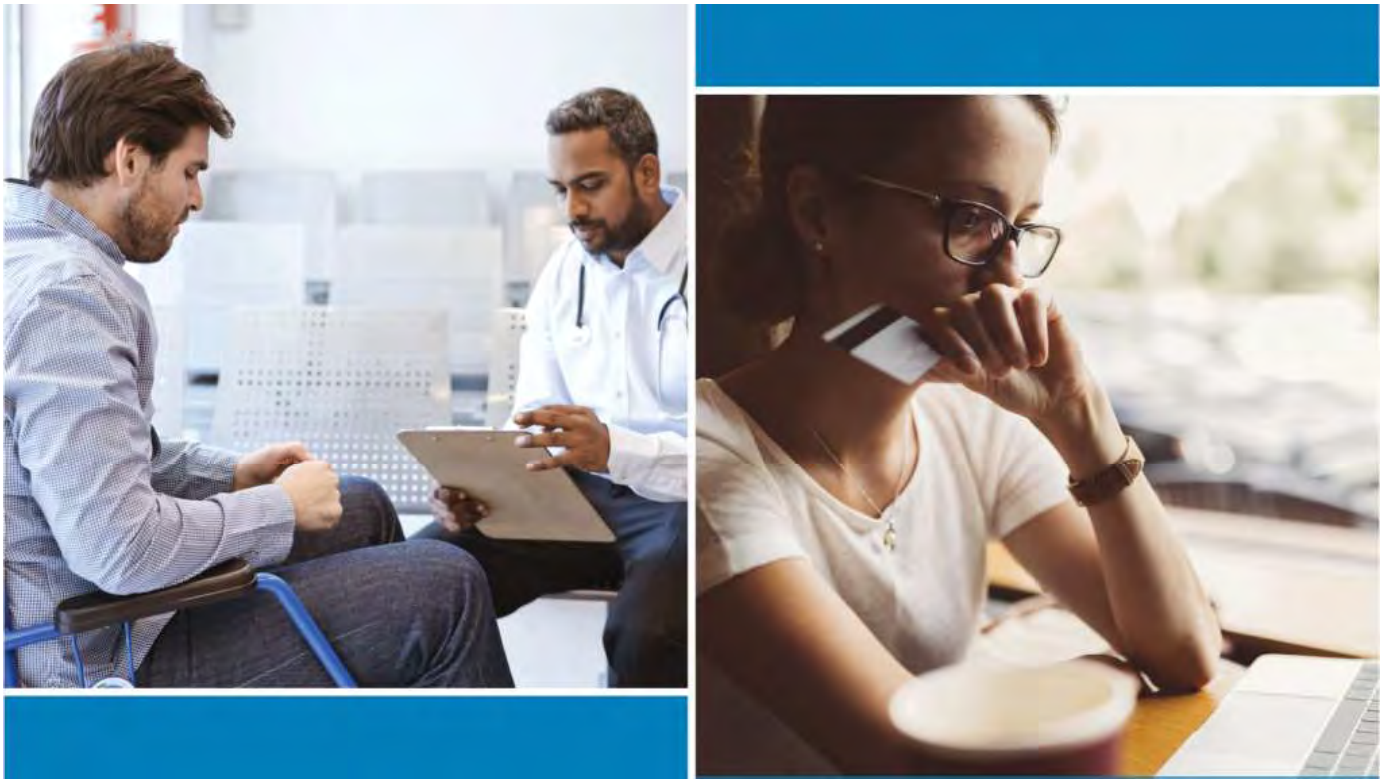
Control Status

Tianeptine is not currently controlled under the Controlled Substances Act. On April 5, 2018, Michigan passed Public Act 107 of 2018 adding tianeptine sodium (a salt form of tianeptine) to Michigan's list of schedule 2 controlled substances (effective July 4, 2018). Tianeptine is not approved by the FDA for medical use within the United States.

Comments and additional information are welcomed by the Drug and Chemical Evaluation Section; Fax 571-362-4250, Telephone 571-362-3249, or E-mail DPE@dea.gov.

[1] Chemical name: 7-((3-chloro-6-methyl-5,5-dioxido-6,11-dihydrodibenzo[c,f][1,2]thiazepin-11-yl)amino)heptanoic acid

Tianeptine Products Linked to Serious Harm, Overdoses, Death



Español (https://www.fda.gov/consumers/articulos-en-espanol/los-productos-de-tianeptina-se-han-asociado-danos-graves-sobredosis-y-muerte)

People seeking to treat their ailments sometimes mistake a product as being safe because it's easily available, whether online or even at gas stations. But availability is no indication of effectiveness or safety. This is especially true of tianeptine, an unapproved drug associated with serious health risks and even death.

Tianeptine is not approved by the U.S. Food and Drug Administration for any medical use. Despite that, some companies are illegally marketing and selling products containing tianeptine to consumers. They are also making dangerous and unproven claims that tianeptine can improve brain function and treat anxiety, depression, pain, opioid use disorder, and other conditions.

Although the FDA has warned consumers about tianeptine (/food/dietary-supplement-ingredient-directory/tianeptine-dietary-supplements), vendors continue to market and sell this drug. The FDA is aware that tianeptine has been sold online, typically in tablet or powder form.

Tianeptine Isn't FDA Approved for Any Medical Use

Tianeptine is an unapproved drug in the U.S. Although other countries have approved tianeptine to treat depression and anxiety, some have restricted how tianeptine is prescribed or dispensed, or revised the drug label to warn of possible addiction.

In the U.S., reports of bad reactions and unwanted effects involving tianeptine are increasing. Poison control center cases involving tianeptine exposure have increased nationwide, from 11 total cases between 2000 and 2013 to 151 cases in 2020 alone.

Tianeptine Presents Safety Risks and Can Be Abused

Cases described in medical journals, in calls to U.S. poison control centers, and in reports to the FDA suggest that tianeptine has a potential for abuse. People with a history of opioid use disorder or dependence may be at particular risk of abusing tianeptine.

Some people have turned to tianeptine as an opioid alternative, or to self-treat anxiety or depression. Medical journals and reports to the FDA suggest that adverse events may occur when tianeptine is taken at doses higher than the doses prescribed in the countries where the drug has been approved. Some people may have difficulty stopping their use of tianeptine and may experience withdrawal symptoms. The clinical effects of tianeptine abuse and withdrawal can mimic opioid toxicity and withdrawal, according to the Centers for Disease Control and Prevention (CDC) (https://www.cdc.gov/mmwr/volumes/67/wr/mm6730a2.htm).

The FDA has identified cases in which people experienced other serious harmful effects from abusing or misusing tianeptine by itself or with other drugs, including antidepressants and anti-anxiety medicines. These effects included agitation, drowsiness, confusion, sweating, rapid heartbeat, high blood pressure, nausea, vomiting, slowed or stopped breathing, coma, and death.

How to Protect Yourself and Your Family

Consumers should avoid all products containing tianeptine, including those claiming to treat an ailment or disorder. Talk to your health care provider if you need help with opioid dependence, depression, anxiety, pain, or other ailments. There are approved treatments for those and related conditions.

Help is available to treat opioid or other substance use disorders. Find state-licensed providers who specialize in treating substance use disorders and addiction at www.findtreatment.gov (http://www.findtreatment.gov/). Or call 1-800-662-HELP (4357).

The FDA has taken steps to protect people from unapproved tianeptine products, including warning consumers that tianeptine is an unsafe food additive and not a dietary ingredient (/food/dietary-supplement-ingredient-directory/tianeptine-dietary-supplements). We have issued warning letters to companies illegally marketing tianeptine products as dietary supplements and unapproved drugs. We also have issued import alerts to help stop tianeptine shipments at our borders.

The FDA will continue to take regulatory action to discourage the importation and marketing of unapproved tianeptine products. In the meantime, you can report an adverse event involving tianeptine by using the FDA's MedWatch Safety Information and Adverse Event Reporting Program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program):

- Complete and submit the report online (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm).
- Download the form (/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting) or call 1-800-332-1088 to request a reporting form sent to you in the mail, then complete and return to the address on the form, or submit it by fax to 1-800-FDA-0178.

If you have a question about a medication, call your pharmacist or the FDA. The FDA's Division of Drug Information (DDI) (/about-fda/center-drug-evaluation-and-research-cder/cder-division-drug-information) will answer almost any drug question. DDI pharmacists are available by email at druginfo@fda.hhs.gov, and by phone, at 1-855-543-DRUG (3784) and 301-796-3400.

Project 7665 - Exempt Final

Board of Pharmacy

September 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 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. Tianeptine.

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.

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

Included in your agenda packet:

- 18VAC110-11

Staff Note: Agencies are required to conduct periodic reviews of regulatory chapters every 4 years. Although this particular chapter is only changed when the Department of Planning and Budget provides new model language, the Board is still required to conduct a periodic review.

Action Needed:

- Motion to initiate periodic review of 18VAC110-11.

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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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 fast-track action to change "nurse practitioner" to "advanced practice registered nurse"

Included in your agenda package are:

- Changes to regulations in Chapter 30 to amend references to nurse practitioner to advanced practice registered nurse.

- Summary page for SB975.

Staff note: Full legislation is not provided in Board agenda packet due to length.

Action needed:

- Motion to adopt fast-track changes to Chapter 30 to amend references to nurse practitioners to advanced practice registered nurses.

Project 7669 - Fast-Track

Board of Pharmacy

Action to change nurse practitioner references to advanced practice registered nurse pursuant to Ch. 183 of the 2023 General Assembly

18VAC110-30-10. Definitions.

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

"Board" means the Virginia Board of Pharmacy.

"Controlled substance" means a drug, substance or immediate precursor in Schedules I through VI of the Drug Control Act.

"Licensee" means a practitioner who is licensed by the Board of Pharmacy to sell controlled substances.

"Personal supervision" means the licensee must be physically present and render direct, personal control over the entire service being rendered or acts being performed. Neither prior nor future instructions shall be sufficient nor shall supervision be rendered by telephone, written instructions, or by any mechanical or electronic methods.

"Practitioner" or "practitioner of the healing arts" means a doctor of medicine, osteopathic medicine or podiatry who possesses a current active license issued by the Board of Medicine. For the purpose of a limited-use permit for a nonprofit facility, a "practitioner" or "practitioner of the healing arts" may also mean a physician assistant with a current active license issued by the Board of Medicine or ~~a nurse practitioner~~ an advanced practice registered nurse with a current active license issued by the Joint Boards of Nursing and Medicine.

"Sale" means barter, exchange, or gift, or offer thereof, and each such transaction made by any person, whether as an individual, proprietor, agent, servant or employee. It does not include the gift of manufacturer's samples to a patient.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open or obtain a toxic or harmful amount of the controlled substance contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"U.S.P.-N.F." means the United States Pharmacopeia-National Formulary.

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 7, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

B. Prior to engaging in the sale of Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances from a nonprofit facility, a doctor of medicine, osteopathic medicine, or podiatry, ~~a nurse practitioner~~ an advanced practice registered nurse, or a physician assistant shall make application on a form provided by the board and be issued a limited-use license.

C. Any disciplinary action taken by the Board of Medicine, or in the case of ~~a nurse practitioner~~ an advanced practice registered nurse, by the Joint Boards of Nursing and Medicine, against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

18VAC110-30-270. Grounds for disciplinary action.

In addition to those grounds listed in § 54.1-3316 of the Code of Virginia, the board may revoke, suspend, refuse to issue or renew a license to sell controlled substances or may deny any application if it finds that the licensee or applicant has had his license to practice medicine, osteopathic medicine, or podiatry or license as a physician assistant or ~~nurse practitioner~~ advanced practice registered nurse suspended or revoked in Virginia or in any other state or no longer holds a current active license to practice in the Commonwealth of Virginia.

2023 SESSION

SB 975 Certified nurse midwives, etc.; designation as advanced practice registered nurses.

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SUMMARY AS PASSED SENATE: (all summaries)

Certified nurse midwives, certified registered nurse anesthetists, clinical nurse specialists, and nurse practitioners; designation as advanced practice registered nurses. Changes references to certain practitioners in the Code to advanced practice registered nurse in order to align the Code with the professional designations established by the *Consensus Model for Advanced Practice Registered Nurses Regulation* established by the National Council of State Boards of Nursing.

FULL TEXT

01/06/23 Senate: Prefiled and ordered printed; offered 01/11/23 23102178D pdf | impact statement

01/23/23 Senate: Printed as engrossed 23102178D-E pdf | impact statement

03/07/23 Senate: Bill text as passed Senate and House (SB975ER) pdf | impact statement

03/22/23 Governor: Acts of Assembly Chapter text (CHAP0183) pdf

AMENDMENTS

Senate subcommittee amendments and substitutes offered

Senate amendments

HISTORY

01/06/23 Senate: Prefiled and ordered printed; offered 01/11/23 23102178D

01/06/23 Senate: Referred to Committee on Education and Health

01/11/23 Senate: Assigned Education sub: Health Professions

01/19/23 Senate: Reported from Education and Health with amendment (14-Y 0-N)

01/20/23 Senate: Constitutional reading dispensed (38-Y 0-N)

01/23/23 Senate: Read second time

01/23/23 Senate: Reading of amendment waived

01/23/23 Senate: Committee amendment agreed to

01/23/23 Senate: Engrossed by Senate as amended SB975E

01/23/23 Senate: Printed as engrossed 23102178D-E

01/24/23 Senate: Read third time and passed Senate (39-Y 0-N)

02/10/23 House: Placed on Calendar

02/10/23 House: Read first time

02/10/23 House: Referred to Committee on Health, Welfare and Institutions

02/14/23 House: Reported from Health, Welfare and Institutions (21-Y 0-N)

02/16/23 House: Read second time

02/17/23 House: Read third time

02/17/23 House: Passed House BLOCK VOTE (99-Y 0-N)

02/17/23 House: VOTE: Block Vote Passage (99-Y 0-N)

03/07/23 Senate: Enrolled

03/07/23 Senate: Bill text as passed Senate and House (SB975ER)

03/08/23 Senate: Signed by President

03/08/23	House: Signed by Speaker
03/13/23	Senate: Enrolled Bill Communicated to Governor on March 13, 2023
03/13/23	Governor: Governor's Action Deadline 11:59 p.m., March 27, 2023
03/22/23	Governor: Approved by Governor-Chapter 183 (effective 7/1/23)
03/22/23	Governor: Acts of Assembly Chapter text (CHAP0183)

Agenda Item: Amendment of guidance documents to reflect title change of nurse practitioners to advanced practice registered nurses

Included in your agenda package are:

- Guidance documents 110-1, 110-7, 110-8, 110-13, and 110-29, all amended to change "nurse practitioner" to "advanced practice registered nurse."

- Summary page for SB975.

Staff note: Full legislation is not provided in Board agenda packet due to length.

Guidance Documents 110-7, 110-8, 110-13, and 110-29 needed additional changes to comply with current requirements of the Office of Regulatory Management. These changes removed copied and pasted statutory and regulatory language that is available in a more updated format on Virginia state websites. For Guidance Document 110-13, removing this copied and pasted language removes the phrase "nurse practitioner" entirely.

Action needed:

- Motion to amend guidance documents 110-1, 110-7, 110-8, 110-13, and 110-29 to amend references to nurse practitioners to advanced practice registered nurses.

VIRGINIA BOARD OF PHARMACY
CATEGORIES OF FACILITY LICENSURE

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

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

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

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

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

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

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

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

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution. This license does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

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

WAREHOUSER: This permit is a "carved out" authority from a wholesale distributor with fewer regulatory requirements. This permit may be preferable to the wholesale distributor license for those entities which distribute prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities which only distribute prescription devices, and no prescription drugs. This permit does not authorize distribution of prescription drugs or devices to the ultimate user, except as authorized in § 54.1-3415.1.

NONRESIDENT WAREHOUSER: This registration is for those entities located outside of the Commonwealth which distribute prescription drugs and/or prescription devices, but are exempted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only distribution of drug samples, or only distribution of medical gases. This registration is for those entities which only distribute prescription devices and no prescription drugs.

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

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

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

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

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

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

PRACTITIONER OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCE FACILITY PERMIT: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

LIMITED USE PRACTITIONER DISPENSING PERMIT: This permit authorizes a ~~nurse practitioner~~ advanced practice registered nurse or a physician assistant who is licensed by the Board of Pharmacy and practicing in a nonprofit facility, to dispense Schedule VI controlled substances (excluding the combination of misoprostol and methotrexate) and hypodermic syringes and needles for the administration of prescribed controlled substances. The ~~nurse practitioner~~ advanced practice registered nurse or physician assistant must also obtain a Limited Use Practitioner Dispensing License.

THIRD-PARTY LOGISTICS PROVIDER:
This permit authorizes the permit holder, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device.

NONRESIDENT THIRD-PARTY LOGISTICS PROVIDER: This registration authorizes a facility outside of the Commonwealth, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, warehouse or dispenser of the drug or device.

*** § 54.1-3455. Schedule VI.**

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

VIRGINIA BOARD OF PHARMACY

PRACTITIONER/PATIENT RELATIONSHIP AND THE PRESCRIBING OF DRUGS FOR FAMILY OR SELF

Several health regulatory boards that license prescribers have adopted regulations regarding a practitioner prescribing for self or family. Regulations for the Board of Medicine (18VAC85-20-25) apply to practitioners of medicine, osteopathic medicine, and podiatry. Identical language is included in regulations for physician assistants (18VAC85-50-176) and ~~nurse practitioners~~ advanced practice registered nurses (18VAC90-40-121). The Board of Optometry addressed this issue in 18VAC105-20-40.

While this issue has not been specifically addressed in regulations of the Board of Dentistry, the requirements of §54.1-3303 would need to be met by all prescribers in order for there to be a valid prescription.

Statutes:

Va. Code § 54.1-3303(B)

Regulations:

18VAC85-20-25
18VAC85-50-176
18VAC90-40-121
18VAC105-20-40

~~18VAC85-20-25. Treating and prescribing for self or family~~

~~A. Treating or prescribing shall be based on a bona fide practitioner-patient relationship, and prescribing shall meet the criteria set forth in § 54.1-3303 of the Code of Virginia.~~

~~B. A practitioner shall not prescribe a controlled substance to himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia, unless the prescribing occurs in an emergency situation or in isolated settings where there is no other qualified practitioner available to the patient, or it is for a single episode of an acute illness through one prescribed course of medication.~~

~~C. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.~~

~~18VAC105-20-40. Standards of conduct.~~

~~The board has the authority to deny, suspend, revoke, or otherwise discipline a licensee for a violation of the following standards of conduct. A licensed optometrist shall:~~

~~9. Treat or prescribe based on a bona fide practitioner-patient relationship consistent with criteria set forth in § 54.1-3303 of the Code of Virginia. A licensee shall not prescribe a controlled substance to~~

~~himself or a family member, other than Schedule VI as defined in § 54.1-3455 of the Code of Virginia. When treating or prescribing for self or family, the practitioner shall maintain a patient record documenting compliance with statutory criteria for a bona fide practitioner-patient relationship.~~

~~**Section of 54.1-3303 (B) from the Code of Virginia**~~

~~B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.~~

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

~~A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient.~~

~~A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient via telemedicine if such prescribing is in compliance with federal requirements for the practice of telemedicine and, in the case of the prescribing of a Schedule II through V controlled substance, the prescriber maintains a practice at a physical location in the Commonwealth or is able to make appropriate referral of patients to a licensed practitioner located in the Commonwealth in order to ensure an in-person examination of the patient when required by the standard of care.~~

~~A prescriber may establish a bona fide practitioner-patient relationship for the purpose of prescribing Schedule II through VI controlled substances by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations; (h) the establishment of a bona fide~~

~~*practitioner-patient relationship via telemedicine is consistent with the standard of care, and the standard of care does not require an in-person examination for the purpose of diagnosis; and (i) the establishment of a bona fide practitioner patient relationship via telemedicine is consistent with federal law and regulations and any waiver thereof. Nothing in this paragraph shall apply to (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.*~~

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

Virginia Board of Pharmacy
Prescriptive Authority in Virginia

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

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

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

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

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

~~Nurse practitioners~~ Advanced practice registered nurses or physician assistants whose prescriptive authority is limited to Schedule VI are not legally required to have a DEA number but will possess a Virginia license. For ~~nurse practitioners~~ advanced practice registered nurses, there is a 10-digit license number beginning with 0024, which should be on the prescription. To verify the license, click on "License Lookup" at www.dhp.virginia.gov using "Licensed ~~Nurse Practitioner~~ Advanced Practice Registered Nurse" for the occupation. On the screen displaying the results of the individual's licensure information, the phrase "Rx Authority" will appear under "Specialization" if the ~~nurse practitioner~~ advanced practice registered nurse is authorized to prescribe drugs. For physician assistants, there is a 10-digit license number beginning with 0011, which can be verified through the web site www.dhp.virginia.gov under "License Lookup" and checking the occupation "Physician Assistant."

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

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

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

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

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

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

Statutes:

Va. Code § 54.1-3303
Va. Code § 54.1-3400 *et seq.*

Section of 54.1-3303 from the Code of Virginia:

A. A prescription for a controlled substance may be issued only by a practitioner of medicine, osteopathy, podiatry, dentistry or veterinary medicine who is authorized to prescribe controlled substances, a licensed nurse practitioner pursuant to § 54.1-2957.01, a licensed certified midwife pursuant to § 54.1-2957.04, a licensed physician assistant pursuant to § 54.1-2952.1, or a TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32.

B. A prescription shall be issued only to persons or animals with whom the practitioner has a bona fide practitioner-patient relationship or veterinarian-client-patient relationship. If a practitioner is providing expedited partner therapy consistent with the recommendations of the Centers for Disease Control and Prevention, then a bona fide practitioner-patient relationship shall not be required.

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

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient.

A practitioner who has established a bona fide practitioner-patient relationship with a patient in accordance with the provisions of this subsection may prescribe Schedule II through VI controlled substances to that patient via telemedicine if such prescribing is in compliance with federal requirements for the practice of telemedicine and, in the case of the prescribing of a Schedule II through V controlled substance, the prescriber maintains a

~~practice at a physical location in the Commonwealth or is able to make appropriate referral of patients to a licensed practitioner located in the Commonwealth in order to ensure an in-person examination of the patient when required by the standard of care.~~

~~A prescriber may establish a bona fide practitioner-patient relationship for the purpose of prescribing Schedule II through VI controlled substances by an examination through face-to-face interactive, two-way, real-time communications services or store-and-forward technologies when all of the following conditions are met: (a) the patient has provided a medical history that is available for review by the prescriber; (b) the prescriber obtains an updated medical history at the time of prescribing; (c) the prescriber makes a diagnosis at the time of prescribing; (d) the prescriber conforms to the standard of care expected of in-person care as appropriate to the patient's age and presenting condition, including when the standard of care requires the use of diagnostic testing and performance of a physical examination, which may be carried out through the use of peripheral devices appropriate to the patient's condition; (e) the prescriber is actively licensed in the Commonwealth and authorized to prescribe; (f) if the patient is a member or enrollee of a health plan or carrier, the prescriber has been credentialed by the health plan or carrier as a participating provider and the diagnosing and prescribing meets the qualifications for reimbursement by the health plan or carrier pursuant to § 38.2-3418.16; (g) upon request, the prescriber provides patient records in a timely manner in accordance with the provisions of § 32.1-127.1:03 and all other state and federal laws and regulations; (h) the establishment of a bona fide practitioner-patient relationship via telemedicine is consistent with the standard of care, and the standard of care does not require an in-person examination for the purpose of diagnosis; and (i) the establishment of a bona fide practitioner patient relationship via telemedicine is consistent with federal law and regulations and any waiver thereof. Nothing in this paragraph shall apply to (1) a prescriber providing on-call coverage per an agreement with another prescriber or his prescriber's professional entity or employer; (2) a prescriber consulting with another prescriber regarding a patient's care; or (3) orders of prescribers for hospital out-patients or in-patients.~~

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

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

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

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

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

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

~~*E. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection B, with the diagnosed patient and (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a*~~

~~communicable disease. In cases in which the practitioner is an employee of or contracted by the Department of Health or a local health department, the bona fide practitioner-patient relationship with the diagnosed patient, as required by clause (i), shall not be required.~~

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

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

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

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

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

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

VIRGINIA BOARD OF PHARMACY

Guidance Regarding Collaborative Practice Agreements

To clarify whether a collaborative practice agreement is required for each patient, the Board offers the following guidance.

1. A pharmacist and a practitioner or other authorized person as found in the definition of "collaborative agreement" in §54.1-3300 may enter into a collaborative practice agreement. Such agreement is not executed for each patient, but rather serves as a general agreement between the pharmacist and practitioner for how a pharmacist may implement, modify, continue, or discontinue drug therapy; order laboratory tests; or complete other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.
2. The agreement may only be implemented for an individual patient pursuant to an order from the practitioner for that patient.
3. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement but who chooses to not participate in a collaborative procedure must notify the prescriber of his/her refusal to participate in such collaborative procedure.

Statutes:

Va. Code § 54.1-3303

Regulations:

18VAC110-40-20

~~**Code of Virginia:**~~

~~***§ 54.1-3300. Definitions.***~~

~~*"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or*~~

~~limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.~~

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

~~A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working in accordance with the provisions of § 54.1-2951.1; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes for patients who meet the criteria set forth in the collaborative agreement. However, no person licensed to practice medicine, osteopathy, or podiatry, or licensed as a nurse practitioner or physician assistant, shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.~~

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

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

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

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

~~**Regulations of the Board:**~~

~~***18VAC110-40-20. Signed authorization for an agreement.***~~

~~*A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a single physical location where patients receive services.*~~

~~*B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of the patient's refusal to participate in such collaborative procedure.*~~

~~*1. The patient may decline to participate or withdraw from participation at any time.*~~

~~*2. The patient shall be informed by the practitioner or the pharmacist of the collaborative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.*~~

~~*3. The practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.*~~

Virginia Board of Pharmacy

Physicians Dispensing Drugs

Dispensing by a physician means the providing of drugs to patients to take with them away from the physician's place of practice. Physicians in Virginia may dispense under certain circumstances without being required to obtain a license to dispense from the Board of Pharmacy. Those circumstances include the dispensing of manufacturer's samples appropriately labeled as samples and not for sale, dispensing in a bona fide medical emergency, and dispensing when pharmaceutical services are not otherwise available. Any other type of dispensing by a physician requires the physician to obtain a license from the Board of Pharmacy. The Board offers two types of license to physicians.

Permitted Physicians – Practice as a pharmacy

One type of license, pursuant to Virginia Code § 54.1-3304 authorizes the Board to license a physician to practice pharmacy when good cause is shown that pharmacy services are not otherwise readily available. This type of license is usually granted to physicians working in rural areas where there is not a pharmacy within at least 15 to 20 miles and there are only a handful of these types of licenses still current. With this type of license, a physician may also fill prescriptions of other practitioners.

Physicians Selling Drugs

The second and more common type of dispensing license for physicians is the license for a practitioner of the healing arts to sell controlled substances. The term "controlled substances" in Virginia includes any drug in Schedule I through VI which is all prescription drugs, not just those drugs which are DEA controlled substances. Another confusing term is the term “sell” or “sale.” Many physicians question why they are required to have this license if they do not charge a patient for the drugs dispensed. The term “sale” is defined in the Drug Control Act as “gift, barter, or exchange.” Therefore, a charge is not required in order for dispensing to become a “sale.” With this license a physician must comply with a set of regulations which relate specifically to this license. If there is more than one physician dispensing within a single practice, each dispensing physician must obtain this license. Effective June 4, 2016, a permit from the Board of Pharmacy must also be obtained for the facility from which practitioners of the healing arts dispense controlled substances and it shall meet compliance with the regulations for practitioners of the healing arts to sell controlled substances. Physicians licensed to sell controlled substances may dispense from any facility permitted for this purpose.

While the regulation allows for a pharmacy technician, or trained nurse or trained physician assistant to assist the licensed physician in preparing the drug for dispensing, the physician is responsible for conducting a prospective drug review, offering to counsel the patient, inspecting the prescription product to verify its accuracy in all respects, and placing his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. The physician may not delegate the responsibility of dispensing a drug to a ~~nurse practitioner~~ advanced practice registered nurse or physician assistant; hence, no drug may be dispensed when a physician is not on-site.

Within this category of licensure, it is possible to request a **limited-use license.** Pursuant to Regulation 18VAC110-30-20 and the delegation of authority to the Executive Director as set forth in Bylaws of the Board, a physician may apply for a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. Under a limited-use license, a waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

Limited-use license for a ~~nurse practitioner~~ advanced practice registered nurse or physician assistant

The Board may also issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to ~~a nurse practitioner~~ an advanced practice registered nurse or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit. The term "non-profit" is defined in the Virginia Tax Code, so those entities satisfying that definition would be recognized as non-profit for the purpose of issuing such a limited-use license.

There is one other exception to the pharmacy act which allows physicians acting on behalf of the state or a local health department to dispense without having to obtain licensure from the Board of Pharmacy. It has been interpreted that this authority can be delegated to other persons authorized to prescribe within the health department system, such as ~~nurse practitioners~~ advanced practice registered nurses, since there is no direct prohibition against such delegation, as is the case with the physician selling drugs license.

Statutes:

Va. Code § 54.1-3301
Va. Code § 54.1-3302
Va. Code § 54.1-3304
Va. Code § 54.1-3304.1
Va. Code § 54.1-2914

~~Excerpts from the Code of Virginia – Pharmacy Act and Medical Practice Act related to physician dispensing~~

~~§ 54.1-3301. Exceptions.~~

~~This chapter shall not be construed to:~~

~~1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;~~

~~2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-~~

~~3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;~~

~~3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;~~

~~6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;~~

~~7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;~~

~~8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;~~

~~9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written or electronic agreement with a physician;~~

~~10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the~~

~~*cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;*~~

~~*11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or*~~

~~*12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.*~~

~~*This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.*~~

~~*§ **54.1-3302. Restrictions on practitioners of the healing arts.***~~
~~*A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.*~~

~~*§ **54.1-3304. Licensing of physicians to dispense drugs; renewals.***~~
~~*For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.*~~

~~***§ 54.1-3304.1. Authority to license and regulate practitioners.***~~
~~*A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.*~~

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

~~*C. The Board of Pharmacy may issue a limited use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles*~~

~~*for the administration of prescribed controlled substances to a doctor of medicine, osteopathic medicine, or podiatry, a nurse practitioner, or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit.*~~

~~***§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.***~~

~~*A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.*~~

~~*B. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.*~~

~~*C. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision A 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.*~~

~~*D. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.*~~

~~*Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.*~~

Agenda Item: 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

Included in your agenda package:

- Guidance document 110-35 with suggested amendments to change "nurse practitioner" to "advanced practice registered nurse" and address DEA's final rule regarding transferring electronic prescriptions.

Action needed:

- Motion to amend guidance document 110-35.

VIRGINIA BOARD OF PHARMACY

GUIDANCE ON
VIRGINIA PRESCRIPTION REQUIREMENTS

Written Prescriptions:

- Written prescriptions shall include the patient's first and last name except for expedited partner therapy pursuant to Virginia Code § 54.1-3303. Patient address may be entered on the prescription either by the prescriber or agent, or recorded by the pharmacist on the prescription or in an electronic prescription dispensing record system.

- For prescriptions which provide expedited partner therapy pursuant to Virginia Code § 54.1-3303, "Expedited Partner Therapy" or "EPT" may be entered for the patient's name and address if otherwise unknown. *See* Va. Code § 54.1-3408.01(A).

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

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

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

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

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

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

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

- While Virginia law does not specifically require that quantity be included on a prescription, written prescriptions must include some direction related to quantity to be dispensed, or authorized duration of the order by which the pharmacist can calculate the authorized quantity using directions for use and duration. Federal regulations require that quantity be indicated on prescriptions for Schedule II-V controlled substances.

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

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

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

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

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

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

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

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

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

Oral Prescriptions:

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

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

Faxed Prescriptions:

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

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

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

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

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

Electronically transmitted prescriptions:

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

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

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

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

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

- Please refer to the federal regulations for additional guidance.

Transfer of electronic prescriptions for Schedules II-V Controlled Substances between pharmacies for initial filling:

- Effective August 28, 2023, § 1306.08 of the Code of Federal Regulations was amended to allow the transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing if allowable under existing State or other applicable law.

- The Board interprets Virginia Code § 54.1-3408.02 and 18VAC110-20-360 to condone the transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing when performed in compliance with federal requirements.

- To further understand federal requirements, refer to DEA's *Discussion of Public Comments* in the Federal Register at https://www.federalregister.gov/documents/2023/07/27/2023-15847/transfer-of-electronic-prescriptions-for-schedules-ii-v-controlled-substances-between-pharmacies-for. Of note, DEA addresses comments on the requirement for patient consent, restriction for initial dispensing only, requirement to transfer as electronic data file, the National Council for Prescription Drug Programs' (NCPDP) new SCRIPT Standard Version 2017071, restriction of transfer for one-time basis only, and transfer between two licensed pharmacists.

- The Board is aware that current challenges with technology may not support operationalizing this allowance. Pharmacists are encouraged to consult with their software vendors as appropriate.

Agenda Item: Amendment to guidance document 110-36 to include additional FAQs related to revisions of USP Chapters <795> and <797>

Included in your agenda package:

- Excerpt from June 2008 Board Minutes regarding flavoring;
- Excerpt from USP FAQs regarding flavoring;
- Guidance document 110-36 with suggested amendments.

Staff note: Changes voted on in this guidance document at the June meeting which are not yet effective are shown in blue underline. New proposed changes are shown in black underline.

Action needed:

- Motion to amend guidance document 110-36.

- Flavoring of Medications

Staff informed the Board that it received frequent calls asking if the addition of flavoring agents to prescription medications constituted "compounding", if the pharmacist would need permission from the prescriber to flavor, and if a pharmacist could flavor a prescription product dispensed by another pharmacy. There was discussion that while this most likely did meet the strict definition of compounding, it was fairly common practice and in most cases in the best interest of the patient by promoting compliance in taking the medication. There were no motions in this matter.

- Guidance Document 110-36, compliance with USP 797

Staff informed the Board that it had already received two requests for extensions from complying with the physical standards of USP 797, and asked how it wanted to handle such requests. Mr. Ison provided a brief summary of the changes to this chapter from the 2004 version, that were published in December 2007, and which took effect June 1, 2008 The current guidance document requires compliance by June 30, 2008. The Board has already given pharmacies a one-year extension to be in compliance, and it considers that pharmacies should have at least complied with the 2004 requirements, if not the 2007 which primarily relate to changes with respect to chemotherapy drug storage in the clean room. Discussion centered on reviewing requests for extensions on a case by case basis, or providing for a blanket one-time extension. It was determined that the blanket extension in the guidance document would be the best way to go, because it would be equitable, and also more efficient. Different deadlines were discussed, but it was considered that four months should be sufficient for any pharmacy to comply as they have been aware of this since at least 2004. It was also requested that the guidance document provide a statement that continued non-compliance would be subject to disciplinary action by the Board. The Board discussed assessing a monetary penalty as probably the appropriate action for this violation, and questioned how much could be assessed. Mr. Casway advised that the Board could assess a monetary penalty not to exceed $5000 per violation, but could impose less. There was discussion as to what constituted a single violation. The violation is the act of compounding a sterile preparation under conditions that do not meet standards, so conceivably each preparation prepared could constitute a separate violation.

17. Who can be the designated person(s)?

The designated person is one or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of compounded nonsterile preparations (CNSPs). Facilities must determine whether they have one or more designated person, select the designated person, and determine how to allocate responsibility if there is more than one designated person.

18. Does the chapter apply for repackaging of a conventionally manufactured product?

No, repackaging of conventionally manufactured drug products is not required to meet the standards in this chapter (see <1178> *Good Repackaging Practices* for recommendations).

19. Please clarify the phrase, "variability from the intended strength of correct ingredients (e.g., ±10% of the labeled strength)".

There may be variability from the labeled strength of a CNSP. The acceptable range is listed in the applicable monograph for official articles. The acceptable range is ±10% of the labeled strength for nonofficial articles (i.e., 90-110%).

20. This section defines altering a drug or bulk drug substance as nonsterile compounding. It is unclear whether flavoring a manufactured liquid would fall under this category or whether the preparation of premeasured kits, such as FIRST Magic Mouthwash and FIRST Omeprazole, would be required to meet the standards of this chapter.

Flavoring a manufactured product is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act. Compounding standards apply to the assembly of premeasured kits.

21. When repackaging capsules into unit dose containers using a robotic system, is the BUD limited to 180 days?

Repackaging nonsterile conventionally manufactured drug products is outside the scope of <795> so the BUD limits in *Table 4* do not apply. See <1178> *Good Repackaging Practices* for recommendations.

Personal Hygiene and Garbing

22. What garb is required for nonsterile compounding?

Gloves must be worn for all compounding activities. Other garb (e.g., shoe covers, head or hair covers, facial hair covers, face masks, and gowns) should be worn as required by the facility's standard operating procedures (SOPs). Garb is recommended for the protection of personnel and to minimize the risk of CNSP contamination. The garb must be appropriate for the type of compounding performed. The garbing requirements and frequency of changing the garb must be determined by the facility and documented in the facility's SOPs.

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

Virginia Code § 54.1-3410.2 and 18VAC110-20-321 require pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection. USP Chapter 800 describes practice and quality standards for handling hazardous drugs to promote patient safety, worker safety, and environmental protection. While full compliance with Chapter 800 is encouraged, only those requirements related to compounding are legally required.

USP often updates and adds to their Frequently Asked Questions site for the general chapters. Please visit the following links to the USP website for frequently asked questions on the listed chapters:

Chapter 795: https://go.usp.org/USP_GC_795_FAQs
Chapter 797: https://go.usp.org/USP_GC_797_FAQs
Chapter 800: https://go.usp.org/General-Chapter-800-FAQ
Chapter 825: https://go.usp.org/frequently-asked-questions/radiopharmaceuticals

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

   A subscription to the current version of USP-NF Chapters may be purchased at https://store.usp.org/usp-nf-online/category/USP-3110.

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

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, <659> Packaging and Storage Requirements, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. Should compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test, gloved fingertip test, and garbing test at each pharmacy where they will prepare CSPs?

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

4. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

5. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

~~No.~~ Virginia Code § 54.1-3410.2 indicates pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian. Virginia Code § 54.1-3301 indicates a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a seven-day supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian.

Of note, Virginia Code § 54.1-3410.2 does authorize pharmacists to provide compounded drugs to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision. The compounded drug must be labeled with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

6. May a prescriber or patient obtain a patient-specific compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at DHP's License Lookup site by searching the business name and choosing "nonresident pharmacy" as the occupation.

7. May a pharmacy or prescriber obtain a compounded sterile product from an out-of-state outsourcing facility that is not registered by the Virginia Board of Pharmacy as a nonresident outsourcing pharmacy?

No, only nonresident outsourcing facilities registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at DHP's License Lookup site by searching the business name and choosing "nonresident outsourcing pharmacy" as the occupation.

8. Is flavoring considered compounding?

Yes. Per USP FAQs for Chapter <795>, "[f]lavoring a manufactured product is compounding and must be conducted under compounding standards in accordance with the exemptions for compounding in the Federal Food, Drug, and Cosmetic Act, otherwise the drug product would be deemed adulterated under the Act. Compounding standards apply to the assembly of premeasured kits."

9. If a pharmacy has one pharmacist (A) that supervises compounding and verifies the compounding of the product but has a separate pharmacist (B) who does NOT supervise compounding and is only responsible for verifying the prescription/order data entry and dispensing of the previously verified compounded drug, is that second pharmacist (B) required to do media-fill testing, gloved fingertip testing, and evaluation?

Per USP Chapter <797>, Table 2, pharmacists who do not have oversight of compounding but only perform final verification of the dispensed drug whose compounding has already been verified (pharmacist B) need only perform initial training and competency as defined per the facility standard operating procedures. Garbing and media-fill competency are not required for pharmacist B.

10. May a pharmacist use camera technology to verify accuracy of a compounded drug product?

USP does not have guidance for when a pharmacist may use a camera to verify accuracy of a compounded product. However, the Board's longstanding position is that audio-visual technology may be used by the pharmacist physically present in the pharmacy to directly supervise compounding.

11. When will the Board begin enforcing USP's revised Chapters <795> and <797> that become effective November 1, 2023?

Virginia Code § 54.1-3410.2 states that "pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding." Therefore, pharmacies must comply with revised USP Chapters <795> and <797> upon the effective date of those revisions, which is November 1, 2023.

Agenda Topic: Amend Guidance Document 110-44, *Protocol for the Prescribing and Dispensing of Naloxone* and *Statewide Protocol for Naloxone*

Staff Note: FDA recently approved two formulations of nalmefene, an opioid antagonist.

1. OPVEE nasal spray is an opioid antagonist indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression.
2. Nalmefene hydrochloride injection is indicated for the complete or partial reversal of opioid drug effects, including respiratory depression, induced by either natural or synthetic opioids. Nalmefene hydrochloride injection is indicated in the management of known or suspected opioid overdose.

Action Needed:

- Motion to amend Guidance Document 110-44 and the Statewide Protocol for Naloxone as presented or amended.

Virginia Board of Pharmacy

Naloxone or Other Opioid Antagonist Protocols

Virginia Code § 54.1-3408(X) and (Y) authorize certain persons to dispense prescription-only naloxone or other opioid antagonists used for overdose reversal pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone or other opioid antagonists pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements. **Note: This protocol does not apply to over-the-counter formulations of naloxone or other opioid antagonists that are available for anyone to obtain without a prescription.**

a. Protocol for the Prescribing and Dispensing of Naloxone or Other Opioid Antagonist by Persons Listed in Virginia Code § 54.1-3408(X)

a. Authorized Dispensers

The following individuals may dispense naloxone or other opioid antagonist pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of § 54.1-3408:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1
- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated by the Director of the Department of Corrections or designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of the Department of Juvenile Justice designated as probation and parole officers or as juvenile correctional officers,
- Employees of regional jails,
- School nurses,
- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and
- Other school board employees or individuals contracted by a school board to provide school health services,
- Firefighters.

b. Required Order

i. Prior to dispensing naloxone or other opioid antagonist, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive ~~naloxone~~ the drug or a standing order issued

by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense ~~naloxone~~ the drug. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in § 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.

ii. If the naloxone or other opioid antagonist is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:
    1. Name of entity or group of entities authorized to dispense ~~naloxone~~ the drug pursuant to standing order;
    2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
    3. Prescriber's signature;
    4. Date of issuance; and
    5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration. Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.	Naloxone 2 mg or 5mg #1 twin pack Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg or 8mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	~~Naloxone~~ Nalmefene nasal spray ~~8mg~~, #1 twin pack Directions: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to ~~3~~5 minutes until emergency medical assistance arrives.

c. Required Labeling and Recordkeeping

i. The dispenser shall affix a label to the naloxone or nalmefene container that bears the name and strength of the dispensed ~~naloxone~~drug, directions as indicated on the oral, written, or standing order, name of

prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of ~~naloxone~~ drug dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.

iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

d. Instruction

While not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone or nalmefene, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. Such instruction may be accomplished by providing the recipient with the current REVIVE! Pharmacy dispensing brochure available on the Department of Behavioral Health and Developmental Services website or by clicking on the link. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

b. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in Virginia Code § 54.1-3408(Y)

a. Authorized Dispensers

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;
- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.
- **Note: §54.1-3408 (Y) does not currently authorize the dispensing of opioid antagonists other than naloxone.**

b. Training

- While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.
- Those persons acting on behalf of such organization and who intend to dispense injectable naloxone formulation with a hypodermic needle or syringe, must first complete training developed by and be authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:
   1. Name of organization authorized to dispense naloxone pursuant to standing order;
   2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
   3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
   4. Prescriber's signature;
   5. Date of issuance; and
   6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	Injection*	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.	Naloxone 2 mg or 5mg, #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Naloxone Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration. Dispenser must dispense 2 single-use 1ml vials, 2	Naloxone nasal spray 8mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional dose in other nostril using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory

Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.		emergency medical assistance arrives.	(3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.	depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

**** Only those DBHDS-approved trainers who have successfully completed DBHDS-approved training on proper drug administration with, and disposal of, hypodermic needles and syringes, who are otherwise authorized to dispense injectable naloxone through a standing order issued in compliance with this protocol, and whose organization has first obtained a controlled substances registration from the Board of Pharmacy may dispense injectable naloxone with hypodermic needles and syringes.***

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. Required Labeling, Recordkeeping, and Storage

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The standing order must be maintained for two years from the last date of dispensing.

iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).

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

f. Instruction

i. While it is not required by law, the dispenser may provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. Such instruction may be accomplished by providing the recipient with the current REVIVE! Pharmacy dispensing brochure available on the Department of Behavioral Health and Developmental Services website or the link above. If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone or Other Opioid Antagonists to Entities Authorized to Possess, Administer, and Dispense ~~Naloxone~~ Such Drugs

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone or nalmefene via invoice to:

i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1; or

ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program~~; or~~.

b. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:

iii. Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone or nalmefene first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

a. REVIVE! Pharmacy dispensing brochure
b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials
e. Dispensers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

VIRGINIA BOARD OF PHARMACY

Pharmacist Naloxone or Other Opioid Antagonist Statewide Protocol

Consistent with the naloxone manufacturer's instructions for use approved by the US Food and Drug Administration, a pharmacist may issue a prescription to initiate treatment with, dispense, or administer the following drugs and devices to persons 18 years of age or older:

- intranasal naloxone (nasal spray formulation or for administration by mucosal atomization device);
- intranasal nalmefene (nasal spray formulation);
- intramuscular naloxone, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone;
- naloxone auto-injector; or,
- any other opioid antagonist formulation approved by the FDA for overdose reversal, including such controlled paraphernalia, as defined in § 54.1-3466, as may be necessary to administer such naloxone.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering naloxone or any other opioid antagonist formulation approved by the FDA for overdose reversal under this protocol, the pharmacist shall be ~~knowledgable~~ knowledgeable of the manufacturer's instructions for use, paraphernalia necessary for administration, and how to properly counsel the patient on recognizing signs of a possible overdose and proper administration of the drug.

PATIENT INCLUSION CRITERIA

Patients eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual, 18 years of age or older, experiencing or at risk of experiencing an opioid-related overdose, e.g., patient has a history of prior overdose, substance misuse, a morphine milligram equivalency of 120MME/day, or is currently prescribed an opioid with a concomitant benzodiazepine present;
- A family member, friend, or other person, 18 years of age or older, in a position to assist an individual who is experiencing or at risk of experiencing an opioid-related overdose.

PATIENT EXCLUSION CRITERIA

Patients NOT eligible for naloxone or other opioid antagonist approved by the FDA for overdose reversal under this protocol:

- An individual less than 18 years of age;
- An individual receiving treatment of acute or chronic pain related to (i) cancer, (ii) sickle cell, (iii) a patient in hospice care, (iv) a patient in palliative care, (v) a patient enrolled in a clinical trial as authorized by state or federal law. Refer patient to primary care provider to determine if naloxone appropriate.

COUNSELING

The pharmacist shall ensure the patient or patient's agent is provided a copy of the REVIVE! Pharmacy dispensing brochure and counsel the patient or the patient's agent on how to properly identify signs of a possible overdose and how to properly administer the naloxone or other opioid antagonist for overdose reversal.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Item: Amendment of Guidance Document 110-46

Included in your agenda package are:

- Guidance Document 110-46 with changes in redline for clean up and to include drone delivery of drugs.

- Clean version of changes to Guidance Document 110-46.

Action needed:

- Motion to amend Guidance Document 110-46 as presented.

Board of Pharmacy

Delivery of Dispensed Drugs

Pursuant to § 314.170 of the Code of Federal Regulations, "All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act." Virginia Code § 54.1.3457 ~~of the Code of Virginia~~ prohibits the delivery of any drug that is adulterated and Virginia Code § 54.1.3461 describes an adulterated drug as one that "purports to be or is represented as a drug the name of which is recognized in an official compendium." Thus, there is a legal expectation that all pharmacies, both resident and nonresident, must deliver drugs in a manner that ensures appropriate temperature ranges or else they may be in violation of possibly delivering an adulterated drug. ~~–~~In addition to guidance provided by the United States Pharmacopeia on temperature storage requirements and excursions, the Board provides the following ~~guidelines~~guidance.~~:~~

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

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

The Board interprets the phrase "delivery service" as used in Virginia Code § 54.1-3420.2 to include drone delivery of prescription drugs.

References:

Va. Code § 54.1-3420.2

~~**Code of Virginia:**~~

~~*§ 54.1-3420.2. Delivery of prescription drug order.*~~

~~*A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly,*~~

~~*to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:*~~

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

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

Board of Pharmacy

Delivery of Dispensed Drugs

Pursuant to § 314.170 of the Code of Federal Regulations, "All drugs, including those the Food and Drug Administration approves under section 505 of the act and this part, are subject to the adulteration and misbranding provisions in sections 501, 502, and 503 of the act." Virginia Code § 54.1.3457 prohibits the delivery of any drug that is adulterated and Virginia Code § 54.1.3461 describes an adulterated drug as one that "purports to be or is represented as a drug the name of which is recognized in an official compendium." Thus, there is a legal expectation that all pharmacies, both resident and nonresident, must deliver drugs in a manner that ensures appropriate temperature ranges or else they may be in violation of possibly delivering an adulterated drug. In addition to guidance provided by the United States Pharmacopeia on temperature storage requirements and excursions, the Board provides the following guidance.

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

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

The Board interprets the phrase "delivery service" as used in Virginia Code § 54.1-3420.2 to include drone delivery of prescription drugs.

References:

Va. Code § 54.1-3420.2

Agenda Item: Adopt statewide protocols for COVID-19, Strep, UTI, Influenza

Included in your agenda package are:

- SB948 as passed by the General Assembly and signed by the Governor (identical to HB2274); and

- Draft protocols developed by pursuant to legislative directive for the following diseases and conditions:

    - COVID-19
    - Group A streptococcal
    - Influenza
    - Urinary tract infection

Action needed:

- Motion to approve protocols for pharmacists to initiate treatment for COVID-19, Group A streptococcal, influenza, and urinary tract infection.

CHAPTER 172

An Act to amend and reenact § 54.1-3303.1 of the Code of Virginia, relating to pharmacist scope of practice; initiation of treatment for certain diseases and conditions.

[S 948]

Approved March 22, 2023

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3303.1 of the Code of Virginia is amended and reenacted as follows:

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

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

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

2. Epinephrine;

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

4. Prenatal vitamins for which a prescription is required;

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

6. Drugs as defined in § 54.1-3401, devices as defined in § 54.1-3401, controlled paraphernalia as defined in § 54.1-3466, and other supplies and equipment available over-the-counter, covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug, device, controlled paraphernalia, or other supplies or equipment;

7. Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19;

8. Tuberculin purified protein derivative for tuberculosis testing;

9. Controlled substances for the prevention of human immunodeficiency virus, including controlled substances prescribed for pre-exposure and post-exposure prophylaxis pursuant to guidelines and recommendations of the Centers for Disease Control and Prevention;

10. Nicotine replacement and other tobacco cessation therapies, including controlled substances as defined in the Drug Control Act (§ 54.1-3400 et seq.), together with providing appropriate patient counseling; ~~and~~

11. *Controlled substances or devices for the initiation of treatment of the following diseases or conditions for which clinical decision making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988: group A Streptococcus bacteria infection, influenza virus infection, COVID-19 virus infection, and urinary tract infection; and*

12. Tests for COVID-19 and other coronaviruses.

B. Notwithstanding the provisions of § 54.1-3303, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons three years of age or older in accordance with a statewide protocol as set forth in regulations of the Board:

1. (Contingent Effective Date) Vaccines included on the Immunization Schedule published by the Centers for Disease Control and Prevention and vaccines for COVID-19; and

2. (Contingent Effective Date) Tests for COVID-19 and other coronaviruses.

C. A pharmacist who initiates treatment with or dispenses or administers a drug or device pursuant to this section shall notify the patient's primary health care provider that the pharmacist has initiated treatment with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. No pharmacist shall limit the ability of notification to be sent to the patient's primary care provider by requiring use of electronic mail that is secure or compliant with the federal Health Insurance Portability and Accountability Act (42 U.S.C. § 1320d et seq.). If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If

the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

D. A pharmacist who administers a vaccination pursuant to subdivisions A 7 and B 1 shall report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

E. A pharmacist who initiates treatment with, dispenses, or administers drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section shall obtain a history from the patient, including questioning the patient for any known allergies, adverse reactions, contraindications, or health diagnoses or conditions that would be adverse to the initiation of treatment, dispensing, or administration.

F. A pharmacist may initiate treatment with, dispense, or administer drugs, devices, controlled paraphernalia, and other supplies and equipment pursuant to this section through telemedicine services, as defined in § 38.2-3418.16, in compliance with all requirements of § 54.1-3303 and consistent with the applicable standard of care.

G. A pharmacist who administers a vaccination to a minor pursuant to subdivision B 1 shall provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

2. That the Board of Pharmacy shall adopt a statewide protocol for the initiation of treatment with and dispensing and administering of drugs and devices by pharmacists in accordance with § 54.1-3303.1 of the Code of Virginia, as amended by this act, by November 1, 2023. Such protocol shall be developed by a work group consisting of representatives from the Board of Pharmacy, the Board of Medicine, and the Department of Health. The work group shall have an equal number of members who are representatives of the Board of Pharmacy and the Board of Medicine.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act to be effective within 280 days of its enactment. Such regulations shall include provisions for ensuring that physical settings in which treatment is provided pursuant to this act shall be in compliance with the federal Health Insurance Portability and Accountability Act, 42 U.S.C. § 1302d et seq., as amended.

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for COVID-19 Virus Infection

Pursuant to the United States Food and Drug Administration's (FDA) Emergency Use Authorization (EUA) for the emergency use of PAXLOVID, a pharmacist may prescribe Paxlovid for the treatment of adults and pediatric patients (12 years of age and older weighing at least 40 kg) with mild-to-moderate coronavirus disease 2019 (COVID-19) who are at high risk for progression to severe COVID-19 under the following conditions:

- Sufficient information is available, such as through access to health records less than 12 months old or consultation with a health care provider in an established provider-patient relationship with the individual patient, to assess renal and hepatic function; and

- Sufficient information is available, such as through access to health records, patient reporting of medical history, or consultation with a health care provider in an established provider-patient relationship with the individual patient, to obtain a comprehensive list of medications (prescribed and non-prescribed) that the patient is taking to assess for potential drug interaction.

PATIENT INCLUSION CRITERIA AND TREATMENT

Pharmacists shall complete the Paxlovid Patient Assessment Form in Appendix A to assist in determining patient eligibility and appropriate treatment.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for COVID-19 pursuant to this Protocol and shall document the results and dispensing of Paxlovid in the prescription record, including documentation of the following:

- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be

stored (and may be off-site) for longer periods to comply with other state and federal laws.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

PAXLOVID PATIENT ASSESSMENT FORM FOR PHARMACIST

PATIENT INFORMATION

Patient Name:	Date:
Address:	Date of Birth:
Tel.:	Email:

PATIENT ELIGIBILITY SCREENING

□ Yes □ No	Patient meets limitations of authorized use for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.
□ Yes □ No	Patient informed to AVOID going into the pharmacy for pick-up (use Drive-Thru, Curbside, Delivery).
□ Yes □ No	Date of Positive Test (Home Test Accepted) and Symptom Onset is within 5 days. Record date of positive test:_____
□ Yes □ No	Renal Function within 12 months is known. Record eGFR:_____
□ Yes □ No	Hepatic Function normal (must be within 12 months, Child-Pugh Class C-Use NOT recommended).
□ Yes □ No	Full Medication List Obtained (including OTCs/herbal supplements)
□ Yes □ No	Reviewed for potential drug interactions and NO dose adjustments/medication modifications are needed.
□ Yes □ No	Modifications to other medications are needed. Pharmacist will not prescribe and will refer for evaluation by a physician, advanced nurse practitioner, or physician assistant.
□ Yes □ No	Paxlovid FDA EUA Fact Sheet given to patient at time of pharmacist prescribing.

THERAPY OPTIONS

❑ Paxlovid Tablets (Standard Dose, eGFR ≥60mL/min):	Dispense: 30 tablets No refills	Sig: Take 2 pink (Nirmatrelvir 150 mg) tablets and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days.
❑ Paxlovid Tablets (Renal Dose, eGFR ≥30 to <60mL/min):	Dispense: 20 tablets No refills	Take 1 pink (Nirmatrelvir 150 mg) tablet and 1 white (Ritonavir 100 mg) tablet by mouth together twice daily for five days.
❑ Paxlovid NOT prescribed. Referred for evaluation by a physician, advanced nurse practitioner, or physician assistant.		

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name:	License Number:

Signature Date

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Acute Group A Streptococcus Bacteria Infection

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for acute Group A streptococcal (GAS) pharyngitis and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute GAS pharyngitis infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Infectious Disease Society of America (IDSA) and the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute GAS pharyngitis. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat acute GAS pharyngitis infection shall treat patients according to current IDSA and CDC guidelines.

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and,
- Reported symptom onset < 96 hours before time of presentation.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced

glomerulonephritis;

- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- A patient who has taken antibiotics for sore throat or upper respiratory infection in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
    - Muffled voice;
    - Drooling;
    - Stridor;
    - Respiratory distress;
    - "Sniffing" or "tripod" positions;
    - Fever and rigors;
    - Severe unilateral sore throat;
    - Bulging of the pharyngeal wall/floor or soft palate;
    - Trismus;
    - Crepitus;
    - Stiff neck; or
    - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's acute GAS pharyngitis status.

- If positive, the pharmacist may proceed to consideration for immediate antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver pursuant to the Counseling section of this Protocol or refer the patient, if clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Mild allergic reactions to penicillin (amoxicillin)
- Mild allergic reactions to cephalosporins (cephalexin)
- Severe allergic reactions to penicillin (amoxicillin and cephalexin)
- Allergic reactions to macrolides (azithromycin and clarithromycin)
- Allergic reactions to clindamycin
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

DRUG INCLUSION CRITERIA

The pharmacist may initiate one the following medication regimens based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

Selection of antibiotic regimen will follow the ordered preference listed below. A lower-ranked regimen will only be prescribed if the patient or pharmacy record indicates a drug allergy or other contraindication to a higher-ranked regimen, or if the drug is not commercially available or appears on the FDA drug shortages list. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction.

If the pharmacist has a recent patient creatinine level and current weight, the pharmacist may adjust the medication dose per the manufacturer package insert for patients with CrCl < 30.

A. First-line treatment
    a. Amoxicillin
        i. Contraindication: Penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days, or

b. Penicillin
    i. Contraindication: Penicillin allergy
    ii. Dosing
        1. Penicillin V, oral – 500mg PO twice daily x 10 days
        2. Penicillin G benzathine – 1.2million units IM, single dose, to be administered by the pharmacist.

B. Second-line treatment
    a. Cephalexin
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 500 mg PO twice daily x 10 days
    b. Cefadroxil
        i. Contraindications
            1. Cephalosporin allergy
            2. Severe penicillin allergy
        ii. Dosing: 1g PO daily x 10 days

C. Third-line treatment *(Note: Potential resistance exists for both clindamycin and azithromycin. Clindamycin is the preferred third-line treatment.)*
    a. Clindamycin
        i. Contraindication: Clindamycin allergy
        ii. Dosing: 300 mg PO three times daily x 10 days
    b. Azithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 500 mg PO once daily x 5 days

D. Fourth-line treatment
    a. Clarithromycin
        i. Contraindication: Macrolide allergy
        ii. Dosing: 250 mg PO twice daily x 10 days

E. The pharmacist may recommend the following adjunctive therapy for treatment of moderate to severe symptoms or control of high fever associated with acute GAS pharyngitis, unless contraindicated:
    a. Acetaminophen PO according to OTC dosing recommendations; and
    b. Ibuprofen PO according to OTC dosing recommendations.

RECORDKEEPING

In any case where amoxicillin is not the selected regimen, the pharmacist shall document the rationale for selecting the antibiotic dispensed. Documentation may include medication sensitivity, cost, and shared clinical decision-making.

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for acute GAS pharyngitis pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;

- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- If CLIA-waived test results are negative, counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, hygiene/infection control measures, drink plenty of fluids, treat symptoms as needed, etc.) or refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.
- If CLIA-waived test results are positive, counsel on CDC guidelines that a patient with a confirmed diagnosis of acute GAS pharyngitis should stay home from work or school until they are afebrile for at least 24 hours after starting antibiotic therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care such as from a primary care provider or urgent/emergent treatment facility if symptoms worsen or do not improve within 48 hours.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Acute Group A Streptococcal Pharyngitis Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18 years of age or older?
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Do you have a history of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis?
□ Yes □ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxycillin, cephalexin, clarithromycin, or clindamycin?
□ Yes □ No Do you have a pending test for your symptoms (COVID, strep, flu)?
□ Yes □ No Have you had a tonsillectomy in the previous 30 days?
□ Yes □ No Have you taken antibiotics in the last 30 days? If yes, why?
When did your symptoms start? □ More than four days ago. □ Fewer than four days ago
Do you have any of the following symptoms (check all that apply)? □ Fever □ Sore throat □ Pain swallowing □ Swollen/tender cervical lymph nodes □ Inflamed or swollen tonsils or uvula □ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
□ Yes □ No Acute altered mental status	Yes
Severe Symptoms of Respiratory Distress	Muffled voice; Drooling; Stridor; Respiratory distress; "Sniffing" or "tripod" positions; Fever and rigors; Severe unilateral sore throat; Bulging of the pharyngeal wall/floor or soft palate; Trismus; Crepitus; Stiff neck; or History of penetrating trauma to oropharynx.
Overt Viral Features	Conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with acute GAS pharyngitis (sore throat, pain on swallowing, fever, swollen or tender cervical lymph nodes, or inflamed or swollen tonsils or uvula); and
- Reported symptom onset < 96 hours before time of presentation.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);

- History of rheumatic fever, rheumatic heart disease, scarlet fever, or acute GAS pharyngitis induced glomerulonephritis;
- Presenting with overt viral features, such as conjunctivitis, rhinorrhea, cough, oral ulcers, and/or hoarseness;
- Known hypersensitivity to all antibiotic therapies available for treatment in this Protocol;
- A patient receiving hospice or home health services;
- History of tonsillectomy within the past 30 days;
- Patient has taken antibiotics for sore throat or upper respiratory infection in the last 30 days.
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Severe symptoms of respiratory distress, including:
    - Muffled voice;
    - Drooling;
    - Stridor;
    - Respiratory distress;
    - "Sniffing" or "tripod" positions;
    - Fever and rigors;
    - Severe unilateral sore throat;
    - Bulging of the pharyngeal wall/floor or soft palate;
    - Trismus;
    - Crepitus;
    - Stiff neck; or
    - History of penetrating trauma to oropharynx; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

□ Positive for acute GAS pharyngitis (continue)

□ Negative for acute GAS pharyngitis (refer to PCP as clinically appropriate + symptomatic treatment)

PATIENT ACTION

□ Yes □ No Acute GAS pharyngitis Diagnosed

□ Yes □ No Antibiotic Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options (Refer to Drug Inclusions section of Protocol for drug order preference)		
Acute GAS Pharyngitis Adult **Treatment**		
Documentation of Rationale for Treatment Selection (if required):		
❑ Oral Amoxicillin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days; or
❑ Oral Penicillin V	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ IM Penicillin G benzathine	Dispense: ❑ 1.2million units IM, single dose No refills	To be administered by the pharmacist
❑ Oral Cephalexin	Dispense: ❑ 500mg #20 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 10 days
❑ Oral Cefadroxil	Dispense: ❑ 1g #10 No refills	Sig: Take 1 (one) (1g) by mouth daily for 10 days
❑ Oral Azithromycin	Dispense: ❑ 500mg #5 No refills	Sig: Take 1 (one) (500mg) by mouth daily for 5 days
❑ Oral Clindamycin	Dispense: ❑ 300mg #30 No refills	Sig: Take 1 (one) (300mg) by mouth three times daily for 10 days
❑ Oral Clarithromycin	Dispense: ❑ 250mg #20 No refills	Sig: Take 1 (one) (250mg) by mouth twice daily for 10 days

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number

SIGNATURE

DATE

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Influenza

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for Influenza and, when diagnostically confirmed, initiate the dispensing of an antiviral to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antiviral therapy is readily available to treat acute influenza infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

A pharmacist shall exercise clinical judgement in assessing patients pursuant to this Protocol outside of the standard influenza season (approximately October 1 – April 30). Resource: https://www.cdc.gov/flu/weekly/

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antiviral therapy under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the Centers for Disease Control and Prevention (CDC)'s current guidelines for the treatment of acute influenza. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antiviral therapy to treat acute influenza infection shall treat patients according to current CDC guidelines.

Any patient who presents to the pharmacy and meets **all** the following criteria:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and,
- Reported symptom onset < 48 hours before time of presentation.

PATIENT EXCLUSION CRITERIA

Any individual who meets **any** of the following criteria:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including

corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- A patient receiving hospice or home health services;
- A patient who has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:
- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential, pregnancy, or breastfeeding status

- Current Medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of flu-like signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's influenza status.

- If positive, the pharmacist may proceed to consideration for immediate antiviral therapy treatment.
- If negative, the pharmacist shall counsel the patient or caregiver on the risk of a false-negative test result and on appropriate self-care (stay home for at least 24 hours after fever subsides, drink plenty of fluids, treat symptoms as needed, and consider influenza immunization) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions.

DRUG INCLUSION CRITERIA

The pharmacist may immediately initiate antiviral therapy only in selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and screening.

A. Oral oseltamivir (Tamiflu)
    a. Contraindications
        i. Known hypersensitivity to oseltamivir or any component
        ii. Patients 18 years and older with CrCl < 10 ml/min. If the pharmacist is unable to obtain a current CrCl for a patient with a history of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.), then the patient should be excluded from receiving Tamiflu. For purposes of this Protocol, current CrCl means a lab value obtained within the past six months and documented by a physician's office, laboratory, or patient electronic health record, or reported by the patient and the pharmacist determines in their clinical judgment the patient report is accurate. The pharmacist shall document this information in the patient record.
    b. Dosing – all doses to be administered x 5 days
        i. Patients 18 years and older: 75 mg twice daily
        ii. Patients 18 years and older with renal impairment
            1. CrCl > 60 ml/min: no dosage adjustment necessary
            2. CrCl > 30 to 60 ml/min: 30mg twice daily
            3. CrCl > 10 to 30 ml/min: 30mg once daily

B. Oral baloxavir marboxil (Xofluza)
    a. Contraindications
        i. Known hypersensitivity to baloxavir or any component
        ii. Weight < 40 kg
    b. Dosing – all doses to be administered as a single dose
        i. Weight-based

1. 40 kg to < 80 kg: 40 mg
2. 80 kg and above: 80 mg

C. Inhaled zanamivir (Relenza Diskhaler)
   a. Contraindications
      i. Known hypersensitivity to zanamivir or any component
      ii. Underlying respiratory disease or asthma
   b. Dosing – all doses to be administered twice daily x 5 days
      i. 10 mg (two 5 mg inhalations)

If the patient qualifies for multiple therapies above, the pharmacist shall document the rationale for selecting the antiviral therapy dispensed. Documentation may include patient preference, cost, and shared clinical decision-making.

The pharmacy shall ensure that a pharmacist that has entered the Protocol shall monitor the patient for continuation or adjustment of therapy, including the following:

- As clinically appropriate, initiate telephone follow-up within 72 hours of dispensing to assess the clinical stability, onset of new symptoms, and medication adverse effects.
- If the patient is 65 years of age or older, telephone follow-up is mandatory within 72 hours of dispensing to assess the above patient status. If an initial follow-up does not result in direct patient contact, a second telephone follow-up attempt shall be made. Follow-up attempts must be documented by the pharmacist.
- Refer to a primary care provider or urgent/emergent treatment facility if any of the following are reported:
  - Significant deterioration in condition or new evidence of clinical instability;
  - Onset of symptoms inconsistent with influenza or indicative of serious complications of influenza; or
  - Medication adverse effects severe enough to warrant discontinuation.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for influenza pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antiviral therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment,

testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on the following:

- Influenza vaccination;
- Appropriate self-care, including symptom control, hygiene, and infection control measures;
- CDC guidelines that a patient with a confirmed diagnosis of influenza should stay home from work, school, or daycare until they are afebrile (100°F) for at least 24 hours without the use of a fever-reducing medication and at least 24 hours after starting antiviral therapy;
- Medication counseling; and
- Signs and symptoms that warrant emergency medical care.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Influenza Patient Form

PATIENT INFORMATION

Name		Date of Birth	Age
Address		Phone	Email
City	State	Zip	County
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18 years of age or older?
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Do you require supplemental oxygen therapy?
□ Yes □ No Have you taken an antiviral in the last 30 days?
□ Yes □ No Do you have a pending test for your flu-like symptoms (COVID, strep, flu)?
□ Yes □ No Have you tested positive for influenza in the previous four weeks?
When did your flu-like symptoms start? □ More than two days ago. □ 2 days ago, yesterday, or today.
Do you have any of the following symptoms (check all that apply)? □ Fever □ Nasal congestion □ Muscle/body aches □ Cough □ Sore Throat □ Other:
Do you have any of the following? □ History of allergic reactions to influenza treatment □ History of physiologic side effects from any previous influenza treatment
Have you received FluMist or a generic equivalent within the past two weeks? □ Yes □ No

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (single criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria)
□ Yes □ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Age 18 years or older and able to give informed consent;
- Complaint of any sign or symptom consistent with influenza (fever, myalgia, headache, malaise, nonproductive cough, sore throat, rhinitis); and
- Reported symptom onset < 48 hours before time of presentation.

Refer to PCP and exclude from testing if:

- Under 18 years old;
- Pregnant or breastfeeding;
- Immunocompromised state (hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than two (2) weeks, HIV/AIDS);
- A positive influenza test within the previous four weeks;
- Any condition requiring supplemental oxygen therapy;
- Known hypersensitivity to all antiviral therapies for influenza or to any common component of the products;
- Administration of FluMist or generic equivalent within the previous two weeks;
- Patient is receiving hospice or home health services;
  Patient has taken an antiviral in the last 30 days;
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms; or
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or

- Temperature > 100.4 degrees Fahrenheit; or

- Any one of the following criteria:
  - Acute altered mental status;
  - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
  - Pulse >125 beats/min;
  - Respiratory rate >30 breaths/min;
  - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
  - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit.

CLIA-WAIVED POC TEST RESULT

□ Positive for influenza (continue)

□ Negative for influenza (refer to PCP + symptomatic treatment)

PATIENT ACTION

□ Yes □ No Influenza Diagnosed

□ Yes □ No Antiviral Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options		
Influenza Adult **Treatment**		
❑ Oral Oseltamivir (Tamiflu)	Dispense: ❑ 75mg #10; No refills ❑ Renal impairment CrCl > 30 to 60 ml/min: 30mg twice daily CrCl > 10 to 30 ml/min: 30mg once daily	Sig: Take 1 (one) (75mg) by mouth twice daily for 5 days
❑ Inhaled Zanamivir (Relenza Diskhaler)	Dispense: ❑ 1 inhaler No refills	2 inhalations by mouth twice daily for 5 days
❑ Oral Baloxavir Marboxil (Xofluza)	Dispense: ❑ 40mg x 1 ❑ 80mg x1 No refills	Take 1 tablet by mouth now

PHARMACIST PERFORMING ASSESSMENT AND/OR INITIATING TREATMENT

Printed Name	License Number

SIGNATURE DATE

VIRGINIA BOARD OF PHARMACY

Pharmacist Protocol for Testing and Initiating Treatment for Suspected Acute Uncomplicated Lower Urinary Tract Infection in Women

Pursuant to § 54.1-3303.1, a pharmacist may initiate CLIA-waived point-of-care testing for acute uncomplicated lower urinary tract infections (UTI) in women and, when diagnostically confirmed, initiate the dispensing of antibiotics to treat the infection for persons 18 years of age or older.

A pharmacist may not initiate assessment or testing unless sufficient antibiotics are readily available to treat acute UTI infection pursuant to this Protocol.

A pharmacist shall ensure that sufficient space is available in or around the pharmacy for safe and confidential assessment and treatment of patients under this Protocol.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating testing and dispensing antibiotic therapies under this Protocol, a pharmacist shall receive and document education and training in point-of-care CLIA-waived testing techniques appropriate to the test employed by the pharmacy. Additionally, the pharmacist shall maintain knowledge of the current Infectious Disease Society of America (IDSA)'s Guidelines for the treatment of Uncomplicated Cystitis and Pyelonephritis (UTI) and the American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for the Treatment of Urinary Tract Infections in Nonpregnant Women. Individuals who will be involved with patient specimen collection shall have documented hands-on training for specimen collection which includes infection control measures and destruction of biohazard materials.

In addition, a pharmacist shall ensure that a private restroom is available for collecting the patient specimen and appropriate procedures are in place to prevent contamination of the specimen and ensure proper cleaning of the restroom.

Informed consent shall include ensuring that the patient understands that this Protocol does not include treating yeast infection, detecting drugs of abuse, detecting pregnancy, produce a urine culture, etc.

PATIENT INCLUSION CRITERIA

Pharmacist(s) authorized to initiate the dispensing of antibiotic therapy to treat UTI shall treat patients according to current IDSA guidelines.

Pharmacists shall assess a patient based on the inclusion and exclusion criteria below based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

Any patient who presents to the pharmacy and meets **all** of the following criteria:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites or leukocytes via a CLIA-waived point-of-care detection test kit.

PATIENT EXCLUSION CRITERIA

Any patient who meets **any** of the following criteria:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;
- Inpatient or hospital stay within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO_2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
    - Flank pain; or
- A patient receiving hospice or home health services.

PROCESS FOR DETERMINING PATIENT ELIGIBILITY

Pharmacists shall assess a patient based on the inclusion and exclusion criteria based on the sample Pharmacist Assessment, Evaluation, and Prescribing Form in Appendix A.

PROCESS FOR HANDLING INELIGIBLE PATIENTS

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate. Patients who do not qualify for antibiotic dispensing following testing will be referred for additional evaluation when the pharmacist has high suspicion of a false-negative result, determines that the patient is at high risk for complications, or otherwise considers additional care to be in the best interest of the patient.

FURTHER CONDITIONS

The pharmacist shall assess the patient's relevant medical and social history:

- Patient demographics
- Medical history
- Relevant social history
- Current clinical comorbidities or disease states, including current mental status
- Current blood pressure, pulse, oxygen saturation, respiratory rate, temperature, and weight
- For females of child-bearing potential: pregnancy and breastfeeding status
- Current medications
- Medication allergies and hypersensitivities (pharmacist shall assess reported allergies for validity by reviewing the patient's pharmacy record, if applicable, and documenting the reported reaction)
- Onset and duration of signs and symptoms

If the patient qualifies for CLIA-waived testing under this Protocol, then the pharmacist shall perform a CLIA-waived point-of-care test to determine the patient's UTI status.

- If positive, the pharmacist may proceed to consideration for antibiotic therapy treatment.
- If negative, the pharmacist shall counsel the patient on the risk of a false-negative test result and on appropriate self-care (get plenty of rest, drink plenty of fluids, treat symptoms as needed, etc.) or shall refer the patient to a primary care provider or urgent/emergency treatment facility as clinically appropriate.

The pharmacist shall evaluate for contraindications and precautions:

- Allergic reaction, hypersensitivity, or contraindication to a treatment listed in this Protocol
- Renal insufficiency (nitrofurantoin monohydrate/macrocrystals and phenazopyridine)
- Previous UTI treatment failure
- History of chronic kidney disease (i.e., creatinine clearance (CrCl) < 60 ml/min, reduced kidney function, etc.)

DRUG INCLUSION CRITERIA

The pharmacist may initiate antibiotic therapy only in selected individuals based on relevant medical and social history and considerations of contraindications and precautions as identified through assessment and

screening.

Selection of an antibiotic regimen will follow the ordered preference from the list below. If the patient is currently receiving another antibiotic, the pharmacist shall not change the dosage of the patient's current medication. The pharmacist shall assess reported drug allergies for validity by reviewing the patient's pharmacy record and documenting the reported reaction. The choice between the antibiotic medication regimens should be individualized and based on patient allergy, contraindications/precautions, adherence history, local community resistance patterns, cost, and availability.

If prior authorization is needed for prescription insurance coverage, the Pharmacist may seek prior authorization or consider use of an alterative antibiotic therapy in the Protocol, if not contraindicated, and shall counsel the patient about cost options.

A. First-line Treatment
    a. Cephalexin
        i. Dosing: 500mg PO BID for 5 days
    b. Cefdanir
        i. Dosing: 300mg PO BID for 5 days
    c. Nitrofurantoin monohydrate/macrocrystals *(for Cephalexin allergy)*
        i. Dosing: 100 mg PO BID for 5 days
B. Alternative Treatment
    a. Fosfomycin trometamol
        i. Dosing: 3 gm PO single dose
C. This Protocol also authorizes pharmacists to initiate the dispensing of the following medication for the treatment of UTI related dysuria: Phenazopyridine 100-200 mg PO three times daily (TID) after meals for up to 2 days when used concomitantly with an antibiotic agent.

RECORDKEEPING

The pharmacist shall create a medication profile record for each patient who is assessed, tested, and/or treated for UTI pursuant to this Protocol and shall document the results and dispensing of any antibiotic therapy in the prescription record, including documentation of the following:

- Presenting signs and symptoms of the patient that warranted testing;
- The manufacturer, lot, expiration date, and result of the CLIA-waived point-of-care test used;
- Patient informed consent and counseling provided, including any patient referral;
- Rationale for the antibiotic therapy selected, if any, and/or OTC medications recommended for symptom management;
- Appropriate clinical follow-up, if any; and
- Notifications to other healthcare providers.

A patient record shall be maintained in compliance with 18VAC110-21-46. Each pharmacist dispensing medication pursuant to this Protocol shall record themselves as the prescriber. The record shall be maintained such that the required information is readily retrievable and shall be securely stored within the pharmacy or electronic pharmacy management system for a period of 6 years from the date of assessment, testing, and/or dispensing. Records may be required to be stored (and may be off-site) for longer periods to

comply with other state and federal laws.

COUNSELING

The pharmacist shall provide counseling to any patient being assessed, tested, and/or treated pursuant to this Protocol on all the following:

- Instructions on when to seek medical attention, including:
  - Symptoms that do not resolve or worsen after 48 hours;
  - Development of a fever (temperature ≥100.4 F, taken orally); or
  - Flank pain;
- Medication counseling;
- Counseling on the importance of adherence to an antibiotic regimen and completion of the entire course; and
- Counseling regarding prevention of UTIs, including signs and symptoms that warrant emergency medical care.

NOTIFICATION OF PRIMARY CARE PROVIDER

In accordance with § 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider, provided that the patient consents to such notification. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Each pharmacist that conducts a CLIA-waived point-of-care test shall provide the patient with a copy of the test result.

Acute Uncomplicated Lower Urinary Tract Infection, Women
Patient Form

PATIENT INFORMATION

Name		Date of Birth	□ Male □ Female
Email			Phone
Address			
City	State	Zip	
Primary Care Provider			
Medication Allergies			
Current Medications (Rx, OTC, herbal, topical, pain or allergy, supplements, vitamins, etc.):			
Treatments tried for current condition (if none, indicate N/A):			

PATIENT ELIGIBILITY

□ Yes □ No Are you 18-64 years of age?
□ Yes □ No Do you have a history of urinary tract infections? If yes, explain how many and over what time period:
□ Yes □ No Are you pregnant or breastfeeding?
□ Yes □ No Are you pre-menopausal?
□ Yes □ No Are you diabetic?
□ Yes □ No Have you ever been diagnosed with a weakened immune system (e.g., cancer, HIV/AIDS, transplant, long-term steroids, etc.)? If yes, explain:
□ Yes □ No Have you ever been diagnosed with c.diff (Clostridioides difficile, formerly Clostridium difficile)?
□ Yes □ No Do you have a history of renal transplant, dysfunction, urologic surgery (ureteral implantation, cystectomy, urinary diversion), or abnormal urinary tract function or structure (indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents)?
□ Yes □ No Do you have a history of allergic reactions to antibiotics, such as penicillin, amoxicillin, cephalexin, clarithromycin, or clindamycin?
□ Yes □ No Are you receiving hospice or home health services?
□ Yes □ No Do you have a pending test for your symptoms?

□ Yes □ No Have you been prescribed antibiotics in the previous 30 days?
□ Yes □ No Have you had an inpatient or hospital stay in the previous 30 days?
When did your symptoms start? □ More than seven days ago. □ Fewer than seven days ago
Do you have any of the following symptoms (check all that apply)? □ Pain when urinating □ Increased urinary frequency or urgency □ Vaginal discharge or itching □ Nausea/vomiting □ Flank pain □ Other:

– PHARMACY STAFF ONLY –

PATIENT ASSESSMENT

Physical Assessment (record values)	**Refer to PCP** if determined clinically unstable in pharmacist professional judgment or **any** of the following criteria:
Blood Pressure	Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg
Respiratory Rate	Respiratory rate >30 breaths/min (single criteria); Respiratory rate >20 breaths/min (dual criteria)
Oxygen Saturation	Oxygen saturation (SpO_2) < 90% via pulse oximetry
Pulse	Pulse >125 beats/min (single criteria); Pulse >90 beats/min (dual criteria)
Temperature	Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit (single criteria); Temperature < 96.8 degrees Fahrenheit (dual criteria); Temperature > 100.4 degrees Fahrenheit (dual criteria, or pyelonephritis possibility in combination with nausea/vomiting or flank pain)
□ Yes □ No Acute altered mental status	Yes

Patients who do not qualify for CLIA-waived testing under this Protocol shall be referred by the pharmacist to a primary care provider or urgent/emergent treatment facility as clinically appropriate.

Treat using protocol if:

- Female patient ≥18 years of age but <65 years, and able to give informed consent;
- Prior history of UTI(s);
- One or more of the following symptoms: dysuria, increased frequency, and/or urgency; and
- Positive urine dipstick for nitrites or leukocytes via a CLIA-waived point-of-care detection test kit.

Refer to PCP and exclude from testing if:

- Male;
- Pregnant or breastfeeding;
- Post-menopausal;
- Vaginitis symptoms (e.g., vaginal discharge or itching);
- Symptom onset >7 days prior;
- Immunocompromised state (e.g., hematologic malignancy, immunosuppressant drug therapy including corticosteroids for greater than 2 weeks, HIV/AIDS);
- Renal transplantation;
- Renal dysfunction (based on individual's report or pharmacy records);
- Diabetes mellitus;
- History of any urologic surgery, including but not limited to ureteral implantation, cystectomy, or urinary diversion;
- History of Clostridioides difficile (formerly Clostridium difficile) a.k.a. c.diff;
- Abnormal urinary tract function or structure (e.g., indwelling catheter, chronic intermittent catheterization, neurogenic bladder, renal stones, renal stents);
- Any pending test at any pharmacy, laboratory, medical care facility, or clinic for the patient's reported symptoms;
- Antibiotic therapy prescribed within the previous 30 days;

- Inpatient or hospital stay within the previous 30 days;
- History of recurrent UTIs (>3 per year)
- Clinical instability of the patient based on the clinical judgment of the pharmacist or:
    - Two or more of the following criteria:
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >90 beats/min;
        - Respiratory rate >20 breaths/min;
        - Temperature < 96.8 degrees Fahrenheit; or
        - Temperature > 100.4 degrees Fahrenheit; or
    - Any one of the following criteria:
        - Acute altered mental status;
        - Systolic blood pressure < 90 mmHg or diastolic blood pressure < 60 mmHg;
        - Pulse >125 beats/min;
        - Respiratory rate >30 breaths/min;
        - Oxygen saturation (SpO2) < 90% via pulse oximetry; or
        - Temperature > 102 degrees (temporal), > 103 degrees (oral), or > 104 degrees (tympanic) Fahrenheit;
- Has or reports symptoms suggestive of pyelonephritis including:
    - Presence of fever (≥100.4 F; taken orally);
    - Nausea and vomiting; or
- Flank pain; or
- A patient receiving hospice or home health services.

CLIA-WAIVED POC TEST RESULT

□ Positive urine dipstick for nitrites or leukocytes indicating UTI

□ Negative for UTI

PATIENT ACTION

□ Yes □ No UTI Diagnosed

□ Yes □ No Antibiotic Treatment Prescribed

□ Yes □ No Refer to PCP

Therapy Options		
□ UTI Antibiotic Treatment Prescribed as Marked Below □ No Treatment – Referred to PCP		
Documentation of Rationale for Treatment Selection (if required):		
First-line Treatment		
❑ Cephalexin	Dispense: ❑ 500mg #10 No refills	Sig: Take 1 (one) (500mg) by mouth twice daily for 5 days.
❑ Cefdanir	Dispense: ❑ 300mg #10 No refills	Sig: Take 1 (one) (300mg) by mouth twice daily for 5 days.

❑ Oral Nitrofurantoin monohydrate/macrocrystals *(for cephalexin allergy)*	Dispense: ❑ 100mg #10 No refills	Sig: Take 1 (one) (100mg) by mouth twice daily for 5 days.
Alternative Antibiotic Therapy		
❑ Oral Fosfomycin trometamol	Dispense: ❑ 3 gm, single dose No refills	Sig: Dissolve one packet (3 grams) in 4 ounces of water and drink as one dose.
For Dysuria		
❑ Phenazopyridine	Dispense: ❑ 100mg #6 ❑ 200mg #6 No refills	Sig: Take 1 tablet by mouth three times daily after meals for up to 2 days.

PHARMACIST PERFORMING ASSESSMENT AND INITIATING THERAPY OPTION

Printed Name	License Number

SIGNATURE

DATE

Agenda Item: Amendments to vaccine protocols for ages 3-17 and adults to include epinephrine to treat anaphylaxis

Included in your agenda package:

- Vaccine protocol for ages 3-17, amended to include administration or initiation of treatment with epinephrine for anaphylaxis following vaccine administration; and

- Vaccine protocol for ages 18 and up, amended to include administration or initiation of treatment with epinephrine for anaphylaxis following vaccine administration.

Action needed:

- Motion to amend vaccine protocols for ages 3-17 and ages 18 and up as presented.

VIRGINIA BOARD OF PHARMACY

Vaccine Statewide Protocol for Persons Ages Three (3) through Seventeen (17)

(Does not include influenza or COVID-19 vaccines)

Except for influenza and COVID-19 vaccines, consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC) and the third enactment clause of HB1323, a pharmacist may issue a prescription to initiate treatment with or administer a vaccine to a persons ages three (3) through seventeen (17) recommended at his or her age, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such vaccine. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine. Please note that this protocol does not authorize the administration of influenza or COVID-19 vaccines to persons ages three through seventeen. COVID-19 vaccines may be administered to this age group pursuant to the PREP Act until such authority expires. Influenza vaccines may be administered to this age group pursuant to the PREP Act until such authority expires or §54.1-3408 (W).

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with a patient, dispensing, or administering vaccines or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

The pharmacist shall review applicable medical history prior to administering a vaccine to ensure the vaccine administration is appropriate for the patient's medical condition(s)

(e.g., pregnancy or immunocompromised state). The following patients are eligible for vaccines under this protocol:

- An individual ages 3 through 17 whose immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule published by the CDC, and
- An individual ages 3 through 17 preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine (other than influenza or COVID-19) is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
The following patients are NOT eligible for vaccines under this protocol:

- An individual less than 3 years of age or older than 17 years of age;
- An individual for whom a vaccine is not recommended by the CDC for reasons such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. The pharmacist shall also provide written notice to the minor's parent or guardian that the minor should visit a pediatrician annually.

VIRGINIA BOARD OF PHARMACY

Pharmacist Vaccine Statewide Protocol for Persons Eighteen Years of Age or Older

Consistent with the Immunization Schedule published by the Centers for Disease Control and Prevention (CDC), a pharmacist may issue a prescription to initiate treatment with, dispense, or administer, or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer vaccines, including vaccines for COVID-19, to persons 18 years of age or older. A pharmacist may also initiate treatment with or administer epinephrine to such person demonstrating signs and symptoms of anaphylaxis following vaccine administration or may direct a pharmacy technician or pharmacy intern under the supervision of the pharmacist to administer such epinephrine.

PHARMACIST EDUCATION AND TRAINING

Prior to issuing a prescription to initiate treatment with, dispensing, or administering vaccine or epinephrine under this protocol, the pharmacist shall be knowledgeable of the manufacturer's instructions for use, the current Immunization Schedule published by the CDC, how to properly identify which vaccines a patient may require, storage and handling requirements, and how to counsel the patient on possible adverse reactions. The pharmacist shall also have a current certificate in basic cardiopulmonary resuscitation.

PHARMACY TECHNICIAN AND PHARMACY INTERN TRAINING

Prior to administering a vaccine or epinephrine, a pharmacy technician, pharmacy technician trainee, or pharmacy intern shall have completed a practical training program that is approved by the Accreditation Council for Pharmacy Education ("ACPE"). This training program must include hands-on injection technique and the recognition and treatment of emergency reactions to vaccines. The pharmacy technician, pharmacy technician trainee, or pharmacy intern shall also have a current certificate in basic cardiopulmonary resuscitation.

PATIENT INCLUSION CRITERIA

Pharmacist shall review applicable medical history prior to administering vaccine to ensure vaccine administration is appropriate for patient's medical condition(s), e.g., pregnancy, immunocompromised state. Patients eligible for vaccine under this protocol:

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine is recommended at his or her age in accordance with the most current Child and Adolescent Immunization Schedule or the Adult Immunization Schedule published by the CDC inclusive of additional information for COVID-19 vaccination;

- An individual, 18 years of age or older, whose immunization history is incomplete or unknown and for whom a vaccine with current emergency use authorization from the U.S. Food and Drug Administration is recommended by the CDC; and,
- An individual, 18 years of age or older, preparing to travel to a destination for which immunization history is incomplete or unknown and for whom a vaccine is recommended by the CDC prior to traveling to the specific destination.

PATIENT EXCLUSION CRITERIA
Patients NOT eligible for vaccine under this protocol:

- An individual less than 18 years of age;
- An individual for whom a vaccine is not recommended by the CDC such as based on the patient's medical condition(s); or
- An individual who has received all CDC recommended doses for their age, medical condition or other indicators.

COUNSELING
The pharmacist shall ensure the patient or patient's agent is provided with written information regarding the vaccine and possible adverse reactions.

RECORDKEEPING
The pharmacist shall maintain records in accordance with Regulation 18VAC110-21-46 and report such administration to the Virginia Immunization Information System in accordance with the requirements of § 32.1-46.01.

NOTIFICATION OF PRIMARY CARE PROVIDER
In accordance with 54.1-3303.1 of the Code of Virginia, the pharmacist shall notify the patient's primary care provider. If the patient does not have a primary care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located.

Agenda Topic: Rescission of pharmaceutical processor permit RFA for HSA I

Included in Agenda Packet:

- 2020 RFA
- September 2022 Frequently Asked Questions regarding RFA
- July 2023 Applicant Notification

Possible Action:

- Motion to rescind RFA No. PHR-2020-01 for awarding a pharmaceutical processor permit in Health Service Area 1 and for staff to refund application fees to the 26 applicants.

Virginia Department of Health Professions

Commonwealth of Virginia

REQUEST FOR APPLICATIONS (RFA)

Issue Date: September 25, 2020 RFA No. PHR-2020-01

Title: Pharmaceutical Processors-Health Service Area I

Issuing Agency: Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Ste. 300
Henrico, VA 23233

Contact Information: Annette Kelley, M.S.; C.S.A.C.
Deputy Executive Director
Virginia Board of Pharmacy
Phone: (804) 367-4456
Fax: (804) 527-4472
Email: cbd@dhp.virginia.gov

Application Due Date: December 4, 2020 **at 2:00 P.M.**

All inquiries for information should be directed to Annette Kelley.

Purpose

The purpose of this Request for Application (RFA) is to solicit applications for a permit to operate a pharmaceutical processor in Health Service Area (HSA) I. As authorized in law, the Virginia Board of Pharmacy (Board) may award conditional approval for no more than one pharmaceutical processor for each of the five health service areas established by the Board of Health. The counties served by HSA I are listed in Attachment 1. A pharmaceutical processor is a facility that is authorized to: cultivate Cannabis plants intended only for the production and dispensing of cannabis oil; produce cannabis oil; and, dispense cannabis oil to patients for treatment or to alleviate the symptoms of any diagnosed condition or disease determined by a practitioner to benefit from such use. With the exception of wholesale distribution to another pharmaceutical processor or cannabis dispensing facility, or delivering dispensed cannabis oil under certain conditions, the cultivation, production, and dispensing will occur on-site at the address of record of the facility.

The application process for the pharmaceutical processor permit in HSA I will occur in three stages: submission of initial application, awarding of conditional approval, and granting of a pharmaceutical processor permit. The review and scoring of the applications will be performed by an ad hoc committee appointed by the Board which will recommend to the Board the awarding of conditional approval or the need to re-issue the RFA should the committee determine there is an insufficient number of qualified applications. Persons interested in being considered for obtaining conditional approval must submit, in accordance with this RFA, the Code of Virginia, and the Regulations Governing Pharmaceutical Processors, an initial application and the non-refundable application fee of $10,000, as listed in 18VAC110-60-20.

If granted conditional approval, an applicant will have one year from date of notification to complete all requirements for issuance of a permit to include the construction or remodeling of a facility, installation of equipment and security, local zoning approval, and employment of a pharmacist-in-charge and other personnel necessary for operation. Upon completion of all requirements, an agent of the Board will perform an inspection of the facility to assess compliance with the granted conditional approval and the relevant laws and regulations. Written corrective action will be submitted to the Board for any deficiencies identified during the inspection and a reinspection will be performed, if necessary. An application for initial permit, along with any required documentation, the initial permit fee of $60,000 and any reinspection fees, if required, will be submitted to the Board prior to performing the inspection. Once the pharmaceutical processor permit is issued, the facility may obtain Cannabis seeds and begin operation. Barring suspension, revocation, or refusal to grant or renew such permit as outlined in 18VAC110-60-160, the permit will be valid for one year from the date of issuance and may be renewed annually pursuant to Board regulations for continued operation.

Background

The Virginia Board of Pharmacy is one of 13 health regulatory boards within the Department of Health Professions, a state agency that licenses and regulates over 380,000 health care professionals across 62 health professions. The Department is also composed of the Board of Health Professions, the Health Practitioners Monitoring Program, the Healthcare Workforce Data Center, and the Prescription Monitoring Program. The mission of the Department is to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public. Information on these health regulatory boards and programs may be accessed on the Department's Web site, http://www.dhp.virginia.gov/.

Legislation was passed during the 2016 Virginia General Assembly Session and reenacted in 2017 (http://leg1.state.va.us/cgi-bin/legp504.exe?171+ful+SB1027ER) which authorized the permitting of pharmaceutical processors. The Virginia Board of Pharmacy subsequently adopted emergency regulations governing pharmaceutical processors, effective August 7, 2017 through February 6, 2019. (18VAC110-60-10 et sec., found at http://register.dls.virginia.gov/details.aspx?id=6508 This created a regulatory framework for "pharmaceutical processors", a term that was defined in Code to mean "a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian for the treatment of intractable epilepsy." Additionally, the Code was amended to authorize a "practitioner" to issue a written certification for the use of cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's intractable epilepsy. The term "practitioner" was defined in Code to mean "a practitioner of medicine or osteopathy licensed by the Board of Medicine who is a neurologist or who specializes in the treatment of epilepsy."

During the 2018 General Assembly Session, several bills were passed that amended the laws associated with pharmaceutical processors:

http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+HB1251ER (2018 Va. Acts of Assembly ch. 246)

http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+SB330ER (2018 Va. Acts of Assembly ch. 567)

http://leg1.state.va.us/cgi-bin/legp504.exe?181+ful+SB726ER (2018 Va. Acts of Assembly ch. 809)

Such amendments included expanding the use of cannabidiol oil and THC-A oil to any diagnosed condition or disease determined by the practitioner to benefit from such use, authorizing any practitioner of medicine or osteopathy licensed by the Virginia Board of Medicine (and registered by the Virginia Board of Pharmacy) to issue written certifications, and further elaborating on allowances and requirements for pharmaceutical processors.

Legislation passed during the 2019 General Assembly Session allowed for physician assistants licensed with the Board of Medicine and nurse practitioners jointly licensed by the Board of Medicine and the Board of Nursing to issue a written certification; the ability for a patient, or the patient's parent or legal guardian to choose a board-registered individual to act as a registered agent to receive cannabis oil on behalf of the patient; and the option for a pharmaceutical processor to wholesale distribute cannabis oil products to another pharmaceutical processor.

https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+SB1557ER+pdf

https://lis.virginia.gov/cgi-bin/legp604.exe?191+ful+SB1719ER+pdf

During the 2020 General Assembly Session, several bills were passed that impact the pharmaceutical processors. Of significance: the definitions of "cannabidiol oil" and "THC-A oil" were replaced with a new definition, "cannabis oil"; practitioners may employ the use of telemedicine consistent with federal requirements for the prescribing of Schedule II through V controlled substances; an individual who temporarily resides in Virginia that has been issued a valid written certification and is registered with the Board may access cannabis oil products; and, the Board may permit up to five cannabis dispensing facilities in each HSA. The dispensing facilities must be owned in part by the pharmaceutical processor permitted in that HSA. Note: The application process for a cannabis dispensing facility permit is independent of this RFA for obtaining a pharmaceutical processor permit. Consideration of a cannabis dispensing facility permit application is contingent upon emergency regulations becoming effective and at least one owner maintaining a current active pharmaceutical processor permit in the same HSA.

https://lis.virginia.gov/cgi-bin/legp604.exe?201+ful+SB976ER2+pdf

Anticipated Timeline

September 25, 2020	Issue RFA
December 4, 2020, 2:00p.m.	Applications due
December 11, 2020	Applications and submitted documentation to ad hoc committee
February 5, 2021	In-person meeting of ad hoc committee to discuss scoring of applicants

February 17, 2021	Board reviews scoring and identifies which Applicants will be awarded conditional approval
February 26, 2021	Deadline for fingerprinting and submission of information for criminal background checks
March 30, 2021	Board reviews results of criminal background check and finalizes the awarding of the conditional approvals

Application Submission and Instructions

In order to be considered for selection, an Applicant must submit a complete Application for a Pharmaceutical Processor Permit for HSA 1 (Attachment 2) with required documentation and application fee in accordance with this RFA no later than December 4, 2020 at 2:00p.m. EST. **Note: Applications submitted without the required fee or information or in a manner that is significantly inconsistent with the RFA will be deemed incomplete and will not be considered for selection, nor will applications received after the submission due date.**

Application Submission: The application and all required attachments must be provided as follows:

1. Twelve (12) hard copies (printed), one marked Original, for a total of twelve (12) copies; and twelve (12) soft copies (CD or thumb drive) with a searchable PDF copy of the complete submission labeled with the RFA number and name and address of the pharmaceutical processor as indicated on the application.

2. All copies of applications and documentation must be mailed or hand-delivered to the address below. Mail sent using the United States Postal Service, including those requesting a certified mail receipt, is received in approximately one week. Mail sent using private mail carriers, e.g., UPS and FedEx, is more efficient as it arrives directly to the Board's address. It is strongly recommended that Applicants track delivery to ensure timely receipt of their mailing.

   Department of Health Professions
   Board of Pharmacy
   Perimeter Center
   9960 Mayland Drive, Suite 300
   Henrico, VA 23233

   Important information for hand-delivering application materials:

   In response to COVID-19 social distancing precautions, the Department of Health Professions' public reception area is currently not accommodating walk-in services. If you wish to hand deliver your application materials prior to December 4, 2020, please

contact Annette Kelley at: cbd@dhp.virginia.gov to coordinate staff availability for delivery. Board of Pharmacy staff will be on-site on December 4, 2020 from 8:15 am until 2:00 pm for receipt of application materials.

In order to be considered for selection, Applicants must submit a complete response to this RFA.

In the event state business operations are suspended (office is closed) on the date set for receipt of applications, applications will be due at the same time on the next regular business day.

3. All packages must be sealed. The following information must be included in the return address and identified as follows:

From: _____
Name of Applicant

RFA Number: PHR-2020-01
Health Service Area I

_____
Street or Box Number

_____
City, State, Zip Code

Pursuant to §54.1-3442.6 of the Code of Virginia, the number of permits that the Board of Pharmacy may issue or renew in any year is limited to one for each health service area established by the Board of Health. There are five health service areas in the Commonwealth. This RFA is for HSA I only. A permit has already been awarded to a facility in each of the other HSAs. Incomplete applications will not be considered. In the event the Board determines that there are no qualified applicants to award conditional approval for a pharmaceutical processor permit in HSA I, the Board may republish, in accordance with 18VAC110-60-100, a notice of open applications for pharmaceutical processor permits.

The Board may disqualify any applicant:

1. Who submits an incomplete, false, inaccurate or misleading application;
2. Who fails to submit an application by the published deadline;
3. Who fails to pay all applicable fees;
4. Who fails to comply with all requirements for a pharmaceutical processor; or,
5. For whom there is evidence of a criminal conviction that would disqualify the applicant under 18VAC110-60-110(D).

The Board, and the ad hoc committee acting on its behalf, reserves the right to waive minor irregularities or to request clarifications, modifications, or amendments to an application, provided such application substantially complies with the RFA. The board also reserves the right to amend the notice of open applications prior to the deadline for submitting an application. Such amended notice will be published in the same manner as the original notice of open applications. The Board may cancel a notice of open applications prior to an award of a pharmaceutical processor permit.

Evaluation Criteria

The evaluation of applications will involve the scoring of each application by the ad hoc committee of the Board. While a maximum of 275 points is possible, proposals must achieve a minimum score of 160 points to be awarded conditional approval for a pharmaceutical processor permit. If an insufficient number of applications obtain a score of at least 160 to award a conditional approval in HSA I, the ad hoc committee may request modifications from those applicants whose scores are closest to 160 so as to render the applications acceptable. Alternatively, if the ad hoc committee determines that sufficient modifications cannot be made to render the applications in HSA I acceptable, the ad hoc committee may recommend to the Board that it re-issue the RFA.

In conducting its evaluation of each of the criteria listed below, the Board, and the ad hoc committee acting on its behalf, may conduct interviews, contact references, contact state or local officials in any other state(s) where the applicant, applicant's backers or others associated with the applicant have engaged, or sought to be engaged in, similar activities and visit the location of the proposed facility or other related businesses associated with the applicant or applicant's backers or key personnel.

The number of points after each component listed below is the maximum number of points that may be awarded for each of the corresponding components of the RFA. For each component, the applicant's score will be based on the totality of the response to the corresponding component. The description listed within each component is not intended to be an exhaustive list of all relevant factors, but rather is intended to provide guidance as to the focus of the Board's analysis.

- ☐ **Financial Position (25 points):** An analysis will be performed of the submitted information detailing the applicant's financial position, indicating all assets, liabilities, income and net worth, to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis oil. This will include an evaluation of financial soundness, funding sources, any evidence of an escrow account, letter of credit, or performance surety bond, and a determination of the applicant's ability to remain a long-term, stable, and sustained source of cannabis oil for patients.

- ☐ **Location within the Health Service Area (25 points):** An analysis will be performed of the submitted description of the facility's proposed location within HSA I as established by the Board of Health, which cannot be within 1,000 feet of a school or daycare. This will include an evaluation of the accessibility to patients, compatibility

with other commercial and residential structures in the immediate neighborhood, any evidence of support from the immediate neighborhood or locality, and ability to safely dispose of unwanted product.

☐ **Security Plans (25 points):** An analysis will be performed of the submitted plans detailing the proposed security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis oil. This will include an analysis of any proposed training opportunities for employees and processes to be implemented to protect against diversion, theft, or loss. Additionally, the analysis will include how the pharmaceutical processor will comply with security requirements pursuant set forth in 18VAC110-60-240 through 18VAC110-60-270 and the requirement for an electronic tracking system pursuant to 18VAC110-60-130 and as defined in 18VAC110-60-10.

☐ **Authorization to Conduct Business (20 points):** An analysis will be performed of the submitted documents sufficient to establish that the applicant is authorized to conduct business in Virginia in good standing, such as through the State Corporation Commission, and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of the permit. This will include the review of any proof of the Applicant's right to occupy the proposed premises.

☐ **Industry Involvement and Disciplinary Action (25 points):** An analysis will be performed of the information submitted regarding previous or current applications for permits, licenses, or registrations related to the cultivation, production, or dispensing of cannabis oil in any state and the status of that application, permit, license, or registration. This will include the review of any disciplinary action taken by any state or federal entity on the permit, license, or registration.

☐ **Agriculture, Production, and Dispensing Expertise (50 points):** An analysis will be performed of the information submitted that describes the collective expertise of the applicant and employees in: agricultural techniques required to cultivate Cannabis for the production of cannabis oil; production techniques for accurately producing unadulterated cannabis oil that satisfies concentrations defined by law and quality assurance testing; and dispensing techniques for safely dispensing cannabis oil to patients, to include counseling patients to ensure appropriate dosing. Consideration will be given to any education obtained and any proposed training opportunities for staff to safely cultivate, and accurately produce and dispense unadulterated cannabis oil.

☐ **Marketing Plans (20 points):** An analysis will be performed of the submitted marketing plan based on its ability to effectively educate patients and others on the medical use of cannabis oils, how to safely secure the oil, and how to properly dispose of unwanted oil. The analysis will include the care that is taken to not promote the use of marijuana or the

cannabis oil for recreational purposes or by persons not authorized to possess and administer cannabis oil.

- ☐ **Facility Exterior and Blueprint (25 points):** An analysis will be performed of the submitted text or graphic material showing the exterior appearance of the proposed pharmaceutical processor. The analysis will include a review of the blueprint of the proposed pharmaceutical processor which shows and identifies square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oil and the location of all areas that may contain Cannabis plants, cannabis oil, showing the placement of walls, partitions, counters and all areas of ingress and egress. The information submitted should also support the Applicant's ability to comply with 18VAC110-60-250. Consideration will be given to any systems that will be used to reduce or prevent off-site odors.

- ☐ **Product and Site Safety (20 points):** An analysis will be performed of the list of cannabis oil products anticipated to be produced and dispensed at the proposed location. It will include an evaluation of the robustness of the Applicant's submitted plan to cultivate Cannabis and produce cannabis oil products that are safe, unadulterated, comply with the legal definitions for cannabis oil, and satisfy quality assurance testing. The analysis will also review the Applicant's submitted plan to produce a safe work environment for its employees.

- ☐ **Expected Hours of Operation (15 points):** An analysis will be performed of the Applicant's proposed hours of operation which will be at least 35 hours per week for eligible persons to purchase oil, except as otherwise authorized by the Board.

- ☐ **Additional Points (25 points):** An evaluation will be performed of each plan listed below and its ability to meet the objectives of the category.
    - Compassionate need plan, e.g., discounted pricing for qualifying patients (5 points)
    - Delivery service plan that mitigates risk of diversion, theft, or loss (15 points)
    - Research plan (5 points)

Maximum Total of Eligible Points = 275

Awarding of Conditional Approval

After completing the review and scoring, the ad hoc committee will rank each application according to its score. The committee will recommend to the Board the issuance of conditional approval to the Applicant in HSA I with the highest ranked score and may recommend an otherwise qualifying alternate Applicant for consideration, should the top Applicant choose to withdraw or

otherwise not accept the conditional approval upon awarding, provided: the recommended Applicant's or alternate Applicant's total scores exceed the minimum established score and no reasons exist to deny issuance of conditional approval. Selection will be made of applicants deemed to be fully qualified and best suited among those submitting applications based on the evaluation criteria and results of the criminal background check. The Board will grant conditional approval to the Applicant that, in its opinion, has made the best application. The Board will notify applicants of denial or conditional approval. The decision of the Board not to grant conditional approval to an applicant will be final.

Criminal Background Check:

The Applicant who is notified of the Board's willingness to grant it conditional approval must, as a condition of the awarding, submit to fingerprinting and provide personal descriptive information to be forwarded along with their fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant. The cost of fingerprinting and the criminal history record search must be paid by the applicant. The Central Criminal Records Exchange will forward the results of the criminal history background check to the Board or its designee, which will be a governmental entity. An analysis will be performed of the results of the criminal history record information, to include a review of any identified irregularities or falsified information submitted on the application.

Attachment 1

HEALTH SERVICE AREA	COUNTY EQUIVALENT	CITY COUNTY
I	**Augusta**	County
I	**Bath**	County
I	**Buena Vista**	(city)
I	**Harrisonburg**	(city)
I	**Highland**	County
I	**Lexington**	(city)
I	**Rockbridge**	County
I	**Rockingham**	County
I	**Staunton**	(city)
I	**Waynesboro**	(city)
I	**Clarke**	County
I	**Frederick**	County
I	**Page**	County
I	**Shenandoah**	County
I	**Warren**	County
I	**Winchester**	(city)
I	**Culpeper**	County
I	**Fauquier**	County
I	**Madison**	County
I	**Orange**	County
I	**Rappahannock**	County
I	**Albemarle**	County
I	**Charlottesville**	(city)
I	**Fluvanna**	County
I	**Greene**	County
I	**Louisa**	County
I	**Nelson**	County
I	**Caroline**	County
I	**Fredericksburg**	(city)
I	**King George**	County
I	**Spotsylvania**	County
I	**Stafford**	County

Attachment 2-Pharmaceutical Processor Application

Virginia Department of Health Professions
Board of Pharmacy

9960 Mayland Drive, Suite 300
Henrico, Virginia 23233
(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
cbd@dhp.virginia.gov
www.dhp.virginia.gov/pharmacy

APPLICATION FOR A PHARMACEUTICAL PROCESSOR PERMIT

Check Appropriate Box(es):

☐ Initial Application	$10,000.00	☐ Initial Permit [2]	$60,000.00
☐ Change of Ownership Requiring Criminal Background[7]	$250.00	☐ Change of Location [4]	$1,000.00
☐ Change of Ownership Not Requiring Criminal Background[7]	$100.00	☐ Remodel, Expansion, Acquisition[5]	$1,000.00
☐ Change of Name	$100.00	☐ Re-Inspection [6]	$1,000.00
☐ Change of Pharmacist-In-Charge [1]	$100.00	☐ Change in Hours of Operation [3]	No fee

Application fees are not refundable. Applications are valid for one year from the date of receipt. The required fees must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials.

Name of Pharmaceutical Processor		Area Code and Telephone Number	
Street Address		Area Code and Fax Number	
City	State	Zip Code	Designated Health Service Area

If a current pharmaceutical processor permit is held, indicate the permit number 02	Area Code and Telephone Number (currently working number)
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming) [1,2]	License Number of the PIC [1,2] 0202-
Effective Date of Change (if change of PIC, date assuming role as PIC) [1]	Email Address of PIC [1,2]
Hours of Operation [1, 2, 3]	Anticipated Opening Date [2]
Name of Owner Applicant	Telephone Number of Owner Applicant
Email Address of Owner Applicant	Expected Completion Date of Remodel or Expansion or Date for Change of Location [4,5]

Requested Inspection Date [2,4,5,6]

FOR OFFICE USE ONLY:

Date processed:				
Assigned Inspection Date:	Check No:		Receipt No:	Application No:
Permit Number 02	Date Inspected:	Reviewed By:	Date Reviewed:	Date Issued:
				Date Scanned to MLO:

OWNERSHIP TYPE — check one:	Corporation ☐	Partnership ☐	Individual ☐	Other ☐
Name of ownership entity if different from name of application:				
Street Address:			Phone No.	
City:		State:	Zip Code:	
State(s) of incorporation:				

List all other trade or business names used by this facility

Name: _____ **Name:** _____

Name: _____ **Name:** _____

LIST OF OWNERS/OFFICERS, RESIDENCE ADDRESSES, AND PERCENTAGE OF SHARES OWNED FOR EACH OWNER OR LIST IS ATTACHED ☐

Name: Title:

_____ _____

Residence Address:

_____

Name: Title:

_____ _____

Residence Address:

_____

[7]**Any owner with 5% or greater share of the total ownership must submit to a criminal history record search and submit the applicable application fee. Instructions will be provided for how to complete the record search once this application is received and processed.**

Please respond to all of the following questions:	
1. Have you, any owner, employee, or agent of this business entity ever been convicted of, pled *nolo contendere* to, or currently have charges pending for 1) any felony, 2) any misdemeanor involving moral turpitude, or 3) violation of any federal or state law relating to controlled substances? If yes, provide name of owner, employee, or agent, name of jurisdiction and date of charges or convictions, explain, and attach copies of any official documents such as warrants and court orders showing the nature and disposition of such charges or convictions.	☐ Yes ☐ No
2. Have you, any owner, employee, or agent of this business ever had any civil action under any federal or state statute or regulation or local ordinance relating to the applicant's, licensee's, permit holder's or registrant's profession, or involving drugs, medical devices or fraudulent practices, including, but not limited to, fraudulent billing practices? If yes, provide name of owner, employee, or agent, name of jurisdiction and date of charges or convictions, explain, and attach copies of any official documents such as warrants and court orders showing the nature and disposition of such charges or convictions.	☐ Yes ☐ No
3. Has any owner, employee, or agent of this business had a license or registration suspended or revoked or denied issuance of such license or registration? If yes, provide name of employee or agent, name of jurisdiction, date of action, and attach copies of any official documents related to the issue.	☐ Yes ☐ No
4. Does a practitioner of medicine or osteopathy licensed by the Board of Medicine, a physician assistant licensed by the Board of Medicine or a nurse practitioner jointly licensed by the Board of Medicine and the Board of Nursing, and who issues written certifications, or such practitioner's co-worker, employee, spouse, parent or child, have a direct or indirect financial interest in this business?	☐ Yes ☐ No

NOTE:

Qualifying applicants will be informed of the need to submit to fingerprinting and providing personal descriptive information to be forwarded along with their fingerprints through the Central Criminal Records Exchange to the Federal Bureau of Investigation for the purpose of obtaining criminal history record information regarding the applicant.

A 14-day notice is required for scheduling an opening or change of location inspection. Cannabis seeds and Cannabis products may not be stocked prior to the initial inspection and approval. An inspector will call prior to the requested date to confirm readiness for inspection or the applicant or PIC may call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

_____ _____

Signature of Owner Applicant Date

_____ _____

Signature of PIC (required except for initial application if PIC not known) Date

Information Required for Initial Application

To be considered for issuance of a conditional approval, the following information must be submitted, in accordance with the current Request for Application (RFA), along with the application form and initial application fee. Refer to the *Evaluation Criteria* found within the RFA for how the submitted information will be evaluated.

- ☐ **Financial Position:** Detailed information regarding the applicant's financial position, indicating all assets, liabilities, income and net worth to demonstrate the financial capacity of the applicant to build and operate a facility to cultivate Cannabis plants intended only for the production and dispensing of cannabis oil. This may include evidence of an escrow account, letter of credit, or performance surety bond.

- ☐ **Location within the Health Service Area:** Description of the facility's proposed location within the health service area as established by the Board of Health.

- ☐ **Security Plans:** Details regarding the applicant's plans for security to maintain adequate control against the diversion, theft, or loss of the Cannabis plants and the cannabis oil.

- ☐ **Authorization to Conduct Business:** Documents sufficient to establish that the applicant is authorized to conduct business in Virginia in good standing, such as through the State Corporation Commission, and that all applicable state and local building, fire, and zoning requirements and local ordinances are met or will be met prior to issuance of the permit.

- ☐ **Industry Involvement and Disciplinary Action:** Information about current or previous involvement in the medical cannabis oil industry. Information about previous applications for permits or registration related to medical cannabis oil in any state and if so, the status of that application, permit, registration including any disciplinary action taken by any state on the permit, registration, or an associated license.

- ☐ **Agriculture, Production, and Dispensing Expertise:** Information regarding expertise in agriculture and other production techniques required to produce cannabis oil and to safely dispense such products.

- ☐ **Marketing Plans:** Information regarding the business and marketing plans related to the operation of the pharmaceutical processor or the sale of cannabis oil.

- ☐ **Facility Exterior and Blueprint:** Any text or graphic material showing the exterior appearance of the proposed pharmaceutical processor. Include a blueprint of the proposed pharmaceutical processor which shall show and identify square footage of each area of the facility, to include the location of all safes or vaults used to store the Cannabis plants and oils and the location of all areas that may contain Cannabis plants, cannabis oil, showing the placement of walls, partitions, counters and all areas of ingress and egress.

- ☐ **Product and Site Safety:** Plan to safely cultivate Cannabis and produce cannabis oil that is safe, unadulterated, comply with the legal definitions for cannabis oil, and satisfy quality assurance testing. Plan to produce a safe work environment for employees.

- ☐ **Expected Hours of Operation:** A facility shall be open a minimum of 35 hours a week for eligible persons to purchase oil, except as otherwise authorized by the Board.

- ☐ **Compassionate Need Plan:** Documents related to any compassionate need program, e.g., discounted pricing for qualifying patients the pharmaceutical processor intends to offer.

- ☐ **Delivery Service Plan:** A plan detailing any delivery service the pharmaceutical processor intends to offer that mitigates any risk of diversion, theft, or loss.

- ☐ **Research Plan:** A plan detailing any research the pharmaceutical processor intends to perform or in which it may participate.

Information Required for Initial Permit

In addition to satisfactory inspection of the facility conducted by the Board or its agent, an applicant that has received conditional approval shall complete the following steps and provide the required information prior to issuance of an initial permit:

- ☐ **Application:** Submission of an Application for a Pharmaceutical Processor Permit. Check the box indicating "Initial Permit", designate the pharmacist-in-charge (PIC), indicate the requested inspection date, and submit the required fee for "Initial Permit".

- ☐ **Criminal Background Checks:** Evidence of criminal background checks of all employees or agents of the processor to ensure compliance with §54.1-3442.6 of the Code.

- ☐ **Electronic Tracking System:** Evidence of utilization of an electronic tracking system.

- ☐ **Attestation:** Submission of an attestation indicating full compliance with all state and local laws and ordinances for the operation of a pharmaceutical processor.

Frequently Asked Questions regarding Request for Applications (RFA) for Pharmaceutical Processors – Health Service Area I

Issue Date: September 25, 2020 RFA No. PHR-2020-01
Title: Pharmaceutical Processors-Health Service Area I
Issuing Agency: Department of Health Professions
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Ste. 300
Henrico, VA 23233

Contact Information: Annette Kelley, M.S.; C.S.A.C.
Deputy Executive Director
Virginia Board of Pharmacy
Phone: (804) 367-4456
Fax: (804) 527-4472
Email: cbd@dhp.virginia.gov

Application Due Date: December 4, 2020 at 2:00 P.M.

Q: Is the Board currently reviewing applications that were submitted prior to the December 4, 2020 deadline?

A: No. PharmaCann appealed the Board's rescission of conditional approval and denial of its application in health service area 1. On January 14, 2021, the Henrico County Circuit Court ordered the Board to cease reviewing applications until further order by the Court. As a result, the Board must wait for the Court's resolution of PharmaCann's appeal.

Q: When will the Board resume review of the applications?

A: Following the Henrico Circuit Court's ruling in the favor of the Board of Pharmacy, PharmaCann submitted an appeal to the Virginia Court of Appeals. The Board must wait for the resolution of PharmaCann's appeal, and authorization by the Court, to resume review of applications.

Q: Will the Board allow for updated information to be submitted prior to resuming review of the applications?

A: The Board is aware that changes in the original application submission, which may include changes in location or ownership, may have occurred since the December 4th deadline. Prior to resuming the application review process, staff will communicate with the applicants and provide a 60-day notice for any changes in the original application to be submitted as a revised application.

Q: If the Henrico County Circuit Court vacates the Board's Order denying PharmaCann's application, what impact will this decision have on the existing RFA?

A: The Board will make a decision on how to proceed in the event that this occurs.

Q: Is the Board able to issue more than one pharmaceutical processor permit in Health Service Area I?

A: Virginia Code § 54.1-3442.6(B) of the Code of Virginia restricts the Board to issuing only one pharmaceutical processor permit per health service area.

July 6, 2023

Dear Applicant,

This communication contains an important update regarding your submission of an application for RFA No. PHR-2020-01, Pharmaceutical Processors-Health Service Area I. Please note that the Board will consider canceling the notice of open application for awarding a pharmaceutical processor permit at its next full board meeting scheduled for September 26, 2023. Should the Board vote in support of this decision, the RFA will be terminated and the application fee of $10,000 submitted in 2020 will be refunded within approximately 6-8 weeks of the decision. Because regulatory oversight for the medical cannabis program will transition to the Virginia Cannabis Control Authority (VCCA) as of January 1, 2024, the VCCA intends to initiate discussion for opening a new RFA for the issuance of a pharmaceutical processor permit in HSA I.

Staff from the Board of Pharmacy and Virginia Cannabis Control Authority have closely and extensively analyzed this matter in consultation with respective counsel from the Office of the Attorney General. The agencies have determined that the Board would be unable to render a final permit prior to the January 1, 2024 transition in oversight to the VCCA. Additionally, applications submitted in 2020 likely contain outdated information regarding ownership structure, funding, proposed location, and do not include information regarding botanical cannabis products or production and distribution allowances that were not authorized in law at that time. As you are aware, the review of the RFA applications was halted on January 14, 2021, by the Henrico County Circuit Court due to the appeal by PharmaCann of the Board of Pharmacy's rescission of conditional approval and denial of its application for a pharmaceutical processor permit in HSA I. PharmaCann further appealed to the Virginia Court of Appeals which also continued the injunction against reviewing the RFA applications. In April 2023, the Virginia Court of Appeals ruled in the Board's favor affirming the Board of Pharmacy's Order to rescind the PharmaCann conditional approval and denial of its application. No subsequent appeal was filed.

Additional information will be communicated as final decisions are rendered, following the September26, 2023 meeting of the Board.

Sincerely,

Caroline D. Juran, RPh
Executive Director
cbd@dhp.virginia.gov
804-367-4456

Agenda Topic: Preliminary maps of current pharmacy locations based on practice type

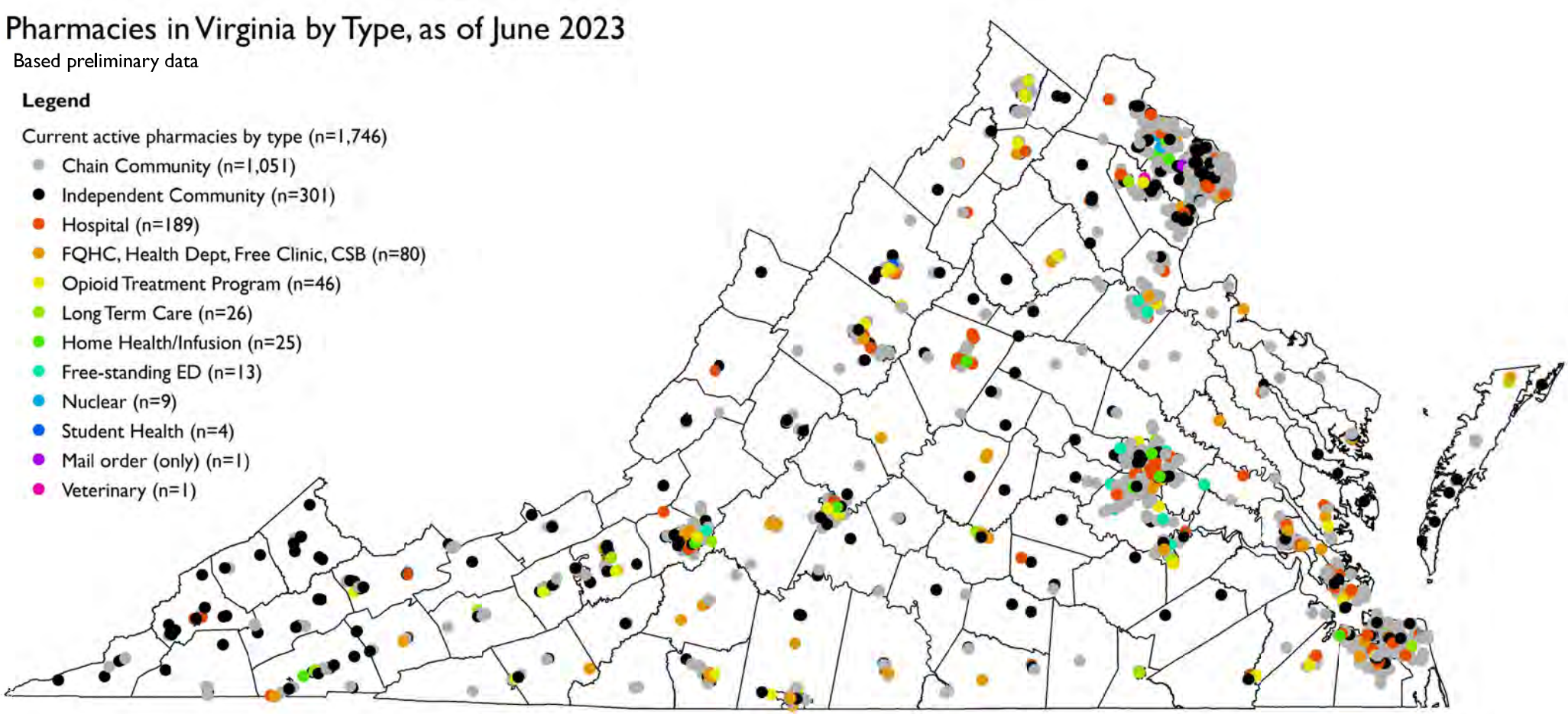
Staff note: To facilitate the Board's recent discussion at the June board meeting regarding pharmacy locations, staff has reviewed the list of current active pharmacy permits and assigned a practice type to each permit. Information has not been verified with permit holder.

Action Needed:

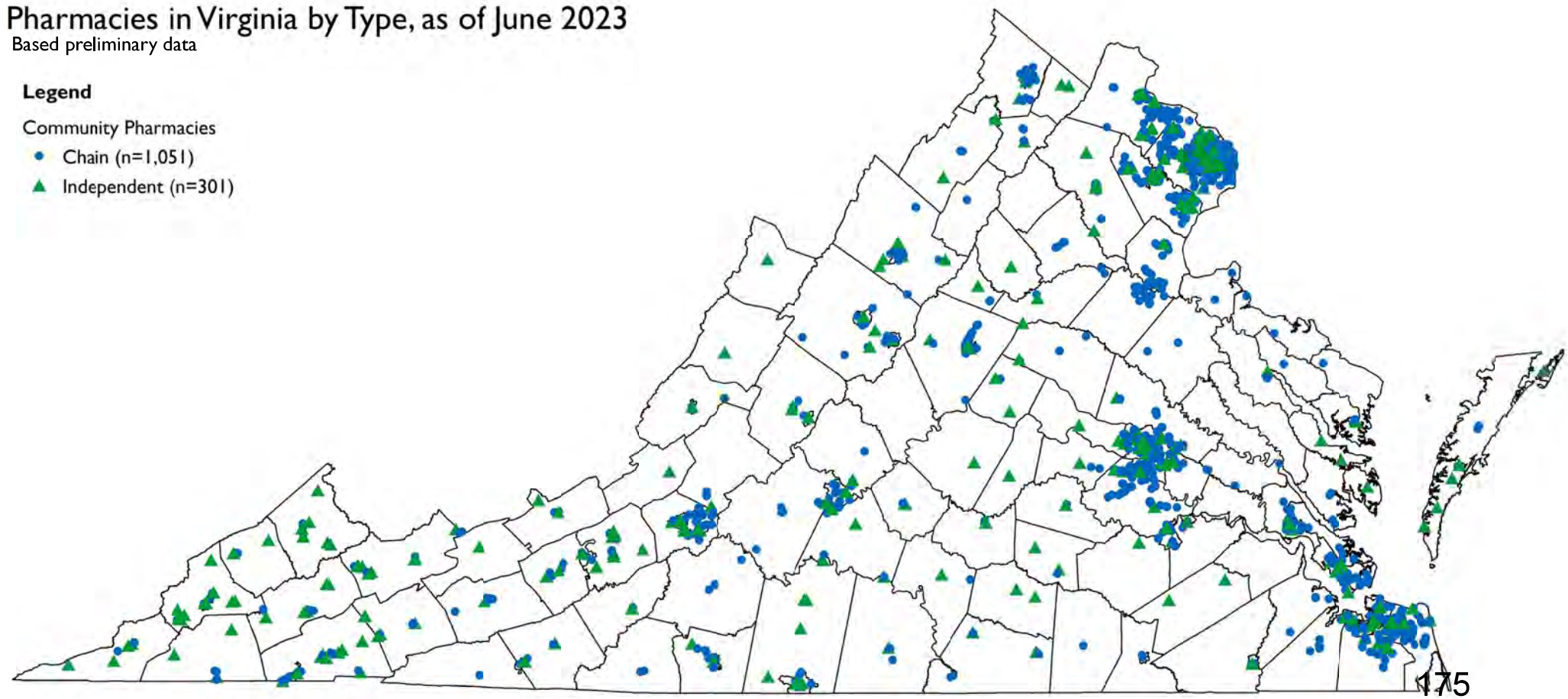
- No action required, for informational purposes.

All

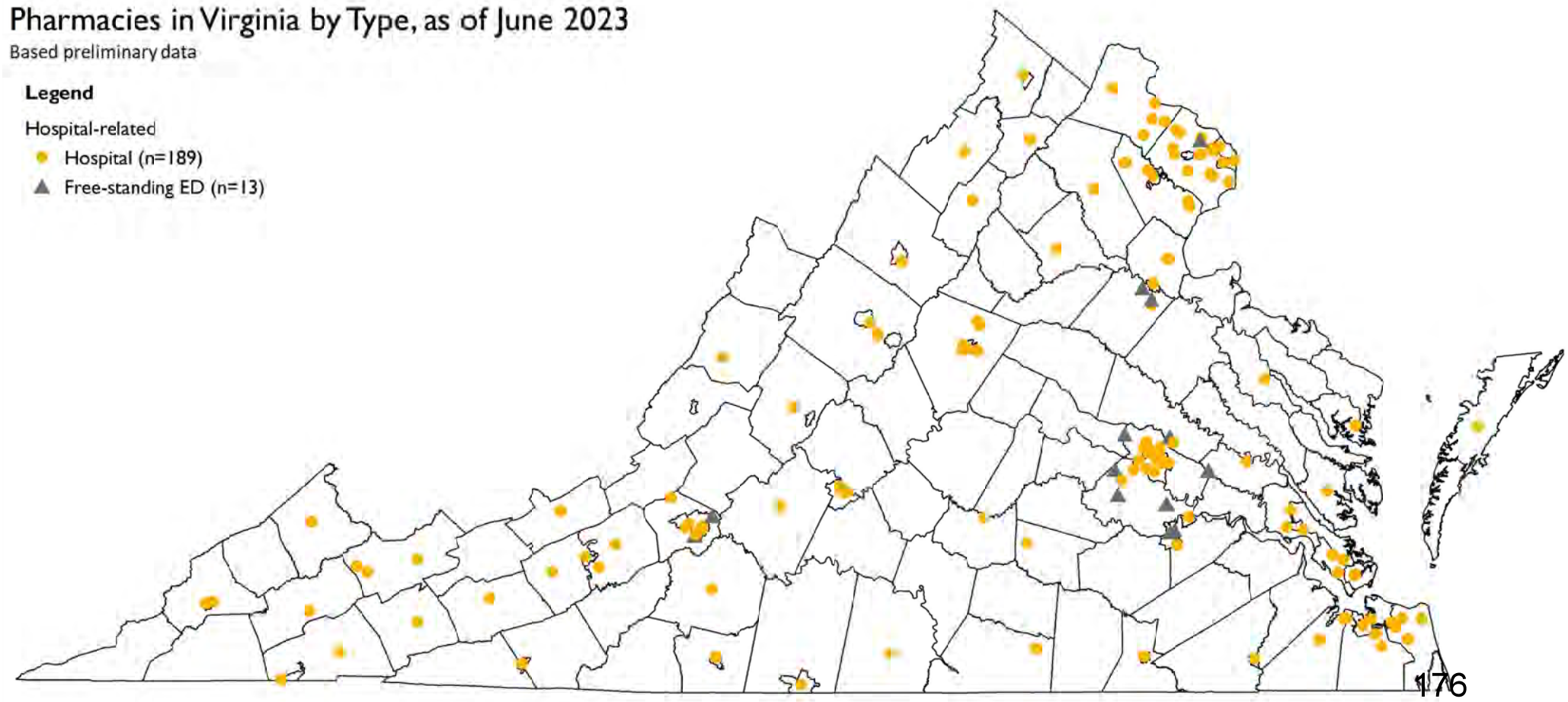
13 licensees excluded because invalid address



Community Pharmacies



Hospital-related



Agenda Item: Board Member Request

Background:

From: wscnash
Sent: Tuesday, September 5, 2023 7:25 AM
To: 'Dale St Clair PharmD; Juran, Caroline (DHP) <Caroline.Juran@DHP.VIRGINIA.GOV>
Subject: Sept 2023 Full Board meeting agenda

Hi Dale and Caroline,

I'm requesting the following be added to our Sept 2023 agenda:

1. Vote on having a one day retreat for the BOD to brainstorm about meeting the needs of current situation in pharmacy in the fall 2023 or Jan 2024
2. Design a dashboard with BOD identified metrics that is presented at each meeting
3. Determine what additional metrics the BOD needs and/or how to tweak the ones we have.

Best,
Wendy

Action Needed:

Discuss and vote on requested items or take no action.

APhA Institute on Substance Use Disorders

SALT LAKE CITY, UT

MAY 31, 2023 – JUNE 3, 2023

HISTORY

Pharmacy Section at the University of Utah School on Alcoholism and Other Drug Dependencies began an annual conference for 32 years.

APhA launched the inaugural session of the APhA Institute on Alcoholism and Drug Dependencies in June 2015.

https://aphainstitute.pharmacist.com/apha-institute/about-institute

Dinosaurs

Program Goals

- introductory or refresher course and a networking opportunity
- provide information, motivation and guidance in the planning, implementation, or strengthening of state-level and campus-level programs
- to help by assisting in finding treatment, ongoing recovery and re-entry into the practice of pharmacy or their pharmacy education
- to better prepare attendees to provide appropriate assistance and support to clients

Planned for

state-level pharmacist recovery programs

state and national pharmacy association executives;

state board of pharmacy officials

pharmacists in administrative positions

college faculty and administrators;

pharmacists, student pharmacists & pharmacy technicians

leaders in firms or organizations that employ pharmacists

pharmacist-related employee assistance program personnel

individuals who are concerned about alcoholism and other drug dependencies among their colleagues

Institute strives to

Define addiction

Explain pharmacology and pathophysiology of addiction

Describe & participate in 12-step programs & other programs

Design intervention strategies and techniques

Develop strategies to assist recovering abusers re-enter the pharmacy profession & recommend ways to monitor them & help them avoid relapse.

Develop an understanding of the use & abuse of alcohol & drugs on college campuses

Name the unique problems of pain management in recovering addicts

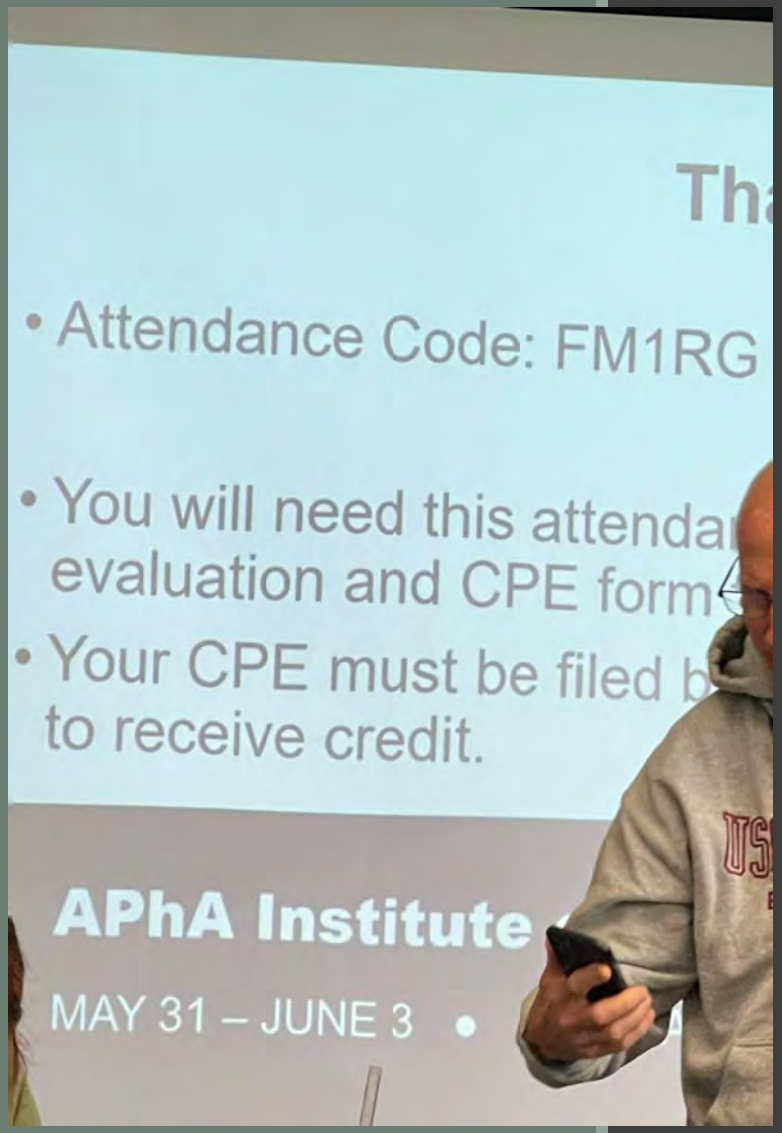
Summarize legal & ethical implications of addiction

Justify the importance of self-care in order to succeed

NABP Support

The National Association of Boards of Pharmacy (NABP) Foundation offered up to ten (10) $1,500 grants (for eligible attendee registration and travel costs) to qualified board of pharmacy members and staff

Available on a first-come, first-served basis



Pharmacists obtain CE credit

Suggested Upgrade is Board Certification credits

Wednesday, May 31

(All session times are listed in MT)

2:00 pm	APhA Institute Registration Opens
3:00 pm	Opening Session: The APhA Institute Experience
4:15 pm	Break
4:30 pm	The Self in Shame: Healing the Wounds of Substance Use Disorders
6:00 pm	Break / APhA Institute Dinner (Box Lunch Provided)
6:45 pm	Introduction to 12-Steps and Alcoholics Anonymous
7:15 pm	Alcoholics Anonymous – Open Meeting
8:15 pm	Small Group - Breakout Meetings
9:00 pm	Adjourn Day 1

Thursday, June 1

7:30 am	Registration Opens
8:00 am	Below the Surface: The Neuroscience of Substance Use Disorders
9:00 am	Break
9:15 am	Below the Surface: The Neuroscience of Substance Use Disorders, Part 2
10:15 am	Break
10:30 am	Substance Use Disorder 101 for Pharmacists
11:30 am	Lunch Break
1:00 pm	Case Study of a Pharmacist
1:45 pm	Break
2:00 pm	Naloxone Access: The Pharmacist's Role
3:15 pm	Break
3:30 pm	Narcotics Anonymous – Open Meeting
4:30 pm	Adjourn Day 2
5:30 pm	(Optional) Group Hike Up the Mountain — Meet at Sage Point Quad* (Optional) Group Walk Through Red Butte Gardens — Meet at Sage Point Quad *All participants must complete an APhA Waiver prior to hiking

Friday, June 2

8:30 am	Crisis Intervention: Safety is Everyone's Responsibility
9:45 am	Break
10:00 am	From Bystander to Advocate – Harm Reduction
11:15 am	Small Group Meeting - Touch Base
11:30 am	Lunch Break
1:00 pm	Workshop: Communication: Practice Makes Almost Perfect
2:15 pm	Break
2:30 pm	Family Matters: Understanding and Addressing the Impact of SUD on Family Units
3:45 pm	Break
4:00 pm	Al-Anon - Open Meeting
5:15 pm	Adjourn Day 3 / (Optional) Visit from Golden Healer Therapy Dogs

Saturday, June 3

8:00 am	(Optional) Ambassador Information Session
8:00 am	(Optional) Dinosaur Debrief
8:45 am	The Not-So-Fine-Line of Stimulant Use vs Stimulant Use Disorders
10:00 am	Break
10:15 am	Breakout Sessions: Track I - Operation Substance Use Disorders Workshop Track II - Pharmacist Recovery Network (PRN) & State Boards of Pharmacy Discussion Track III - Faculty Member / APhA Pain & Palliative Care SIG Networking Roundtable
11:30 am	Lunch Break
1:00 pm	12-Step Meeting
2:00 pm	Break
2:15 pm	Closing Session: Developing Positive Personal Power
3:45 pm	Closing Remarks
4:00 pm	Adjourn APhA Institute / Depart for Airport / Free Time in Salt Lake City / Park City

University of Utah campus

Is stunning

Architects and landscape architects have done a fabulous job , great vision

Olympics held in Salt Lake City

Some Olympic housing on campus

Embrace the Vistas

Dorm Sweet Dorm

- Stay in the dorm!!!!!
- Listen to the students' dreams
- About 40 to 50% of attendees are students
- They obtain college credit
- Do NOT lose your key. $125 replacement
- Say hello to cafeteria food. It ain't what it used to be

View from beside my dorm

Be challenged by a student's zest for life—
All 5 Utah National parks in 5 days!

- Make new friends
- Network
- Learn about current trends in pharmacy schools—3 vs 4 yr
- Foreign pharmacists attending College of Appalachia

Explore!


STATE OF UTAH

Start Yodeling
Or
Singing Climb Every Mountain

Virginia Board of Pharmacy
September 26, 2023
Licenses Issued

	2/1/22 - 4/30/22	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	License Count 8/1/2023
Business CSR	35	30	32	25	26	38	1,500
CE Courses	1	0	0	0	0	0	9
Limited Use Pharmacy Technician	0	0	0	0	0	0	7
Medical Equipment Supplier	0	4	3	3	6	12	226
Non-restricted Manufacturer	0	2	1	1	1	0	35
Outsourcing Facility	0	0	0	1	0	0	1
Permitted Physician	1	0	0	0	0	0	0
Pharmacist	187	265	252	164	144	237	16,547
Pharmacist Volunteer Registration	1	0	2	1	0	4	0
Pharmacy	9	11	10	11	11	11	1,755
Pharmacy Intern	88	56	96	179	91	71	1,176
Pharmacy Technician	360	531	430	311	339	469	13,224
Pharmacy Technician Trainee	1042	777	1,226	1,185	789	1,074	7,851
Physician Selling Controlled Substances	17	33	27	43	16	15	593
Limited Use Practitioner Dispensing	0	1	1	0	0	0	4
Physician Selling Drugs Location	2	6	2	3	3	5	134
Pilot Programs	2	1	1	0	0	2	16
Registered Practitioner For Medical Cannabis	106	56	147	84	89	35	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	1	0	0	0	0	6
Warehouser	1	1	0	2	3	1	126
Limited Use Facility Dispensing	0	0	0	2	1	0	3
Wholesale Distributor	0	0	0	0	0	0	60
Total	**1,853**	**1,775**	**2,230**	**2,015**	**1,519**	**1,974**	**44,358**

Virginia Board of Pharmacy
September 26, 2023
License Count for Select Categories

	3-May-22	11-Aug-22	15-Nov-22	21-Feb-23	22-May-23	9/13/2023
Pharmacist Virginia Current Active	8,716	8,822	8924	8690	8749	8898
Pharmacist Virginia Current Inactive	181	181	184	182	182	181
Pharmacist Out of State Current Active	6,570	6,794	6921	6609	6766	6981
Pharmacist Out of State Current Inactive	456	457	470	487	486	481
Total for Pharmacist	15,932	16,262	16508	15976	16191	16549
Pharmacy Intern Virginia	921	877	866	795	813	768
Pharmacy Intern Out of State	360	371	397	337	396	410
Total for Pharmacy Intern	1,281	1248	1263	1132	1209	1178
Pharmacy Technician Virginia Current Active	11,638	12172	12547	11135	11572	12097
Pharmacy Technician Out of State Current Act	955	1068	1147	950	1049	1129
Total for Pharmacy Technician	12,593	13240	13695	12086	12622	13228
Pharmacy Technician Trainee Virginia	5,728	6239	7247	8160	7962	7587
Pharmacy Technician Trainee Out of State	206	220	266	279	263	267
Total for Pharmacy Technician Trainee	5,934	6459	7513	8439	8225	7854

Virginia Board of Pharmacy
September 2023
Full Board Meeting
Nonresident Licensure Report

	License Count Aug 2022	License Count Nov 2022	License Count Feb 2023	License Count May 2023	License Count Aug 2023
Nonresident Manufacturer	215	221	227	226	226
Nonresident Medical Equipment Supplier	356	365	371	354	359
Nonresident Outsourcing Facility*	31	33	34	34	33
Nonresident Pharmacy*	903	911	925	926	910
Nonresident Third Party Logistics Provider	189	201	209	216	225
Nonresident Warehouser	99	109	114	113	117
Nonresident Wholesale Distributor	638	644	644	618	629
Total	**2,431**	**2,484**	**2,524**	**2,487**	**2,499**

Nonresident Pharmacy - 141 pharmacies perform both sterile and nonsterile compounding, 75 pharmacies perform sterile compounding only, and 166 pharmacies perform nonsterile compounding only. 526 nonresident pharmacies do not compound.

*Nonresident Pharmacies and Nonresident Outsourcing Facilities expire annually the last day of the month of initial registration.

**All other nonresident facility categories expire annually the last day of February.

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 4 - Fiscal Year 2023

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	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	CURRENT Q4 2023
Audiology/Speech Pathology	5,765	5,375	5,527	5,662	5,114	5,432	5,605	5,756	5,894	5,671	5,809	5,975	6,117
Counseling	33,789	34,028	35,176	34,246	31,769	33,693	35,020	36,141	37,436	36,097	37,512	38,791	40,118
Dentistry	14,491	14,982	15,133	15,286	14,768	15,171	15,290	15,284	15,238	15,421	15,275	15,037	15,186
Funeral Directing	3,090	3,161	3,205	3,190	3,114	3,187	3,247	3,295	3,182	3,254	3,308	3,379	3,287
Long-Term Care Administrators	2,141	2,190	2,226	2,274	2,152	2,226	2,293	2,352	2,146	2,232	2,288	2,345	2,159
Medicine	75,417	75,040	74,654	75,929	76,642	78,312	79,452	80,957	82,857	83,193	83,804	85,497	87,470
Nurse Aide	52,341	51,407	50,753	51,820	49,909	50,322	49,967	49,911	50,189	50,085	50,216	50,278	50,817
Nursing	169,204	171,004	170,050	172,380	172,263	174,791	174,984	176,169	177,138	179,221	179,997	181,279	181,581
Optometry	1,970	2,010	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826
Pharmacy	37,236	38,167	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486
Pharmaceutical Processing	4,440	7,162	9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625
Physical Therapy	14,143	14,588	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270
Psychology	6,089	6,016	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246
Social Work	11,041	11,051	11,443	11,805	11,302	11,868	12,405	12,799	13,138	12,952	13,598	14,241	14,913
Veterinary Medicine	8,234	8,384	7,894	8,181	8,442	8,615	8,723	8,429	8,648	8,826	8,947	8,711	9,016
Agency Total	439,391	444,565	441,815	457,898	464,278	482,398	494,685	505,753	518,191	514,037	512,996	505,591	499,117

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 4 - Fiscal Year 2023

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

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Quarter Date Ranges	
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BOARD	Occupation	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	CURRENT Q4 2023
Optometry	Optometrist	87	87	87	88	77	77	77	78	65	65	65	65	49
	Optometrist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	-	-	-
	Professional Designation	260	260	-	-	-	-	-	-	-	-	-	-	-
	TPA Certified Optometrist	1,623	1,663	1,693	1,720	1,680	1,716	1,736	1,749	1,708	1,758	1,784	1,808	1,777
	Total	1,970	2,010	1,780	1,808	1,757	1,793	1,813	1,827	1,773	1,823	1,849	1,873	1,826
Pharmacy	Business CSR	1,430	1,447	1,458	1,378	1,461	1,478	1,510	1,399	1,463	1,507	1,529	1,423	1,465
	CE Courses	9	9	9	9	9	9	9	9	9	9	9	9	9
	Humane Society	-	-	-	-	-	-	-	-	-	-	-	-	-
	Limited Use Facility Dispensing	-	-	-	-	-	-	-	-	-	-	1	2	3
	Limited Use Pharmacy Technician	11	11	7	8	8	8	8	7	7	7	7	7	7
	Limited Use Practitioner Dispensing	-	-	-	-	-	-	-	1	2	2	3	3	3
	Medical Equipment Supplier	228	233	233	224	223	230	229	209	217	223	226	213	220
	Non-Resident Manufacturer	196	199	200	194	202	209	215	206	213	218	224	217	226
	Non-Resident Medical Equipment Supplier	345	358	375	322	349	363	373	331	354	361	369	346	355
	Non Resident Outsourcing facility	31	32	33	33	33	34	33	30	29	32	33	35	33
	Non Resident Pharmacy	808	827	841	866	874	876	885	882	898	910	911	924	923
	Non-Resident Wholesale Distributor	625	629	634	604	635	644	660	624	634	643	641	610	624
	Non Restricted Manufacturer	31	32	32	28	28	29	30	31	32	34	34	35	35
	Non-Resident Third Party Logistics Prov.	140	146	161	169	182	186	191	181	181	194	206	207	219
	Non Resident Warehouser	58	69	78	79	91	96	101	98	99	105	115	109	114
	Outsourcing Facility	-	-	-	-	-	-	-	-	-	-	-	1	1
	Permitted Physician	-	-	-	-	-	-	-	-	-	-	-	-	-
	Pharmacist	15,561	15,916	15,326	15,668	15,865	16,210	16,445	15,858	16,079	16,414	16,619	16,064	16,273
	Pharmacist-Volunteer Registration	-	-	-	-	-	-	-	-	-	-	-	-	1
	Pharmacy	1,771	1,772	1,769	1,772	1,771	1,770	1,767	1,773	1,768	1,765	1,765	1,762	1,755
	Pharmacy Intern	1,649	1,578	1,368	1,464	1,489	1,499	1,457	1,247	1,312	1,267	1,352	1,166	1,235
	Pharmacy Technician	13,162	13,699	11,838	12,751	13,248	13,689	14,042	12,421	12,924	13,522	13,875	12,312	12,871
	Pharmacy Technician Trainee	-	-	-	831	2,406	3,309	4,628	5,930	6,258	6,977	8,041	8,581	8,178

Virginia Department of
Health Professions

Current Count of Licenses

Quarterly Summary

Quarter 4 - Fiscal Year 2023

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

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Quarter 4	April 1 - June 30

BOARD	Occupation	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	CURRENT Q4 2023
Pharmacy	Pharmacy Technician Training Program	130	125	119	126	136	138	133	128	126	-	-	-	-
	Physician Selling Controlled Substances	626	662	526	558	571	614	631	537	571	600	645	543	565
	Physician Selling Drugs Location	174	172	139	163	165	168	167	160	160	160	164	125	131
	Pilot Programs	22	22	24	24	24	17	20	18	25	23	20	15	15
	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	44	43	39	41	41	41	36	36	36	36	33	32
	Third Party Logistics Provider	6	6	6	7	7	7	7	8	7	7	7	6	6
	Warehouser	112	111	115	119	120	121	122	117	121	121	122	123	125
	Wholesale Distributor	65	66	67	64	65	66	66	60	62	64	63	60	60
	Total	37,236	38,167	35,403	37,502	40,005	41,813	43,772	42,303	43,589	45,203	47,019	44,933	45,486
Pharmaceutical Processing	Pharmaceutical Processor Permit	3	4	4	4	4	4	4	4	4	4	4	4	4
	Registered Agent For Medical Cannabis	7	11	20	65	103	141	162	180	179	181	166	158	137
	Registered Practitioner for CBD/THC-A Oil	401	528	633	685	797	920	997	720	873	1,059	1,164	938	1,051
	Registered Par/Guard For Medical Cannab	51	70	77	136	183	212	235	258	262	210	163	133	74
	Registered Patient For Medical Cannabis	3,978	6,535	8,754	17,257	26,136	33,204	39,468	47,466	52,903	45,434	38,071	29,214	16,201
	Registered Product	-	14	59	216	372	568	842	1,178	1,566	1,949	2,271	2,770	3,158
		4,440	7,162	9,547	18,363	27,595	35,049	41,708	49,806	55,787	48,837	41,839	33,217	20,625
Physical Therapy	Direct Access Certification	1,298	1,308	1,323	1,333	1,345	1,376	1,384	1,396	1,406	1,420	1,427	1,437	1,448
	Physical Therapist	9,094	9,380	8,372	8,603	8,901	9,161	9,245	9,382	9,634	9,906	10,022	8,878	9,146
	Physical Therapist Assistant	3,751	3,900	3,574	3,641	3,714	3,816	3,852	3,901	3,969	4,061	4,093	3,615	3,676
	Total	14,143	14,588	13,269	13,577	13,960	14,353	14,481	14,679	15,009	15,387	15,542	13,930	14,270
Psychology	Applied Psychologist	28	28	29	29	24	26	27	27	28	25	25	25	25
	Clinical Psychologist	3,885	3,907	4,042	4,130	3,888	4,082	4,224	4,325	4,418	4,230	4,360	4,461	4,573
	Resident in School Psychology	10	10	11	11	11	12	13	13	13	21	24	26	27
	Resident In Training	859	795	370	373	368	376	376	380	380	397	395	392	392
	School Psychologist	96	93	97	102	90	97	98	99	100	96	96	100	103
	School Psychologist-Limited	634	615	633	648	560	622	640	658	673	550	569	583	598
	Sex Offender Treatment Provider	437	429	442	447	414	433	437	444	455	421	427	439	450
	SOTP Trainee	140	139	131	135	131	125	110	99	100	95	97	79	78
	Total	6,089	6,016	5,755	5,875	5,486	5,773	5,925	6,045	6,167	5,835	5,993	6,105	6,246

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Quarterly Review – Date Range 01/01/2023 ending 03/31/2023:

Numbers of Inspections Completed by License Type:

Insp Status	License Type	Change of Location	Compliance	Focus	New	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	9			24	3	11	75	122
	Cannabis Dispensing Facility				3	1			4
	Limited Use Facility Dispensing					1			1
	Medical Equipment Supplier	7			4			36	47
	Non-resident Medical Equipment Supplier				1				1
	Non-restricted Manufacturer	1			1	2			4
	Outsourcing Facility					1			1
	Pharmacy	6	2	1	13	13	43	186	264
	Physician Selling Drugs Location				2	1		16	19
	Warehouser				1			16	17
	Wholesale Distributor							4	4
Completed Total		23	2	1	49	22	54	333	484
Completed Virtual	Business CSR					1	4	2	7
	Pharmacy				1	4	5		10
	Physician Selling Drugs Location				1				1
	Warehouser				1				1
Completed Virtual Total					3	5	9	2	19
Grand Total		23	2	1	52	27	63	335	503

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Quarterly Review – Date Range 01/01/2023 ending 03/31/2023:

Routine Inspections, Deficiencies by License Type:

License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	2	32		43	77
Medical Equipment Supplier	2	12		22	36
Pharmacy		62	78	46	186
Physician Selling Drugs Location		11		5	16
Warehouser		5		11	16
Wholesale Distributor	1	2		1	4
Grand Total	5	124	78	128	335

** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

Enforcement Division Inspections Report:
Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Date Range: 01/01/2023 ending 03/31/2023:
Categories of Deficiencies for Occurrences, Routine Inspections Only
Recorded >20 Times with Examples:

Description	**Number of times for occurrence**
110-20-110	*20*

Deficiency 1: No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location.
Deficiency 2: Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe
Deficiency 113: Inventories taken on time, but not in compliance, i.e., opening or close.

110-20-180	*35*

The device does not fully protect the prescription department and shall be capable of detecting breaking by any means when activated.
Security: The alarm system does not include a feature by which any breach in the alarm shall be communicated by the monitoring entity to the PIC
The monitoring entity did not receive a signal from each motion sensor on the primary line of communication
The security system only has a cellular line of transmission. There is not a hard-wired line or a secondary line of communication
Deficiency 9a: The alarm system does not include a feature by which any breach shall be communicated to the PIC
Deficiency 10: Unauthorized access to locking device to the prescription department.

110-20-190	*28*

Deficiency 11: Insufficient enclosures or locking devices. One of the entry doors to the prescription department was propped open
Deficiency 12: Storage of prescription drugs not in the prescription department.
Deficiency 108: Emergency access key not maintained in compliance. The access key was not in a properly sealed envelope

110-20-240	*39*

Deficiency 14: The Pharmacist-in-Charge inventory was taken 4 days prior to the effective date of change
Deficiency 15: Perpetual inventory not being maintained as required
Deficiency 17: Hard copy prescriptions not maintained
Deficiency 113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close

Enforcement Division Inspections Report:
Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Description	Number of times for occurrence
110-20-355	*22*

Deficiency 20: Pharmacist not checking and documenting repackaging or bulk packaging
Deficiency 109: Dispensed drugs being returned to stock not in compliance. Drugs being returned to stock are not used to fill the next prescription
Deficiency 127: Repackaging records and labeling not kept as required or in compliance

110-20-700	*22*

Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration
Supervising practitioner on CSR identified, but not correct.
The facility did not submit an application to change the supervising practitioner within 14 days of the departure of the previous supervising practitioner.
The Medical Operations Manager, Medical Assistants, & Peer Recovery Coach have access to the medications room and locked medication storage at all times, not just for emergencies. There is no list of those who have access for emergency access.

54.1-3404	*37*

Deficiency 13: No biennial inventory, or over 30 days late
Deficiency 16: Theft/unusual loss of drugs not reported to the Board as required
Deficiency 112: Biennial taken late, but within 30 days
Deficiency 113: Inventories taken on time, but not in compliance
Deficiency 148: Unusual loss of drugs reported to board but report not maintained by pharmacy

54.1-3410	*21*

Deficiency 116. Prescriptions do not include required information. Prescriptions not transmitted as required
Deficiency 124: Labels do not include all required information

Enforcement Division Inspections Report:
Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Description	Number of times for occurrence
54.1-3410.2	*185*

84 Occurrences -Not counted as a deficiency - Assessment of risk has been performed
800: Assessment of Risk has not been performed - Separated from the Section upon Board Request –

Deficiency 130: Required compounding records not complete
Records are maintained within the pharmacy software system
The fungal results from the most recent certification have not come back yet.
Sterile compounding; have clean room, but not all physical standards in compliance

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Two Year Review - Date Range: 12/31/2020 ending 12/31/2022:

Number of Inspections Completed by License Type:

Insp Status	License Type	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	53		1	179		10	21	689	953
	Cannabis Dispensing Facility				12		4			16
	Limited Use Facility Dispensing				3					3
	Medical Equipment Supplier	15			18				95	128
	Non-resident Medical Equipment Supplier				1					1
	Non-restricted Manufacturer	1			8		5	1	3	18
	Outsourcing Facility				1					1
	Pharmaceutical Processor Permit	1					1	13	13	28
	Pharmacy	33	8	5	82	1	44	288	1460	1921
	Physician Selling Drugs Location	5	1		24		4	2	119	155
	Pilot Programs					9				9
	Restricted Manufacturer	1			1				1	3
	Third Party Logistics Provider	1			2				5	8
	Warehouser	10			10		3	4	71	98
	Wholesale Distributor	6			2			3	34	45
Completed Total		126	9	6	343	10	71	332	2490	3387
Completed Virtual	Business CSR	14			59	1	6	12	160	252
	Medical Equipment Supplier	2			4			1	5	12
	Non-restricted Manufacturer						1	1		2
	Pharmacy	1		1	3		18	47	1	71
	Physician Selling Drugs Location	1			2		2	1	5	11
	Pilot Programs					4				4
	Third Party Logistics Provider				1					1
	Warehouser	1			1		1	1	4	8
	Wholesale Distributor				1		1	1		3
Completed Virtual Total		19		1	71	5	29	64	175	364
Grand Total		145	9	7	414	15	100	396	2665	3751

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Quarterly Review – Date Range 04/01/2023 ending 06/30/2023:

Numbers of Inspections Completed by License Type:

Insp Status	License Type	Audit	Change of Location	Compliance	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR		4		28	1		4	89	126
	Cannabis Dispensing Facility				3				4	7
	Medical Equipment Supplier		1		10				13	24
	Non-restricted Manufacturer				1					1
	Pharmaceutical Processor Permit								3	3
	Pharmacy	1	1	1	11		13	66	166	259
	Physician Selling Drugs Location				5		1		9	15
	Third Party Logistics Provider								1	1
	Warehouser		1		3		1		11	16
	Wholesale Distributor								5	5
Completed Total		1	7	1	61	1	15	70	301	457
Completed Virtual	Business CSR				4		1		2	7
	Medical Equipment Supplier		1							1
	Pharmacy		1		1		2	14		18
	Physician Selling Drugs Location		1		1					2
	Wholesale Distributor		1							1
Completed Virtual Total			4		6		3	14	2	29
Pending	Business CSR									

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

	Medical Equipment Supplier									
	Pharmacy									
	Physician Selling Drugs Location									
	Wholesale Distributor									
Pending Total										
Grand Total		1	11	1	67	1	18	84	303	486

** New, Change of Location, Remodel, Reinspection, Pilot, and Compliance Inspections Removed*

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Quarterly Review – Date Range 04/01/2023 ending 06/30/2023:

Routine Inspections, Deficiencies by License Type:

License Type	Attempted-No Inspection Required	Deficiency	Deficiency & IPHCO	No Deficiency	Grand Total
Business CSR	2	27		62	91
Cannabis Dispensing Facility		3		1	4
Medical Equipment Supplier		5		8	13
Pharmaceutical Processor Permit		3			3
Pharmacy		52	65	49	166
Physician Selling Drugs Location		9			9
Third Party Logistics Provider		1			1
Warehouser		2		9	11
Wholesale Distributor		2		3	5
Grand Total	2	104	65	132	303

Enforcement Division Inspections Report:
Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Date Range: 04/01/2023 ending 06/30/2023:
Categories of Deficiencies for Occurrences, Routine Inspections Only
Recorded >20 Times with Examples:

Description	**Number of times for occurrence**
110-20-180	*35*

Security. The device is not maintained in operating order, does not fully protect the prescription department
Deficiency 9a: The alarm system does not include a feature by which any breach shall be communicated to the PIC or a pharmacist working at the pharmacy.
Deficiency 10: Unauthorized access to alarm to the prescription department. During the inspection, a floater pharmacist was on duty
The device is not capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational.

110-20-190	*22*

Deficiency 11: Insufficient enclosures or locking devices. One of the entry doors to the prescription department was propped open
Deficiency 12: Storage of prescription drugs not in the prescription department.
Deficiency 108: Emergency access key not maintained in compliance. The access key was not in a properly sealed envelope

110-20-240	*33*

Deficiency 15: Perpetual inventory not being maintained as required
Deficiency 15: Perpetual inventory not being maintained as required, to include not noting explanation for any difference between
Deficiency 113. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close
Deficiency 115: Other records of distributions not maintained as required
Deficiency 148: Theft/unusual loss of drugs reported to board but report not maintained by pharmacy.

110-20-418	*21*

Deficiency 142: No record maintained and available for 12 months from date of analysis of dispensing errors to include any zero reports
Deficiency 148: Unusual loss of drugs reported to board but report not maintained by pharmacy.

Enforcement Division Inspections Report:
Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Description **Number of times for occurrence**

54.1-3404		*33*

Deficiency 13: Biennial inventory substantially incomplete, i.e., did not include any drugs in Schedules III-V
Deficiency 16: Theft of drugs not reported to the Board as required.
Deficiency 148. Theft/unusual loss of drugs reported to board but report not maintained by pharmacy
No Biennial Inventories located.
Distribution record did not include appropriate documentation of waste. All staff were not electronically documenting waste on three controlled substances administrations. This is a repeat deficiency from the inspection conducted on August 4, 2020.

54.1-3410.2	*138*

72 Occurrences -Not counted as a deficiency - Assessment of risk has been performed
800: Assessment of Risk has not been performed - Separated from the Section upon Board Request –

54.1-3434	*23*

Deficiency 1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location
Deficiency 2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe
Deficiency 14: No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Two Year Review - Date Range: 03/31/2021 ending 03/31/2023:

Number of Inspections Completed by License Type:

Insp Status	License Type	Change of Location	Compliance	Focus	New	Pilot	Reinspection	Remodel	Routine	Grand Total
Completed	Business CSR	57		1	196		12	30	744	1040
	Cannabis Dispensing Facility				15		5			20
	Limited Use Facility Dispensing				3		1			4
	Medical Equipment Supplier	20			21				123	164
	Non-resident Medical Equipment Supplier				2					2
	Non-restricted Manufacturer	2			8		7	1	3	21
	Outsourcing Facility				1		1			2
	Pharmaceutical Processor Permit	1					1	12	11	25
	Pharmacy	36	10	5	91		53	306	1493	1994
	Physician Selling Drugs Location	4	1		24		4	1	132	166
	Pilot Programs					7				7
	Restricted Manufacturer				1				1	2
	Third Party Logistics Provider	1			2				5	8
	Warehouser	8			8		3	4	81	104
	Wholesale Distributor	6			2			3	37	48
Completed Total		135	11	6	374	7	87	357	2630	3607
Completed Virtual	Business CSR	5			44	1	7	14	88	159
	Medical Equipment Supplier				2				3	5
	Non-restricted Manufacturer						1	1		2
	Pharmacy			1	4		19	46	1	71
	Physician Selling Drugs Location	1			2		2	1	3	9
	Pilot Programs					1				1
	Warehouser				1		1		2	4
	Wholesale Distributor						1	1		2
Completed Virtual Total		6		1	53	2	31	63	97	253

Enforcement Division Inspections Report:

Prepared for the September 26, 2023 - Board of Pharmacy Meeting

Grand Total		141	11	7	427	9	118	420	2727	3860

Reports Extracted on 09/05/2023.

- Data extrapolated from My License Office (MLO) / Inspection Completed Detail Reports /Inspection Result Detail Reports
- Report contains additional data since I was unable to attend the last Board of Pharmacy Meeting

A few items to note:

- Enforcement Director position under recruitment.
- Pharmacy Wage (Part time) Inspector position under recruitment. Plans to post and hire are underway.
- Both the Pharmacy Inspectors and Senior Inspectors from the Enforcement Division conduct facility inspections for the BOP and work on cases as/when needed.
- Pharmacy Inspectors have been working with team members from Cannabis Control Authority (CCA) while prepping for the Jan 1, 2024
    - Pharmaceutical Processors and Cannabis Dispensing Facilities will be under that new authority at the beginning of next year.
- Attempted-No Inspection Required – Recent updated the data to include this type of inspection result for facilities that no longer need an inspection performed, but work has already been completed by the Inspectors. This will give us the ability to track those occurrences now and account for the time that was spent more adequately.

Report prepared by: Melody J. Morton, Inspections Manager Enforcement Division

Pharmaceutical Processors Report-September 26, 2023

- Three additional cannabis dispensing facility haves been permitted during the last quarter, for a total of 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 89% decrease in patient applications. Registration renewals have also significantly decreased.
- Board staff have worked to implement statutory changes to the program effective July 1, 2023, to include practitioners no longer being required to register with the Board, registered agents no longer being required to register with the Board if their name appears on the written certification, and product changes related to labeling.
- The Regulations Governing Pharmaceutical Processors approved at the September, 2022 Board Meeting became effective August 16, 2023. These included changes to product applications, wholesale distribution of bulk cannabis material and the allowance for hydrocarbon-based solvent processing of cannabis products.
- Board and agency staff continue work to develop specific components of the new patient/product registration platform. It is anticipated that the platform will be operational in September.
- Board and agency staff continue to meet bi-monthly with the Virginia Cannabis Control Commission to address the anticipated transition of the medical cannabis program to the VCCA on January 1, 2024.

Pharmaceutical Processors Program-By the Numbers
As of 9/11/2023

Registered Patients	7,425
Registered Parents/Guardians	37
Registered Agents	108
Registered Cannabis Products (cumulative)	3,392

Discipline Program Report

Open Cases as of 9/6/23:

	PC	APD	Investigation	FH	IFC	Other	Pending Closure	Entry	TOTALS
Patient Care Cases	64	26	100	3	9	1	0	5	208
Non-Patient Care Cases	119	9	55	3	8	1	15	0	210
						TOTAL:			**418**

- The Board has two cases currently being appealed in circuit court (Category: Other).
- Total caseload remaining high.
- Recently sent 19 CE cases to APD for IFC due to no response.

Upcoming Disciplinary Proceedings:

October 10, 2023	Full Board	Formal Hearings
October 11, 2023	St.Clair/Yuan	Pilot Committee
October 18, 2023	Garvin/Nash	Informal Conferences
November 6, 2023	Yuan/Richards-Spruill	Informal Conferences
November 8, 2023	Full Board	Formal Hearings
November 29, 2023	Ratliff/Dowdy	Informal Conferences
December 6, 2023	Full Board	Full Board Mtg & Formal Hearings
December 14, 2023	Gavin/Nash	Informal Confernces

Virginia Department of Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 4 – Fiscal Year 2023

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

Virginia Department of Health Professions

Cases Received, Open & Closed

Agency Summary

Quarter 4 – Fiscal Year 2023

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

		Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023	Q2 2023	Q3 2023	CURRENT Q4 2023
Pharmacy	**Number of Cases Received**	103	127	138	145	160	212	208	220	185	215	210	204	249
	Number of Cases Open	286	289	263	300	332	350	329	399	409	416	437	384	442
	Number of Cases Closed	103	131	174	115	131	193	228	154	181	228	214	288	220
Physical Therapy	**Number of Cases Received**	7	8	12	12	20	11	9	15	3	15	13	10	4
	Number of Cases Open	36	33	29	33	47	46	47	46	39	35	34	36	35
	Number of Cases Closed	6	12	19	8	7	12	8	18	10	21	18	8	5
Psychology	**Number of Cases Received**	28	27	37	36	31	37	32	24	34	20	18	22	31
	Number of Cases Open	87	92	106	130	132	140	159	144	162	163	169	174	172
	Number of Cases Closed	46	25	26	13	32	29	13	39	22	26	16	24	49

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q4 2019 - Q4 2023

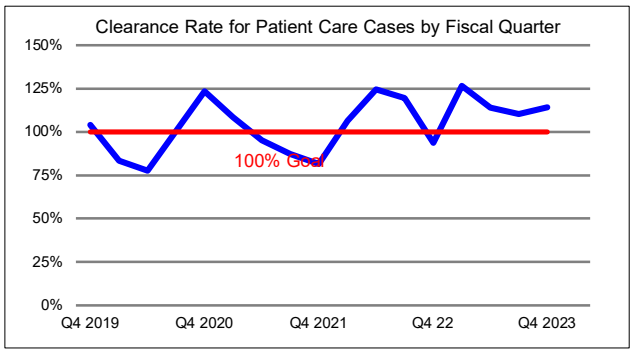
Arne W. Owens
Director

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

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

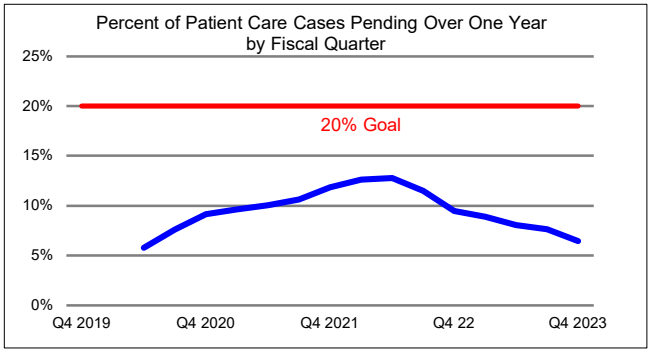
Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

The current quarter's clearance rate is 114%, with 1089 patient care cases received and 1,244 closed.



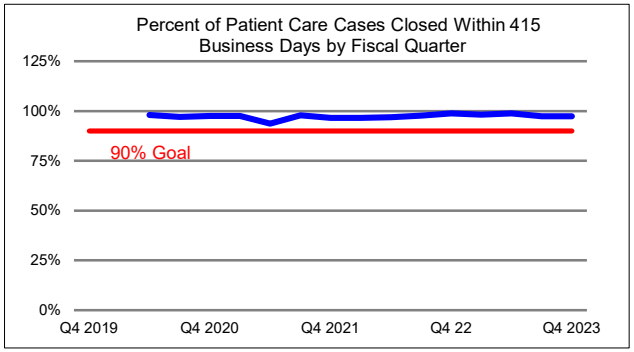
Age of Pending Caseload - the percent of open patient care cases over 415 business days old. This measure tracks the backlog of patient care cases older than 415 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older than 415 business days at no more than 20%.

The current quarter shows 6% patient care cases pending over 415 business days with 3,488 patient care cases pending and 225 pending over 415 business days.



Time to Disposition - the percent of patient care cases closed within 415 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest cases on the measure. The goal is to resolve 90% of patient care cases within 415 business days.

The current quarter shows 98% of patient care cases being resolved within 415 business days with 1,160 cases closed and 1,131 closed within 415 business days.



Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days), by Board

Medicine

Clearance Rate: 94%
385 Cases Received
362 Cases Closed

Pending Caseload Over 415 Days: 4%
38 Cases Pending over 415 Days

Time to Disposition Within 415 Days: 100%
424 Cases Closed within 415 Days

Dentistry

Clearance Rate: 63%
90 Cases Received
57 Cases Closed

Pending Caseload Over 415 Days: 1%
3 Cases Pending over 415 Days

Time to Disposition Within 415 Days: 100%
89 Cases Closed within 415 Days

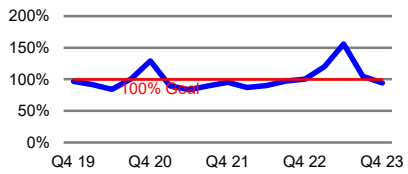
Pharmacy

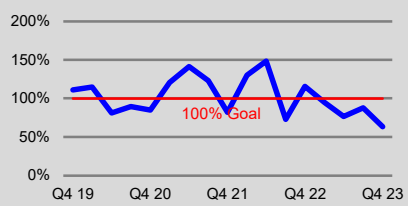
Clearance Rate: 85%
82 Cases Received
70 Cases Closed

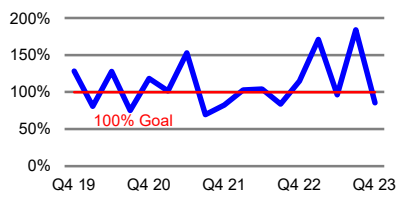
Pending Caseload Over 415 Days: 3%
6 Cases Pending over 415 Days

Time to Disposition Within 415 Days: 99%
127 Cases Closed within 415 Days

Clearance Rate

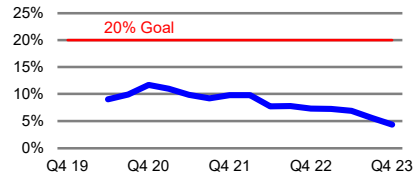


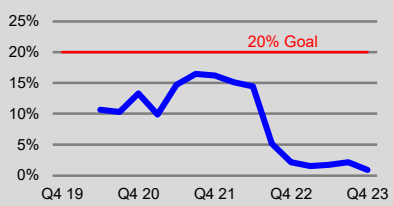


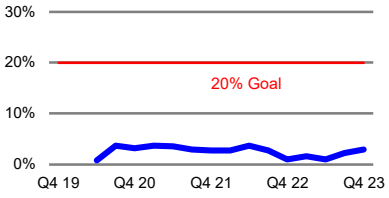


Age of Pending Caseload

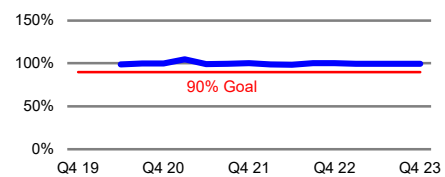
(percent of cases pending over one year)

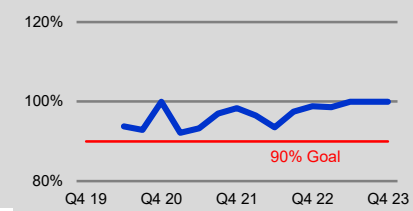


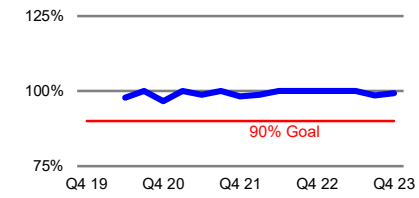




Time to Disposition







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

Virginia Department of Health Professions

Patient Care Disciplinary Case Processing Times (with Continuance Days): Quarterly Performance Measurement, Q4 2019 - Q4 2023

Arne W. Owens
Director

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

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

Clearance Rate - the number of closed cases as a percentage of the number of received cases. A 100% clearance rate means that the agency is closing the same number of cases as it receives each quarter. DHP's goal is to maintain a 100% clearance rate of allegations of misconduct.

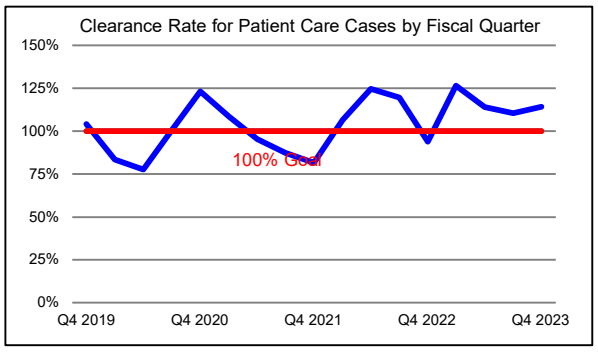
Age of Pending Caseload - the percent of open patient care cases over 250 business days old. This measure tracks the backlog of patient care cases older than 250 business days to aid management in providing specific closure targets. The goal is to maintain the percentage of open patient care cases older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

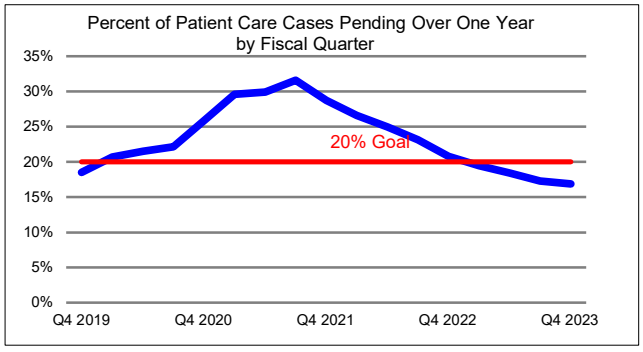
Time to Disposition - the percent of patient care cases closed within 250 business days for cases received within the preceding eight quarters. This moving eight-quarter window approach captures the vast majority of cases closed in a given quarter and effectively removes any undue influence of the oldest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

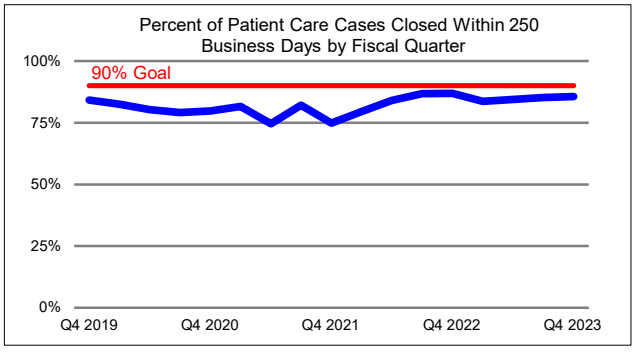
The current quarter's clearance rate is 114%, with 1089 patient care cases received and 1,244 closed.

The current quarter shows 17% patient care cases pending over 250 business days with 3,488 patient care cases pending and 588 pending over 250 business days.

The current quarter shows 86% of patient care cases being resolved within 250 business days with 1160 cases closed and 993 closed within 250 business days.







Virginia Department of Health Professions - Patient Care Disciplinary Case Processing Times (with Continuance Days), by Board

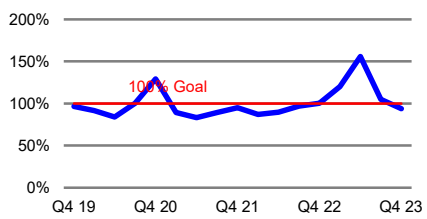
Medicine

Clearance Rate: 94%
385 Cases Received
362 Cases Closed

Pending Caseload: 8%
71 Cases Pending over 250 Days

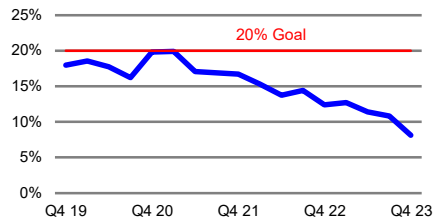
Time to Disposition: 95%
406 Cases Closed within 250 Days

Clearance Rate

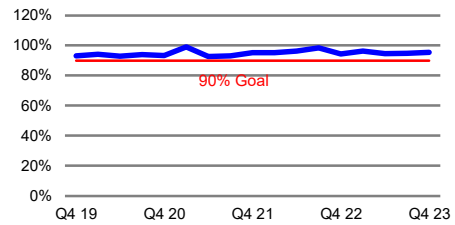


Age of Pending Caseload

(percent of cases pending over one year)



Time to Disposition

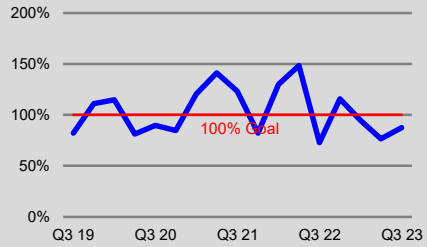


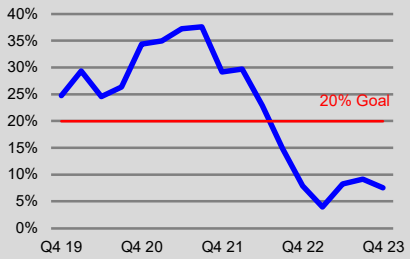
Dentistry

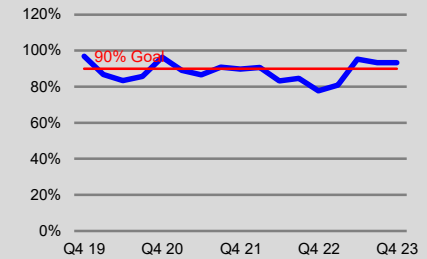
Clearance Rate: 63%
90 Cases Received
57 Cases Closed

Pending Caseload: 8%
25 Cases Pending over 250 Days

Time to Disposition: 93%
83 Cases Closed within 250 Days





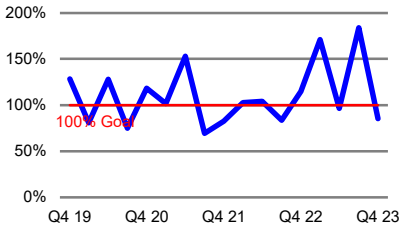


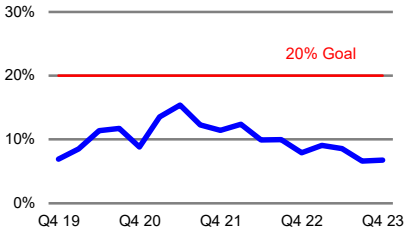
Pharmacy

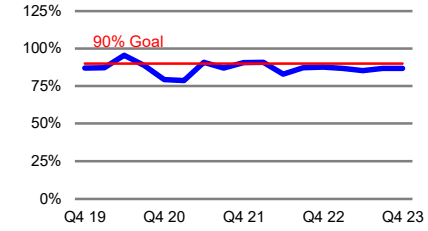
Clearance Rate: 85%
82 Cases Received
70 Cases Closed

Pending Caseload: 7%
14 Cases Pending over 250 Days

Time to Disposition: 87%
111 Cases Closed within 250 Days







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

Executive Director's Report – September 26, 2023

In-person or Virtual Meetings Recently Attended:

- VPhA Law Update Webinar - presenter
- Forensic Science Board Meeting -Vice-Chair
- HIV Services in Community Pharmacies Initiative – NABP workgroup member
- APhA/ASHP/NABP-hosted: I*mplementing Solutions: Building a Sustainable, Healthy Pharmacy Workforce and Workplace* – NABP workgroup member
- DHP Monthly Executive Director Meeting and Executive Leadership Team Meeting
- NABP Monthly Executive Director Meeting
- Pulse by NABP meetings – pilot participant
- Department of Environmental Quality Webinar on Hazardous Waste
- FDA webinar on Wholesaling Guidance
- FDA Webinar on IV Hydration Clinics – panel moderator
- Virginia Health Sciences & Human Services Regulatory and State Agency Working Group hosted by Claude Moore Foundation and Deloitte – workgroup member
- Health Distribution Alliance Traceability Seminar – panelist
- DMAS Pharmacist as Providers Workgroup
- Veterans Affairs National Standards of Practice Listening Session
- SAMHSA Region 3 Meetings regarding Buprenorphine Access
- Virginia Tech Carillion School of Medicine – presenter re cannabis
- RxPartnership Board Meeting
- NABP/AACP Districts 1 & 2 Meeting, New Jersey

Upcoming Meetings:

- DMAS Pharmacist as Providers Workgroup
- NABP Monthly Executive Director Meeting
- DHP Monthly Executive Director Meeting and Executive Leadership Team Meeting
- RxPartnership Board Meeting
- NABP Executive Officer/Legal Counsel/Compliance Officer Forum
- Virginia Association of Community Service Boards – presenter on CSB repackaging
- FDA 50-State Compounding Meeting
- VSHP Fall Seminar - presenter